Assessing Gait speed to Inform frailty Evaluation (AGILE)

Abstract

Americans age 65 and over account for over one-third (34%) of U.S. health care expenses−a figure expected to rise. Improper clinical decision when treating older patients (providing care that is *too aggressive* in patients with limited survival, or *failing to recommend care* for those with robust health) can result from failing to appreciate comorbidities and disability that frequently, but variably, accompany aging. Within epidemiological studies, the *frailty* conceptualization has emerged to help explain why some individuals are physiologically older than their chronological age, and more vulnerable to adverse health outcomes. A key metrics of this frailty construct predictive of adverse outcomes is *slowness*−operationalized across multiple studies as speed of walking, or "gait speed." Data consistently show a strong, dose-dependent association between gait speed and survival. An ongoing Emory surgical cooperative has shown that gait speed can be collected in a research-pilot setting and that such information provides predictive validity with respect to post-operative complications. Even with compelling epidemiological evidence and proof of feasibility and promising early results within the clinical setting, we as a health care system have been slow to gather such potentially useful, cost-effective, and easily collected clinical frailty.

Among its many potential uses, a validated tool to measure gait speed can assist health care providers in early detection of elderly patients at risk of adverse outcomes and/or hospital readmissions and help them make better informed decisions regarding use of curative versus palliative care, including determining feasibility of surgery or chemotherapy and practicality of ordering expensive and often invasive preventive screening tests.

The goals of this innovative T4 project is to refine a mobile technology and recommend a protocol and develop a pilot device to easily and reliably measure gait speed in a variety of outpatient and inpatient clinical settings, including development of a second-generation smart-phone application, which will allow clinicians access to a median life expectancy and 5-year and 10-year survival rates. Projected outcomes include: development of multiple reliable and facile ways of measuring gait speed; ability to integrate these data into the Cerner EMR system and the TEC Health Prevention module; and development of two products with commercialization potential−a gait speed measurement device and a mobile application.

The proposed project, which expands on an ongoing pre-operative pilot study of older patients conducted at Emory University, has **three specific aims: 1)** Integrate an existing smart phone application developed to measure gait speed in pre-operative older patients into the current workflow of two health care settings, where it has high potential for improving clinical effectiveness, and assess its use among medical assistants and nursing personnel working in these settings, including identifying any barriers that may exist and determining the most appropriate location within the electronic medical record to store this information; **2)** Based on workflow analysis from Aim 1, develop and test a deployable, easily-installed, low-cost fixed device that can be incorporated into a variety of out- and inpatient clinical settings to generate a gait speed over a 4-meter course; and **3)** Use the first generation prototype developed and tested as part of Aims 1 and 2 to create an advanced, second-generation smart-phone application that also can assess gait speed, and, with inputs of age and gender, predict median life expectancy and 5-year and 10-year survival rates. An **overall goal** of the AGILE project is to improve clinical effectiveness.

Additional resources for this protocol include the Georgia Tech Aware Home Research Initiative, the Center for Assistive Technology and Environmental Access (CATEA), and the Resource Engineering Research Center on Disability and Aging; the Emory Center for Health in Aging; the Birmingham/Atlanta VA Geriatric Research Education and Clinical Center; and the Nell Hodgson Woodruff School of Nursing. Investigators from across schools, departments, and campuses with a strong history of funding will be participating on this project at no cost.

A. Introduction

Increasing life-expectancy is a clear victory for public health, yet in 2010 the 13% of Americans age 65 and over were responsible for 34% of total U.S. health care expenditures[1]. Data from 2008 show that this population accounts for about 26% of all physician office visits, 35% of all hospital stays, and 38% of all EMS responses [2]. By 2030, one of every five Americans—approximately 72 million people—will be age 65 or older [3]. This population represents a heterogeneous group in terms of comorbidities, health, and disability.

Older adults have worse clinical outcomes on average, yet some "old" people present physiologically older than their chronological age. Linda Fried described this vulnerability towards disability and disease as *frailty*. While frailty remains a distinct concept from comorbidity and disability, overlaps exist [4]. In her landmark paper using data from the Cardiovascular Health Study, Fried showed frailty (both intermediate and severe) at baseline to be predictive in a dose dependent fashion of important clinical outcomes, including death, first hospitalization, falls, and worsening functional status and mobility disability. Fried categorized frailty by questionnaire measurement of weight loss, exhaustion, and low activity and by performance tests for weakness (grip strength) and slowness (**gait speed**) [4].

