# COMPREHENSIVE HEALTH ASSESSMENT: DECREASING PREVENTIVE CARE GAPS IN OLDER ADULTS

by

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#### **ABSTRACT**

GEORGETTA E. WRIGHT. Comprehensive health assessment: Decreasing preventive care gaps in older adults. (Under the direction of DR. MEREDITH TROUTMAN-JORDAN)

Less than 50% of adults aged 65 and older complete annual recommended preventive care. Preventive care is important since a major risk factor for cancer is aging. Colon cancer occurs in more than 70% of people aged 65 and older. The most common cancer among U.S. women, breast cancer is mostly diagnosed in women aged 55 and older. Both are the second most common causes of death in men and women respectively. The purpose of this study was to examine completion rates of breast and/or colon cancer screenings among Medicare beneficiaries 66 to 75 years of age who complete two different office visits. The study included 20 participants (14 were in the nurse-only visit group and 6 were in the CHA visit group). The intervention participants received a 75-minute CHA with the nurse and the provider and received a preventive plan of care with referrals for a mammogram, colonoscopy or Cologuard. Patients in the comparison group were scheduled for a 60-minute nurse-only visit and received a preventive plan of care and no further follow-up. Twenty individuals participated: 6 in the CHA group and 14 in the nurse-only group. The average age was 70.75 years old. The age range was 66 to 75. (SD = 2.83). In the CHA group, 3 did breast cancer screening (1 did not, 2 were ineligible). In the nurse group, 8 did breast cancer screening (2 did not, 4 were ineligible). The difference was not statistically significant,  $\chi^2(2) = 0.09$ , p = .958. In the CHA group, 1 did colon cancer screening (2 did not, 3 were ineligible). In the nurse group, 2 did colon cancer screening (6 did not, 6 were ineligible). The difference was not statistically significant,  $\chi^2(2) = 0.16$ , p = .923.

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#### **DEDICATION**

To my mom, Jania Olivia Early, thank you for seeing my vision and supporting me. There were many days I wanted to give up, but your love, strength, smile, and encouraging words kept me through the journey. For that, I am forever grateful to you. I am so hurt you are not here with me to witness in person what we both have talked about, dreamed of, and longed for since I was a teenager and over the last six months. Some of the last words you spoke to me were "you are going to make it" you are already there; you are a doctor" and for me to be proud of this. I will keep these words with me deep in my heart and soul. I love you. I am proud of you for fighting cancer the way you did the last six months with such tenacity. You gave me the strength to continue. While you take your rest, I will take each day God gives me to love on people harder, care for patients more passionately and give out of a pure heart knowing this is my purpose and calling. To my children Azariah and Takari, you are my biggest supporters. I am so proud of both of you. I am thankful you two feel honored to have me as your mother. Every time you told me how proud of me you were and how strong I was for going to school, working fulltime, taking care of you two and your grandmother melted my heart. All I do and will continue to do on this journey called life will always be for the two of you. I love you.

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FIGURE 1: Kurt Lewin Theory of Planned Change

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### LIST OF ABBREVIATIONS

ACA Affordable Care Act

ACS American Cancer Society

APRN Advance Practice Registered Nurse

AWV Annual Wellness Visit

CDC Centers for Disease Control and Prevention

CHA Comprehensive Health Assessment

DNP Doctor of Nursing Practice

EMR Electronic Medical Record

HRA Health Risk Assessment

IPPE Initial Preventive Physical Examination

MD Medical Doctor

MA Medical Assistant

NCI National Cancer Institute

ODPHP Office of Disease Prevention and Health Promotion

PCP Primary Care Provider

PA Physician Assistant

QI Quality Improvement

RN Registered Nurse

SWOT Strength Weakness Opportunities Threats

TPC Theory of Planned Change

#### **CHAPTER 1: INTRODUCTION**

By 2030, one out of every five people in the United States will be 65 years of age or older (Simpson et al., 2018a). The population growth is expected to increase through 2060, resulting in 98 million older adults (Watkins & Astroth, 2020). Multimorbidity is common among Medicare beneficiaries, with close to 72% of the population having two or more chronic conditions, commonly referred to as comorbidities (Maciejewski & Hammill, 2019). Among the multiple comorbidities is cancer. The Centers for Disease Control and Prevention (CDC, 2022) reported population aging is attributing to a rising number of new cancer cases in the U.S. with two-thirds of all new cancers diagnosed among adults 60 years of age or older. Without a consistent focus on preventive health care in the aging population, the number of cancer diagnoses is projected to increase by 2050, impacting over 2.2 million adults 75 years of age and older (CDC, 2022). To address the anticipated rising cases among older adults, this study examined the completion rates of breast and/or colon cancer screenings among Medicare beneficiaries 66 to 75 years of age who complete two different office visits.

# 1.1 Background

To assist the aging population and their disease burden, the Patient Protection and Affordable Care Act (ACA) in 2011 eliminated cost sharing for preventive care services (Toseef, 2020). This policy change allowed Medicare beneficiaries to receive preventive care screenings without a financial burden and led to the creation of an annual free preventive care visit known as the Medicare Annual Wellness Visit (AWV). The purpose of the AWV is to identify care gaps by

completing a health risk assessment (HRA) with the patient and developing a personalized preventive plan of care essential for health promotion and the well-being of older adults (Galvin et al., 2017). Care gaps are defined as a missing recommended preventive care service (AmeriHealth Caritas Delaware, 2022).

The AWV visit is completed with the patient by a provider, a registered nurse (RN), or a pharmacist every 12 months. Providers for the context of the project are defined as Medical Doctors/Primary Care Provider, Physician Assistants, and Advance Practice Registered Nurses, (MDs, PCPs, PAs, APRNs). Benefits of the AWV include health risk reduction by assessment of health risk factors such as depression, poor nutrition, fall risk, medication management, chronic disease, and social determinants of health (Watkins & Astroth, 2020). A list of the recommended preventive care screenings and services (see Appendix A) to decrease care gaps a list is reviewed and discussed with the patient. The patient is provided a personalized plan of care with the recommended preventive screenings to promote health and wellness.

This project focused on the breast cancer and colorectal cancer screening part of an AWV. Despite the benefits of the AWV, the visit remains underutilized and less than 50% of adults aged 65 years and older are completing the recommended preventive services (Farford, et al., 2021). Low utilization is attributed to the patients' and providers' lack of understanding of the purpose of the AWV, confusion around billing and covered services, lack of knowledge of screening options, documentation requirements, time constraints, and patient requests to address acute medical needs during an AWV (Farford, et al., 2021).