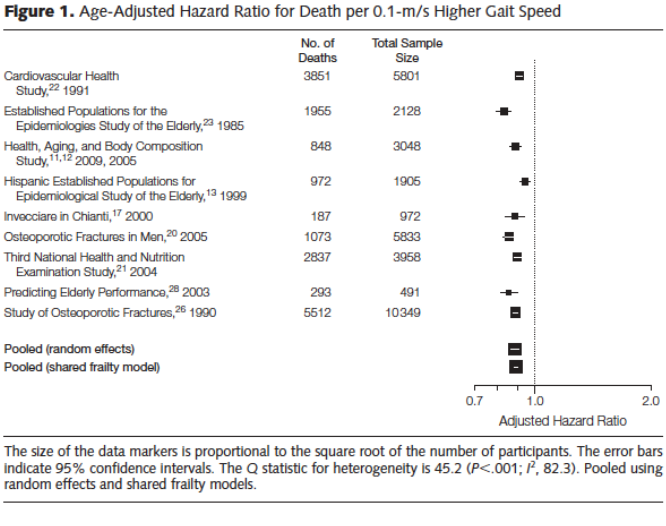


Figure 1. Age-Adjusted Hazard Ratio for Death per 0.1-m/s Higher Gait Speed

The size of the data markers is proportional to the square root of the number of participants. The error bars indicate 95% confidence intervals. The Q statistic for heterogeneity is 45.2 ($P<.001$; I^2, 82.3). Pooled using random effects and shared frailty models.

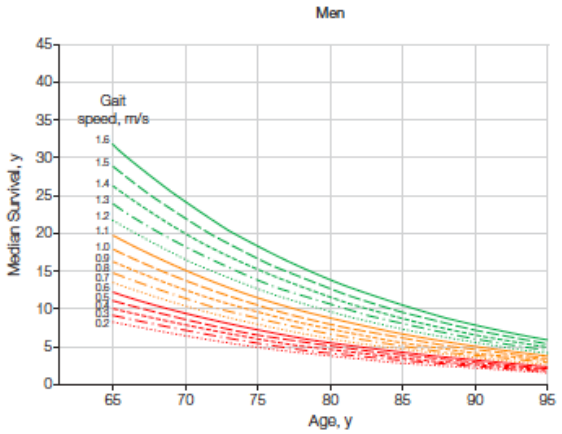
This Forest plot shows means and confidence interval for the Hazard Ratio of Mortality for each 0.1 meters/second decrease in comfortable walking speed for adults greater than 65 years of age. Source: Studenski, et al. Gait Speed and Survival in Older Adults. JAMA 2011, 305 (1): 50-58

A recent article shows that one of the physiological measures from Fried's construct−gait speed−even when used alone is highly predictive of survival [5]. The Forest plot from this article (**Figure 1**) shows marked consistency across multiple studies, indicating that each 0.1 meter per second (m/sec) drop in gait speed is associated with reduced survival. Synthesizing all data across studies provides a predictive model of years of life remaining (**Figure 2**). In line with this predictive model, evidence from other epidemiologic and clinical literature supports potential applicability of frailty assessment, estimated years of life remaining, or gait speed measurement for use in the following clinical practices: 1) detecting risk of hospital readmission [6]; 2) making decisions about screening for prevention in primary care [7]; 3) deciding between curative versus palliative oncologic surgery [8]; 4) assessing surgical risk, both work done at Emory [9] and elsewhere [10]; 5) making timely referrals to palliative or hospice care services, which might affect the 25% share of Medicare payments going to persons in the last year of life [11]; and 6) assessing fall risk [12]. Not taking these differences into account could contribute to inappropriate clinical decisions that would result in adverse patient outcomes and disparities in health care.

This existing evidence suggests that utilizing markers of frailty, such as gait speed, in clinical practice and in our shared decision-making with patients about their healthcare has great potential to improve clinical effectiveness by reducing health care costs and improving health outcomes. While gait speed is consistently and strongly associated independently with survival in older populations in the epidemiological literature and demonstrated to be of utility in multiple clinical demonstration settings, lack of widespread adoption and use in the clinical setting

likely stems from inattention to its integration into the workflow because of the complexity of obtaining it in the current configuration. Therefore, the goals of the proposed T4 AGILE project are to develop a technology and protocol to easily and reliably measure gait speed in a variety of out- and inpatient clinical settings, including development of a second-generation smart-phone application that will include use of the formulae that generate patient-specific predictions of median life expectancy and % 5-year and 10-year survival. Projected outcomes include: development of multiple reliable and facile ways of measuring gait speed; ability to integrate these data into the Cerner EMR system and the TEC Health Prevention module; and development of two products with commercialization potential-gait speed measurement device and mobile application.