Efforts to increase AWV utilization and decrease preventive care gaps in breast and colorectal cancer screening are ongoing in ambulatory practice. Increasing access to preventive care services is critical to the long-term wellbeing of older adults. Ambulatory nurses, in

collaboration with other health care team professionals, can address patients' wellness, chronic disease conditions, disability and end-of-life care and translate a collaborative plan of care into achievable actions to meet the health care needs of the patient (Mastal, 2010). One collaborative initiative to address care gaps in the older adult population is the introduction of a team-based Comprehensive Health Assessment (CHA) visit.

The CHA is a preventive visit with a same day problem-oriented visit where the RN and providers use a team approach to proactively improve patients' outcomes, focusing on preventive health by identifying patient needs, addressing care gaps, capturing disease burdens, and connecting the patient with support teams and available resources as appropriate (Care Management, Diabetes Education, etc.). On the day of their appointment, the patients complete their AWV with the RN before meeting with their provider for the problem-based visit to ensure critical patient needs are addressed. The aim of the DNP scholarly project is to translate evidence into practice by implementing a small pilot of the CHA appointment model. The expected outcome of the project is to see a decrease in care gaps, specifically in breast and colorectal cancer screenings, for adults 66-75 years of age.

## 1.2 Significance of Problem

The American Cancer Society (ACS, 2022) reports breast cancer as the most common cancer among women in the U.S.; it accounts for 30% of all new female cancer diagnosis each year. The prevalence of breast cancer in women has increased by 0.5% each year with an average age of 62 at diagnosis (ACS, 2022). For both men and women, colorectal cancer is the third most common cancer and represents 7.9% of all new cancer cases in the U.S. (American Cancer Society, 2020). An estimated 106,180 new cases of colon cancer and 44,850 cases of rectal cancer were diagnosed in 2022 National Cancer Institute [NCI], 2022). Cancer screening is important since

the lifetime risk of women diagnosed with breast cancer is 13% and is most common in middle-aged and older women, followed by 4.3% of men and 4.0% of women diagnosed with colorectal cancer.

In addition, breast cancer is the second leading cause of cancer related death in women; colorectal cancer is the second most common cause of cancer death of men and women combined (ACS, 2022). Earlier screening and identification of colon polyps and breast abnormalities can lead to treatment in the early stages of the diagnosis, increase cancer survivorship, and possibly prevent further spread of the disease. In current practice, breast and colorectal cancer screenings are recommended, but not tracked for completion following the standard nurse only AWV.

The Office of Disease Prevention and Health Promotion (ODPHP, 2022) listed the two preventive care screenings national benchmarks at 80% for breast cancer and 74.4% for colorectal screening. Atrium Health has set benchmarks for these screenings that are close to the national benchmarks (74.1% for breast cancer and 67.9%). It is important to discuss these care gaps because cancer is the second leading cause of death in the US after heart disease (ODPHP, 2022). The CHA provides a potential solution to address the low cancer screening rates. This method will be implemented as a pilot visit at Shiland Family Medicine. The practice is part of Atrium Health, a healthcare network headquartered in Charlotte, North Carolina that consists of over 800 ambulatory care practices.

#### 1.3 Problem Statement

Ambulatory practices throughout the organization are challenged with finding an efficient way to decrease care gaps for breast and colorectal cancer screening in the older adult population. The standard practice is to schedule older adults 66-75 years of age for a nurse-only

visit. Appointment cancellations and no-show rates increased during nurse-only appointments due to some patients' preference to have an appointment with their provider. As a result, preventive screenings, breast and colorectal cancer are left delinquent if a provider does not address them with the patient during the problem-based appointment.

### 1.4 Purpose of the Project

The purpose of this Doctor of Nursing Practice (DNP) was to pilot a Comprehensive Health Assessment office visit model using a standard workflow between the AWV RN and the PCPs to identify, address and decrease preventive care gaps breast and colorectal cancer screening at the point of care for Medicare beneficiaries 66-75 years of age. A secondary aim was to determine if the rate of screening increases among this patient population after completing a shared appointment.

### 1.5 Clinical Question

The PICO question for this scholarly project is: Do adults 66-75 years of age, who complete a comprehensive health assessment visit, compared to the standard nurse-only visit, complete the recommended breast cancer and/or colorectal cancer screening at a higher rate over a period of eight weeks?

### 1.6 Project Objectives

The objectives of this DNP scholarly project were to: (1) implement a shared appointment known as the Comprehensive Health Assessment to identify and address preventive care gaps at the point of care through deliberate communication and collaboration between RNs and providers (2) increase breast and colorectal cancer screening uptake in the older adults aged 66-75 years (3) increase access to preventive care services and screening by closing the loop with appointment scheduling (4) increase the utilization of AWV (5) observe the rates of

screening completion, comparing the two groups to see if either group had a statistically significant greater rate of follow through with the breast and/or colon cancer screening than the other group.

### **CHAPTER 2: LITERATURE REVIEW**

A literature review was conducted to better understand preventive care utilization in the older adult population. Information was obtained using databases: PubMed, ProQuest Central (NC Live), EBSCOhost CINAHL Plus, Elsevier ScienceDirect, the American Cancer Society (ACS), Medicare.gov, the Centers for Medicare & Medicare Services (CMS), Center for Disease Control and Prevention (CDC) and the Office of Disease Prevention and Health Promotion (ODPHP). The search yielded over 800 research studies that mentioned wellness but not all were specific to the Medicare Annual Wellness Visit. Using the search terms *Medicare Annual Wellness Visit* returned 92 research articles published from early 2010 to 2021.

The results were further narrowed searching key words: health promotion in older adults, Affordable Care Act, colonoscopy, mammography, preventive service use in older adults, AWV utilization, AWV team-based care, preventive screening in older adults, colon cancer and breast cancer screening in older adults and preventive care in older adults. The selected collection of resources contained 23 peer-reviewed articles identified as follows: 7 cohort studies, 6 systematic literature reviews, 1 nonexperimental comparative study, 3 QI projects, 1 longitudinal study, 1 cross-sectional study, 1 correlational study, 1 quasi-experimental study, 1 descriptive exploratory study, 1 case report, 1 qualitative descriptive study and 1 non-experimental comparative survey.

Out of the 25 research studies, 10 confirmed low utilization of preventive care services among older adults, 6 discussed breast, and colorectal cancer screenings in the study population, and 14 supported a team-based approach as an intervention to increase access and improve the utilization of preventive care services among adults 66-75 years of age with Medicare insurance.

These research articles support the purpose of the pilot study, confirming that preventive care is an under-utilized service in the older adult population and that team-based care is an intervention that can potentially increase preventive care uptake and decrease care gaps in breast cancer and colorectal cancer screening. This project hopes to address issues with low utilization of preventive care services at the project site and build a team-based approach to decrease care gaps guided by Lewin's Theory of Planned Change.

#### 2.1 Contributors to Low Utilization of Preventive Care

Low utilization of preventive care services in the older adult population aged 66-75 years is a well-documented problem in literature. The Affordable Care Act addressed the problem by eliminating cost sharing for preventive care services, such as colon cancer and breast cancer screening and implemented a free preventive care visit known as the Medicare Annual Wellness visit (AWV). The Medicare Annual Wellness Visit (AWV) is focused solely on preventive health care and the purpose is to increase preventive care services in older adults (Farford et al., 2021). Medicare beneficiaries meet with an advance practice provider, a physician, registered nurse, or pharmacist to identify health risks. Beneficiaries complete a health risk assessment, review family medical history, assess lifestyle behaviors and identify health risks. A personalized preventive plan is provided with the identified health risk and a schedule of the recommended preventive care services (Jiang 2018; Simpson et al., 2021a; Simpson et al, 2021b).

Despite the evidence-based approach of the AWV to address preventive care gaps, less than 20% of Medicare beneficiaries are completing an AWV (Gardenier et al., 2021). Several contributors to low utilization of an AWV and preventive care services have been identified. Providers' and patients' lack of understanding of the value and purpose of the AWV was identified in literature as a significant contributor to low utilization of the AWV and obtaining

preventive care services (Farford et al., 2021). Some physicians focus on managing acute and chronic conditions and overlook preventive care as part of their standard of practice. Themes identified in literature were time constraints; competing demands; large patient panels; the complexity of care during a problem-based appointment does not allow time to address preventive care; confusion over covered services; and billing requirements and the documentation requirements of an AWV as barriers to completing an AWV with their patients (Farford et al., 2020; Gardenier et al., 2021; Simpson et al., 2018; Simpson, 2018b; Toseef 2020).

Older adults reported a lack of awareness of the AWV and confusion of covered services as reasons why they were less likely to schedule an appointment to address preventive care, and stated they are more likely to complete the AWV and adhere to the preventive care services if they are recommended by their physician (Bluestein et al., 2017; Chung et al., 2018). Access to care was another barrier reported in literature to decrease the utilization of preventive care services (Simpson et al., 2021a; Simpson et al., 2021b). Unanswered phone calls to get orders for screenings or other services, and long waits times on the phone to schedule procedures were a few of the barriers patients at Shiland Family Medicine confirmed along with the literature were barriers to them receiving care.

Increasing awareness and access of the AWV will support older adults' efforts at health promotion. Physicians and providers should encourage patients to complete an AWV and follow through with the recommended preventive care services (Simpson et al., 2018; Simpson et al., 2021a; Tao, 2018). Physicians and providers should also address patient concerns with completing screenings that require preparation. For example, the preparation for a colon cancer screening, such as a colonoscopy or Cologuard is reported by patients to be time consuming. Other patients report fear of not waking up from sedation or the side effects of preparation

medications or the procedure itself. Addressing these factors plays an important role in patient choices to complete preventive screenings (Cooper et al., 2017).

These barriers are areas that RNs are skilled at addressing through assessment and education; however, in current practice, some patients do not see the value of an office visit with the RN to complete the AWV and choose to only see the provider for a problem-based visit. Within the RN's scope of practice is the knowledge of population health promotion, disease prevention, and disease self-management care planning. Registered Nurses practicing at the top of their licensure can assist with increasing preventive care delivery, clinic revenue, and quality care outcomes (Bogrett & Carriel, 2018; Tetuan et al., 2014; Watkins & Astroth, 2020).

Although patient visits with RNs to complete an AWV are proven to be an effective way to assist Medicare beneficiaries with identifying preventive care gaps, there are benefits from a shared medical appointment with the nurse and provider (Simpson et al., 2018).

### 2.2 The Team-Based Approach

Nearly 71.7% of Medicare beneficiaries have two or more chronic diseases (Maciejewski & Hammill, 2019). Older adults with multiple comorbidities are less likely to address preventive care needs and schedule a separate visit to complete the AWV (Chung et al., 2018; Gardenier, 2019). To reach the larger percentage of the older adult population, increasing access to preventive care services is essential, literature suggests a team-based approach as an possible intervention (Bluestein et al., 2017; Bogrett & Carriel., 2018; Cuenca, 2012; Chung et al., 2018; Farford et al., 2021; Galvin et al., 2017; Moyer, 2018; Simpson et al., 2018; Simpson & Kovich; 2019; Simpson et al., 2021; Watkins & Astroth, 2020). A team-based approach must include the PCP and other multidisciplinary licensed professionals to promote care coordination and increase

access and to improve preventive care services and screening uptake in older adults. (Farford et al.,2021; Watkins & Astroth, 2020).

Registered nurses are key members of the team-based approach to increasing AWV and preventive care utilization (Bogrett & Carriel, 2018). The RN can decrease the workload of the PCPs, allowing time to focus on higher acuity needs of beneficiaries during a problem-based visit while the RN assists the Medicare beneficiaries with their preventive health care needs (Farford et al., 202; Watkins & Astroth, 2020). Although an RN-led AWV is the standard and the primary solution to increase access, promote quality of care, and increase revenue in primary care practices, knowledge is needed to determine if a team-based approach increases the utilization of AWV and preventives care services (Watkins & Astroth, 2020).

Tracking the outcomes of those recommended preventive care services following a CHA visit is a starting point to gathering this knowledge. Two desired outcomes of the pilot study were to see an increase screening and close care gaps, specifically with breast cancer and colorectal cancer screening. Increased screening and early detection of potential cancer risk will promote the health and well-being of older adults (Farford et al., 2021; Simpson et al., 2018).

2.3 Breast Cancer and Colorectal Cancer in Older Adults

By 2050, it is estimated that over 2.2 million older adults in the U.S. will have some form of cancer (CDC, 2022). Among the predicted diagnoses are breast and colorectal cancer, are the two most prevalent forms of cancer in the U.S. that are most common in older adults (ACS, 2022). A reduction in mortality from the diseases is attributed to early screening, detection, and treatment (Lissenden et al., 2017). Beneficiaries who complete an AWV are more likely to follow through with the recommended cancer screening than those who do not (Tetuan et al, 2014). A shared appointment (team-based) approach could increase AWV usage and close care

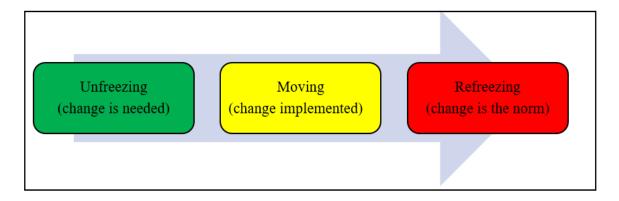
gaps, increasing the rate of breast cancer and colorectal cancer screening in adults 66-75 years of age.

#### 2.4 Theoretical Framework

The pilot study was implemented using Kurt Lewin's (1951) Theory of Planned Change (TPC). Lewin's theory is based on the idea that people's attitudes, thoughts, and behaviors influence their response through the change process (Shirey, 2013). Lewin described the cycle of change in three stages (see Figure 1).

Figure 1

Kurt Lewin's 1951 Theory of Planned Change



The first cycle of change described in Lewin's theory is the unfreezing stage. It requires leaders within the organization to evaluate the current state of practice and barriers contributing to not meeting the benchmark for breast cancer and colorectal cancer screening at the project site. A two-month period of weekly review of the Family Medicine/Internal Medicine population health report, the project coordinator noticed that patients with low percentages of breast and colorectal cancer screening were mostly attributed to providers with less than five years of experience. After completing a need assessment, the study coordinator scheduled a meeting with the clinic office manager to discuss the observation. The meeting revealed that the need assessment conducted at Shiland Family Medicine was accurate, and that the project idea was

aligned with Atrium Health's systemwide initiative to decrease care gaps in breast and colorectal screenings in the adults 66-75 years of age. The study coordinator identified positive forces driving change and negative forces resisting change. This is described by Lewin as the Force-Field Analysis (FFA). A SWOT analysis (see Appendix B) was completed to assess internal and external driving forces that could impact the desired change.

The second cycle of change, known as the moving stage, involves stakeholders adopting a new workflow. The project coordinator moved forward with the project idea, drafting a project plan, and engaged the stakeholders for further review and discussion. The benefits of the pilot study were presented and how it would address barriers that exist with screening compliance was explained. The leadership became more engaged and interested to see if the model would be useful in decreasing care gaps with breast and colorectal cancer screening.

The pilot study was implemented, and the AWV RN and providers collaboratively addressed care gaps in breast and colorectal cancer screening during the CHA visit. The patients' received a personalized preventive plan of care and a referral for the recommended cancer screening. At the conclusion of the project the strengths and weaknesses of the pilot, and the systemic challenges faced during the project implementation were discussed with the project site.

The third cycle of change, known as the refreezing stage, provided a foundation and standard of practice for the RN and providers to feel comfortable sharing a collaborative relationship with the patients' and having a role in identifying and addressing care gaps in older adults. Lewin's TPC was appropriate for the pilot project because it helped stakeholders to understand the why behind the change and how it benefited them and the patients.

#### **CHAPTER 3: METHODS**

### 3.1 Project Design

This study design involved an intervention and comparison group to determine if a Comprehensive Health Assessment would increase breast cancer and colon cancer screening outcomes in older adults 66-75 years of age. The pilot study began September 1 and continued through October 31, 2022.

### 3.2 Sample

The office staff included 1 Registered Nurse (RN), 2 Physician Assistants, 12 Medical Assistants and 10 Medical Physicians. Out of the 25 staff members, a sample of 1 RN, 6 providers, 6 Medical Assistants and a total of 26 adults 66-75 years of age were included in the pilot. For practical reasons, convenience sampling was used, and the pilot was limited to patients who were eligible for an AWV and the recommended breast and/or colon cancer screening during the study period. The initial study sample was anticipated to be 60 patients: 30 in the intervention group and 30 in the control group. After a running a query of eligible patients from a population health report, 47 participants were identified as eligible for an annual wellness visit and had a delinquent breast and/or colon cancer screening.

The inclusion criteria for the study sample were older adults 66-75 years of age who had not completed an Initial Preventive Physical Examination (IPPE), also known as a Welcome to Medicare Visit with a Primary Care Provider (PCP) within one calendar year of the study period, were eligible for an AWV, and had identified preventive care gaps for breast and colorectal cancer screening between the study period of September 1<sup>st</sup> and October 31<sup>st</sup> of 2022. Women aged 65-74 are eligible for a breast cancer screening mammography; men and women aged 65-75 are eligible for a colon cancer screening. Patients were excluded from the study based on the

criteria set by the United States Preventive Services Task Force and Atrium Health quality department: a documented history of a Total Colectomy or a history of colon cancer, a self-reported CT Colonography, or a documented history of a bilateral breast mastectomy.

The project was implemented at Shiland Family Medicine in Rock Hill, South Carolina. The practice is part of Atrium Health, a healthcare network headquartered in Charlotte, North Carolina. According to the U.S. Census Bureau (2022), the city of Rock Hill has an estimated population of 74, 372 with 14.3% of the population over the age of 65. Approximately 1680 Medicare beneficiaries are served annually at Shiland Family Medicine by the RN-Led Annual Wellness program. The demographics of the population are mixed race, White or Caucasian, Black or African American, Non-Latino, Asian, American Indian, or Alaska Native, Hispanic, and Native Hawaiian or Pacific Islander. The larger percentage of the patient population served was predominately White or Caucasian followed by Black or African American.

### 3.4 Intervention

3.3 Setting

The pilot began with the identification of patients that were eligible for an AWV and had a delinquent breast and/or colorectal cancer screening. The second step was to schedule the patients for an appointment with the nurse and the provider or a nurse-only visit. A list of patients was provided to the patient contact specialist in a central call center for outreach and scheduling of the CHA visit and nurse-only visit appointment. Patients who could not be reached were left a voicemail message asking them to return the phone call to a central scheduling phone line. Patients who had an active MyAtriumHealth account were sent an email communication from the study coordinator, letting them know they were eligible for an AWV, along with information about identified care gaps. Patients without an active MyAtriumHealth account

received the same information by mail. A second call attempt to schedule the appointment was completed by the study coordinator; the third and final call, if needed, were made by the AWV RN.

The third step was the appointment. On the day of their appointment, the patients completed the AWV with the RN before meeting with their provider for the problem-based visit. During the AWV, the RN obtained informed consent and met with the patient for 45 minutes to complete a health risk assessment. During the remaining 15 minutes of the appointment, the patient and RN discussed the individualized plan of care, using the health risk assessment form located in the patient's chart. The patient was provided education on the recommended screenings, including appointment scheduling information and breast and colorectal cancer screening locations.

Patients receiving a referral for a breast cancer screening were provided a Charlotte Radiology card with information on how to schedule their appointment by scanning a QR code on the front of the card or by calling one of the center locations' phone numbers. As time permitted, the RN assisted the patient with online appointment scheduling through the Charlotte Radiology scheduling portal. Patients receiving a referral for a colorectal cancer screening were provided with three options to complete the screening: an electronic referral through the EMR for a colonoscopy, an electronic order sent to Exact Sciences for mail order delivery of a Cologuard kit to the patients' home, or a Screening Fecal Occult Blood (FIT) test the patient could take home or complete at the office, then provide the sample to the lab.

Patients choosing a Cologuard screening were provided a pamphlet with a QR code to scan to view video instructions on how to collect the stool sample and how to return the specimen to Exact Sciences. Patients choosing a colonoscopy were provided an information

sheet with the location and phone number of a testing center since there was not an option to schedule patients directly from the website or a scheduling portal.

At the conclusion of the visit the AWV RN, entered orders for the breast and/or colorectal cancer screening in the electronic health record. The AWV RN escorted the patient to the provider appointment and provided the "Preventive Screening Services Checklist" with the identified care gaps to discuss with the PCP. The plan of care and a summary of the AWV was sent to the PCP electronically. The PCP reviewed the summary with the patient and signed the visit to acknowledge the plan of care was discussed with the patient and the CHA visit was completed.

Patients who were not able to schedule their screening(s) during the CHA visit received a seven day post visit follow-up phone call from the study coordinator to determine if preventive screening(s) had been scheduled. Within 30 days, an additional call occurred to complete a telephone survey with participants and to determine if the recommended preventive screenings were completed. Patients who declined the recommended preventive screenings during the visit were documented as a refusal in the personalized prevention plan of care in the EMR.

#### 3.5 Measurement Tools

Preventive care gaps for breast and colorectal cancer were identified in the electronic medical record (EMR) and documented using a preventive services and screening care gap checklist provided by the Annual Wellness Visit RN team. Patient demographic data and screening outcomes were documented on a seven-question telephone survey (see Appendix C) created by the study coordinator. Information collected included a yes or no response to screening completion, age, gender, marital status, level of education and the reason(s) for completing or not completing the screening.

#### 3.6 Data Collection Procedures

After the approval from the University of North Carolina at Charlotte and the project site institutional review board (IRB), using the preventive services and screening checklist (Appendix D), the study coordinator collected data using two methods: chart review and a population health report to identify patients during the study period who had preventive care gaps breast and colorectal cancer screenings and were due for an AWV. A retrospective chart review was performed by the project coordinator to observe patient visit and screening outcomes. Patients who completed the recommended screening had a documented diagnostic report and result in the EMR. Patients who declined the screenings were listed on the Excel spreadsheet in addition to patients who previously stated they would complete the screenings but did not do so during the pilot period.

The data was collected over two-month period. An Excel spreadsheet was used to keep a record and organize the data by patients' age, race, gender, marital status, level of education, provider, and the preventive screening outcomes (completed or not completed). The study coordinator tracked the completion rates of the recommended breast and colorectal cancer screenings from September 1<sup>st</sup> through December 31<sup>st</sup>, 2022. The timeframe was chosen to account for delays in appointment scheduling, cancellations, or rescheduling that occurred during the study period of September 1<sup>st</sup> through October 31<sup>st</sup>.

### 3.7 Data Analysis

Demographic and quantitative data were analyzed using R computing statistical software version 4.2.2. Descriptive statistics were used to describe the sample and the average age of the participants. A chi-square analysis was conducted to compare differences in the rates of

screening between the two study groups and to determine statistical significance. A content analysis was conducted to identify themes from the telephone survey open-ended responses.

#### 3.8 Ethical Considerations

The DNP scholarly project posed no risk of harm to patients during the study, which only investigated the outcomes of routine care received. This pilot study was approved and deemed exempt by the University of North Carolina at Charlotte and Atrium Health IRBs (Appendix F). Patient participation in the pilot study was voluntary. Patients were provided an Informed Consent Information Sheet (Appendix E) during the appointment. To ensure privacy, the diagnostic centers were not made aware that patients were being studied for completion of the breast and/or colorectal screening. Patient referral orders were processed in the same manner as all patients who completed an AWV. Study participants' medical information was discussed in private with the PCPs and Medical Assistants to ensure other patients in the care area did not overhear information about the patient and the study.

Data collected from the chart review and documented on the preventive screening services checklist and telephone survey was stored in a secure, locked file drawer in the locked office of the AWV RN. To ensure confidentiality study participants were labeled with a unique identifier and listed on a password protected Excel spreadsheet secured on a hard drive behind a firewall password protected desktop computer located in a locked office at Shiland Family Medicine. Per the policy of the IRB at the project site, all study data will be securely stored for a period of three years after the completion of the project and then will be destroyed.

Dissemination of the study results will be kept in aggregate form to protect individual study participants responses.

#### **CHAPTER 4: RESULTS**

The purpose of this study was to examine the completion rates of breast and/or colorectal cancer screening among Medicare beneficiaries 66 to 75 years of age. The study results cannot be generalized to the larger population of older adults.

# 4.1 Characteristics of Sample

The initial study was anticipated to have 60 patients: 30 in the intervention group (CHA) and 30 in the comparison group (nurse-only). A query of a population health report identified 47 participants: 13 men and 34 women as eligible for an AWV, and as having a delinquent care gap in breast cancer and/or colon cancer screening. Among these individuals, 26 were scheduled for the pilot study; 5 men and 21 women. Of these, 2 did not attend the scheduled appointment and 3 participants completed the recommended screening(s) prior to the appointment.

In total, 20 individuals participated in the study, with 6 in the Comprehensive Health Assessment group and 14 in the nurse only group. Their average age was 70.75 years old (ranging from 66 to 75, SD = 2.83). Among these individuals, 18 of them were female and 2 were male; 6 were African Americans and 14 were Caucasians; 10 completed some college; and 9 were married.

In the Comprehensive Health Assessment group, 3 people did breast cancer screening (1 did not and 2 did not meet criteria), whereas in the nurse group, 8 people did breast cancer screening (2 did not and 4 did not meet criteria). The difference was not statistically significant,  $\chi^2(2) = 0.09$ , p = .958. in the rate of follow through for breast cancer screening in either group.

In the Comprehensive Health Assessment group, 1 person did colon cancer screening (2 did not and 3 did not meet criteria), whereas in the nurse group, 2 people did colon cancer screening (6 did not and 6 did not meet criteria). The difference was not statistically significant,  $\chi^2$  (2) = 0.16, p = .923. in the rate of follow through for colon cancer screening in either group.

For mammograms, 11 women scheduled and 2 did not. All those who scheduled the breast cancer screening completed it. The difference was not statistically significant,  $\chi^2(1) = 6.45$ , p = .011, however adherence to scheduled mammograms showed clinical significance. 4.2 Participant Feedback

A total of 20 telephone survey calls were made at the completion of the study.

Participants were asked the reason they completed or did not complete the recommended screening(s). Six categories were identified: family history, provider/family recommendation, breast changes, screening appointment scheduling wait time, the timing of the screening and health promotion. Their responses were transcribed verbatim, and a content analysis was done to assess for themes. A second investigator then appraised the themes for convergent validity.

4.3 Family History

Two participants spoke about their family history of breast cancer or other cancers as the reason they chose to schedule an AWV and follow up with the recommended preventive screening mammogram. One of the participants stated she "did not see a need for annual mammograms until her maternal aunt was diagnosed with breast cancer at age 74." The other participant stated, "my diagnosis with ovarian cancer led to my decision to follow through with the recommended breast cancer screening."

### 4.4 Provider and Family Recommendation

Provider and family in the support role can potentially increase patient engagement in adhering to the recommended preventive screenings. One participant's daughter spoke intensely during the visit about the patient completing the mammogram. The patient states her PCP was just as vocal about following through with the mammogram. She stated, "Dr. Fulmer emphasized

breast cancer screening is a service covered by Medicare and advised I complete the recommended screening since I have not completed one before."

### 4.5 Breast Changes

Two participants spoke about having pain or a lump in the breast as the reason they chose to follow up with the recommended preventive screening. One stated she noticed something did not feel right when she would wear a bra. She described the discomfort as pain and decided to have her breast evaluated. The other participant said she noticed a lump in her breast while doing a self-breast examination. Both participants' mammograms were abnormal and required further evaluation and intervention by an oncology provider.

#### 4.6 Time

Participants reported issues with scheduling colon cancer screening. Long wait times were reported by patients as barriers to adherence with colon cancer screening and the preparation beforehand. There were two others who did not have the time to follow through with the recommended preventive screenings. Both participants stated they had other competing priorities and would have to work around a family member's schedule. One participant stated "my husband already used a lot of his time off this year to get me to my medical appointments and for his. I must wait until next year when he has more time off." The other participants stated, "I do not have the time right now and must focus on the medical appointments for that family member I am caring for. I will get it scheduled sometime next year."

### 4.7 Health Promotion

Two participants were adamant about keeping a healthcare routine that included preventive care services. One participant stated, "If I had an illness, I would like to know about it early on before it gets to a place where it can't be treated." The other participant stated, "It's the

right thing to do for me to stay on top of my health and fitness. I exercise, I try to eat right, and I complete my preventive health care so I can remain healthy."

#### **CHAPTER 5: DISCUSSION**

This study assessed utilization of two preventive care services, breast cancer and colorectal cancer screening and if a team-based CHA appointment visit would increase cancer screening outcomes in a sample of older adults 66-75 years of age.

### 5.1 Impact of Comprehensive Health Assessment

Prior research studies supported a team-based approach as an intervention to increase access to and the utilization of preventive care services to improve health promotion and disease prevention in older adults (Bluestein et al., 2017; Bogrett & Carriel., 2018; Cuenca, 2012; Chung et al., 2018; Farford et al., 2021; Galvin et al., 2017; Moyer, 2018; Simpson et al., 2018; Simpson & Kovich, 2019, Simpson et al., 2021; Watkins & Astroth, 2020). This pilot study showed that a comprehensive health assessment (CHA) appointment was not associated with increased rates of breast and/or colorectal cancer screenings in the study sample. The sample size of the participants who completed the team-based approach CHA appointment was small compared to the participants who completed the nurse-only appointment. Contributing factors include the length of time it took to get stakeholders on board, the scheduling process, the length of the project period, and the patients understanding of the preventive care visit. Therefore, differences in the outcomes of the screening rates between the two groups did not reach statistical significance and cannot be generalized to the larger population.

Stakeholder engagement at the project site was a key factor in planning and implementing the pilot study. A needs assessment was conducted in the fall of 2020, during a surge of COVID-19 cases in Rock Hill, SC, and the surrounding counties. The increase in the number of cases led to a policy wide change within the organization to decrease outpatient clinic operations. This led to limited in-person care and a transition to telehealth care appointments,

which were mostly reserved for sick visits. Interest in the project was very low due to the circumstances and the project intervention requiring an in-person visit with the patient, the RN, and a provider.

The process of scheduling patients for in-person visits was affected by the change in clinic operations. Although the AWV RN can schedule patients, this is primarily the role of the scheduling team. The downside to this standard of practice is the role is often performed by non-clinical personnel who might not understand how to identify care gaps. Patient appointment history with their PCP was one-way for schedulers to identify patients who need a preventive and problem-based visit. Schedulers are not trained to look at appointment history and do not have access to medical information about the patient; therefore, opportunities to identify patients who could benefit from the CHA appointments were missed. In addition, if schedulers do not explain correctly to the patients the reason for the visit, patient no-show rates increase, creating another barrier to increasing preventive healthcare utilization in older adult patients.

The length of the pandemic made it difficult for the project lead to recruit participants for in-person visits. Patients were apprehensive about the in-person visit and opted for a virtual visit which was not within scope for the pilot study. The six-to-eight-week period of project implementation also made it challenging for the study coordinator to enroll a larger number of participants. In addition, for patients who declined either appointment, reasons for doing so were very similar to those discussed in the literature. A lack of understanding of the purpose of an AWV was a reason given for not scheduling an additional office visit with the nurse by participants in the study sample.

Medicare beneficiaries under 70 years of age and who considered themselves healthy did not see a need to see a nurse and their provider. Interestingly, the average age of the participants

for this study was 70.75 years and the majority were women, which is consistent with the literature findings of participants age and gender when completing AWVs and the recommended preventive care services (Galvin et al., 2017; Jiang et al., 2018; Simpson et al., 2019; Simpson 2021a; Simpson 2021b). This is a meaningful observation and is important for the implications of practice and next steps for future projects. Medicare beneficiaries aged 70 years or younger have preventive care gaps that need to be addressed and should be included in project discussions to achieve the organization's strategic goal.

# 5.2 Impact of Increased Access to Care

Lack of access to necessary preventive health care is a social determinant of health that negatively impacts efforts to decrease care gaps in older adults. (U.S. Department of Health and Human Services, 2023). Regular health screenings, such as mammograms and colorectal cancer screenings are important to identify cancer risk earlier on, promote healthy aging and prevent disease and death in older adults (U.S. Department of Health and Human Services, 2023). Participants who completed the recommended screening did so based on their personal experiences and family history of cancer. Others followed through at the recommendation of a family member or provider who, in their opinion, "deeply cares for them." This feedback suggests these participants understand the importance of preventive care and the influence of others in their health promotion behaviors.

RNs scheduling mammograms during the appointment seemed to be an effective intervention to increase adherence with the recommended screening. Scheduling during an appointment is an intervention consistently supported in the literature (Tetuan et al., 2014). Other participants who did not complete their recommended screening stated other family

responsibilities took precedence over them acting upon the recommended preventive screening at that time.

#### 5.3 Recommendations for Practice

Although a CHA did not increase the likelihood of participants completing the recommended mammogram and/or colorectal cancer screening when compared with the nurse-only visit group, this study suggests having an RN perform the preventive care visit has value; it increases access to preventive care services, improves the chance of patient adherence with the recommended screenings and other services, and increases access to physicians, allowing them time to focus on the patient's acute and chronic care needs.

The RN has a one-hour timeframe with the patient to perform a health risk assessment, review their medical history, reconcile medications, identify other providers involved in the patients care, coordinate patient care, address care gaps, and develop a personalized preventive plan of care. RNs can address stigmas around preventive healthcare and older adults and provide appropriate education for patients to make informed decisions about care. In addition, RNs can help patients understand the difference between a preventive care visit, a regular office visit and an annual physical examination and Medicare insurance coverage of each service.

The provision of clinical services by RNs practicing at the top of their licensure and scope of practice during a preventive care visit meets multiple strategic objectives of the organization. This includes addressing nursing sensitive indicators that measure what nurses do such as an assessment of patients' pain, risk for high blood pressure or diabetes, fall risk, obesity, and depression. These actions promote the practice of ambulatory care nurses increasing their

role as leaders in the transformation of care delivery models. In addition, the preventive care visit performed by the RN generates revenue for the organization.

## 5.4 Study Limitations

The pilot study was conducted at one ambulatory practice clinic. The population of the study was limited to patients with Medicare insurance 66-75 years of who needed breast and colorectal cancer screening. This left other adults aged 65 not participating in the preventive care visit with the nurse. The sample of participants at the project site in both groups were less than 30 participants, and therefore the study results are not generalizable to the population of adults 66-75 years of age in Rock Hill, South Carolina. The recruitment and scheduling of participants were the responsibility of the project coordinator. Few physicians recommended to their patients to complete a preventive care visit with the nurse prior to a visit with them.

### 5.5 Conclusion

With the projected increase in the aging population between 2030 and 2060, unidentified and unaddressed preventive care gaps and the utilization of breast and colorectal cancer screening services can no longer be a low priority when managing the health of older adults. An innovative approach, such as a preventive care visit with the nurse to increase access to care and improve patient outcomes in the population through care coordination, is one way to develop an evidence-based approach to decreasing preventive care gaps. The nurse visit will allow the PCPs the time needed to focus on problem-based visits while the AWV RNs support the patient in taking actionable steps towards managing their health. The overall goal of this project was to improve the lives and health of older adults, keeping the population healthier and happier.

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### APPENDIX A: Medicare Preventive Care Services

- Abdominal aortic aneurysm screening
- Alcohol misuse screenings & counseling
- Bone mass measurements (bone density)
- Cardiovascular disease screenings
- Cardiovascular disease (behavioral therapy)
- Cervical & vaginal cancer screening
- Colorectal cancer screenings
  - o Multi-target stool DNA tests
  - o Screening barium enemas
  - o Screening colonoscopies
  - o Screening fecal occult blood tests
  - o Screening flexible sigmoidoscopies
- Depression screenings
- Diabetes screenings
- Diabetes self-management training
- Flu shots
- Glaucoma tests
- Hepatitis B shots
- Hepatitis B Virus (HBV) infection screening
- Hepatitis C screening test
- HIV screening
- Lung cancer screening
- Mammograms (screening)
- Nutrition therapy services
- Obesity screenings & counseling
- Pneumococcal shots
- Prostate cancer screenings
- Sexually transmitted infections screening & counseling
- Shots:
  - o COVID-19 vaccines
  - o Flu shots
  - o Hepatitis B shots
  - o <u>Pneumococcal shots</u>
- Tobacco use cessation counseling

Source: Medicare.gov

## APPENDIX B: SWOT ANALYSIS

## Strengths

- Atrium's Health Impact 2025 strategic plan and the overall mission
- Value-based contract initiative for Medicare beneficiaries to complete cancer screenings.

### Weaknesses

- Time-constraints
- · Process for scheduling AWV and problem-based appointments

## Opportunities

- Increase breast and colon cancer screening rates
- · Increase access to preventive and screening services
- · Implement team-based approach to address care gaps

## Threats

- Appointment cancellations
- No Shows

# APPENDIX C: TELEPHONE SURVEY

Telephone Survey

| Study  | Participant ID:                           |
|--------|---|
| Date o | of CHA/Nurse Only visit:                  |
|        | Recommended Preventive Screening          |
| Breast | t cancer screening (Mammogram) completed: |
| Yes    |   |
| No [   |   |
| Reaso  | n(s) completed or not completed:          |
|        |   |
|        |   |
| Color  | ectal cancer screening completed:         |
| Yes    |   |
| No [   |   |
| Туре   | of screening completed:                   |
| •      | Colonoscopy                               |
| •      | Cologuard                                 |
|        | FIT or Guaiac Stool FOBT                  |
|        | CT colonography                           |
| •      | Sigmoidoscopy                             |
| Reaso  | n(s) completed or not completed:          |
|        |   |
|        |   |

# APPENDIX D: CARE GAP CHECKLIST

| Study Participant ID:                   | Medicare Annua | l Wellness Visit Care Gap Checklist | RN Visit: CHA Visit: |  |  |  |  |  |  |  |
|---|----------------|-------------------------------------|----------------------|--|--|--|--|--|--|--|
|   |                | Appointment://                      | at/                  |  |  |  |  |  |  |  |
| Shiland Family Medicine-Rock Hill       |                |                                     |                      |  |  |  |  |  |  |  |
| CARE GAP ALERTS (highlighted in yellow) |                |                                     |                      |  |  |  |  |  |  |  |
| AAA                                     |                | Diabetic Foot Exam                  |                      |  |  |  |  |  |  |  |
| Breast Cancer Screening                 | ;              | Diabetic Eye Exam                   |                      |  |  |  |  |  |  |  |
| Dexa Scan                               |                | Covid Vaccine                       |                      |  |  |  |  |  |  |  |
| Colorectal Cancer Scree                 | ning           | Influenza Vaccine                   |                      |  |  |  |  |  |  |  |
| Diabetes A1c Screening                  |                | Pneumonia Vaccine                   |                      |  |  |  |  |  |  |  |
| Hep C Screening                         |                | PSA                                 |                      |  |  |  |  |  |  |  |
| Lung Cancer Screening                   |                | Shingles Vaccine                    |                      |  |  |  |  |  |  |  |

### PREVENTIVE CARE AND SCREENING SERVICES (LAST DOCUMENTED)

| Preventive Screenings  | Date | Result | Vaccines                 | Date | Result |
|------------------------|------|--------|--------------------------|------|--------|
| AAA                    |      |        | Covid Vaccine #1         |      |        |
| Breast Cancer          |      |        | Covid Vaccine #2         |      |        |
| Dexa Scan              |      |        | Covid Vaccine #3         |      |        |
| Colorectal Cancer      |      |        | Influenza Vaccine        |      |        |
| Cardiovascular Disease |      |        | Prevnar 13<br>(PCV13)    |      |        |
| Diabetes A1c           |      |        | Pneumovax 23<br>(PPSV23) |      |        |
| Diabetic Foot Exam     |      |        | PSA                      |      |        |
|                        |      |        |                          |      |        |
| Hep C                  |      |        | Shingles #1              |      |        |
| Lung Cancer            |      |        | Shingles #2              |      |        |

## **AWV SUMMARY**

|  |        |    | Comments |
|--|--------|----|----------|
| Advance Directives                     | Yes    | No |          |
| Fall Risk                              | Yes    | No |          |
| Opioid Use                             | Yes    | No |          |
| Hearing Aids and/or Hearing Impairment | Yes    | No |          |
|  | Scores |    |          |
| ADL index                              |        |    |          |
| Mini Cog                               |        |    |          |
| PHQ2/PHQ9                              |        |    |          |
| Pain                                   |        |    |          |

### APPENDIX E: INFORMED CONSENT INFORMATION SHEET



ATRIUM HEALTH SHILAND FAMILY MEDICINE

Comprehensive Health Assessment: Decreasing Preventive Care Gaps in Older Adults

Informed Consent Form Information Sheet to Participate in Research Study

\*\*Jennifer Brady, MD\*\* Principal Investigator

\*\*Georgetta E. Wright, MSN, RN Study Coordinator\*\*

# STUDY SUMMARY

You are invited to participate in a research study. You are being asked to voluntarily participate in a research study. We are asking you to be in this study because we would like to learn more about the reasons older adults aged 66-75 do not complete the recommended preventive care, breast cancer and colorectal cancer screenings. You are invited to be in this study because you are completing an Annual Wellness Visit (AWV). If you complete a nurse-only visit, the visit will be one hour. If you are complete a Comprehensive Health Assessment, which is a visit with the nurse and your primary care provider, the visit could take one hour and twenty minutes. The timeframe of the study is September 1st through October 31st, you will only complete one visit.

If you agree, we will conduct two follow up phone calls with you to ask you the action you took with the recommended preventive screening(s). The first phone call will happen one week after your appointment to determine if you have scheduled the recommended preventive care services, breast cancer and/or colorectal cancer screening(s). If you have not scheduled and/or completed the recommended preventive care services, you will receive a second phone call thirty days after your visit. If you have not scheduled or completed the recommended preventive screenings within 30 days, you will be asked to give a brief reason why. We hope to determine ways we can support our older adults with completing recommended preventive healthcare.

All research studies involve some risks. You should experience minimal risk during the study since it aims to only determine outcomes of care. The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need further understanding of the study.

If you have any questions, suggestions, or concerns about your rights as a volunteer in this research, contact the *Institutional Review Board at 336-716-4542 or the Research Subject Advocate at Atrium Health Wake Forest at 336-716-8372.* 

#### APPENDIX F: INSTITUTIONAL REVIEW BOARD APPROVALS



To: Georgetta Wright

University of North Carolina at Charlotte

From: Office of Research Protections and Integrity

RE: Notice of Exemption with Limited Review Approval

 Approval Date:
 14-Jun-2022

 Exemption Category:
 2~3~4

 Study #:
 IRB-22-1148

Study Title: Comprehensive Health Assessment: Decreasing Care Gaps in

Older Adults

This submission has been reviewed by the Office of Research Protections and Integrity (ORPI) and was determined to meet the Exempt category cited above under 45 CFR 46.104(d). In addition, this Exemption has received Limited Review by the IRB under 45 CFR 46.111(a)(7). This determination has no expiration or end date and is not subject to an annual continuing review. However, you are required to obtain IRB approval for all changes to any aspect of this study before they can be implemented and to comply with the Investigator Responsibilities detailed below.



Office of Research
Institutional Review Board

### MEMORANDUM

To: Jennifer Brady and Georgetta E. Wright

Atrium/ Carolinas Healthcare System

From: Brian Moore, Chair

Institutional Review Board

Date: 6/2/2022

Subject: Exempt Protocol: IRB00084968

Comprehensive Health Assessment: Decreasing Care Gaps in Older Adults

No protected health information will be used or disclosed in this research proposal; therefore, the requirement for individual Authorization does not apply.

This approval includes a limited waiver of HIPAA authorization to identify potential subjects for recruitment into this research study, as allowed under 45 CFR 164.512. This temporary waiver provides access to protected health information (PHI) to confirm eligibility and facilitate initial contact, after which consent and HIPAA autorization will be sought. Access and use is limited to the minimum amount of PHI necessary to review eligibility criteria and to contact potential subjects.

This research meets the criteria for a waiver of HIPAA authorization according to 45 CFR 164.512.