Figure 2. Predicted Median Life Expectancy by Age and Gait Speed



This graph depicts median years of remaining expected life by age (x-axis) and each gait speed (each curve)[5]. Only men are represented on this graph; women are shown on a separate graph. A 65-year old man with a gait speed of 0.5 m/sec would have a median life expectancy of 8-years, whereas a gait speed of 1.4 m/sec would be associated with a 20-year median life expectancy. Utilization by a smart phone of the formulae used for generating these graphs would allow an easily accessible, individualized median life-expectancy predictions. This degree of difference would significantly impact clinical decision making on surgery, prevention, and risk assessment. From [5]

B. Specific Aims and Questions to be Addressed

Clearly, patients can benefit from health care providers' ability to routinely measure and utilize the concept of frailty within clinical decision-making. This task needs to be easy to accomplish, be part of the normal workflow, be done reliably, and be easily placed and located within the electronic medical chart. The proposed project, which expands on an ongoing pre-operative pilot study of older patients conducted at Emory University and related support from the Georgia Tech Resource Engineering Resource Center, addresses these important needs. The three specific aims are to**:**

1) Integrate an existing smart phone application to measure gait speed into the current workflow of two specific health care settings, where it has high potential for improving clinical effectiveness, and assess its use among medical assistants and nursing personnel working in these settings, including identifying any barriers that may exist, and determine the most appropriate location within the electronic medical record to store this information.

2) Based on workflow analysis from Aim 1, develop and test a deployable, easily-installed, low-cost fixed device to generate a gait speed over a 4-meter course that can be incorporated into a variety of outpatient and inpatient clinical settings.

3) Use the first generation prototype developed and tested as part of Aims 1 and 2 to create an advanced, second-generation smart-phone application that can assess gait speed, and, with inputs of age and gender, also predict median life expectancy and % 5-year and 10-year survival.

C. Methodology

C.1. Methods Used to Address Specific Aim 1:

In the first phase of the project, we will integrate an existing smart phone app developed and validated for accuracy (comparison of app's gait speed calculation versus videotaped, timed analysis) through funding through the Georgia Tech Research Engineering and Resource Center to measure gait speed in older patients (age ≥ 65) into the current workflow of two health care settings: 1) a pre-operative assessment at Emory [9] where data will be collected as part of an ongoing frailty assessment and 2) an outpatient geriatrics clinical setting where these data will be collected as part of the Medicare Annual Wellness Visit [13] protocol. We will perform a workflow analysis (Clevenger, Wright) to assess use of the smart phone application by medical assistants and nursing personnel working in these settings and identify any potential barriers that may exist. Initial workflow analysis will be performed by graduate students and post-doctoral fellows using standardized tools from the Health Resources and Services Administration (HRSA) [14] for implementing information technology solutions within a health care setting. Students working under the direction of Jon Sanford, M.Arch., will assess the layout of the environment and patient flow, in order to ensure that the work steps make sense spatially. The goal of this step is to ensure that the time required to collect gait speed data is minimal and will not disrupt workflow. These assessments and informal interviews with clinic staff will identify salient aspects of gait speed use as it relates to workflow, and inform questions for subsequent focus groups. Under the direction of Molly Perkins, Ph.D., graduate students and/or post-doctoral fellows will conduct two focus groups in each clinic setting, one with medical assistants and one with nursing personnel. The focus group method is ideal for examining clinicians' shared experiences and gathering their reactions and will be used to: 1) identify barriers and facilitators; 2) gauge the perceived appropriateness of gait speed to guide health care decisions; and 3) identify concerns and ideas about integrating the smart phone application into workflow. To facilitate group discussion by all participants, the sample size for each group will be limited to five participants per group. Each group will be conducted by two researchers, a moderator and an observer. The observer will assist with the process and record observations of participants' nonverbal interactions and behaviors. Focus group questions will begin broad and become more focused and be designed to assess participants' attitudes, knowledge, and experiences. Focus groups will last approximately 90 minutes and be digitally-recorded and transcribed verbatim. All focus group data will be entered into NVivo 10.0, a qualitative software package specifically designed for managing qualitative data and for facilitating qualitative data analysis. We will use inductive coding techniques and thematic analysis to analyze these data and identify common themes within and across different groups and clinic settings. Focus group transcripts will be coded by a minimum of two team members, and differences in coding brought to the research team for discussion and reconciliation. The accuracy of our interpretations will also be assessed through member checking (soliciting feedback from focus group participants).

C.2. Methods Used to Address Specific Aim 2:

We will use the first generation prototype developed and tested as part of Aims 1 and 2 to create an advanced, second-generation smart-phone application that also can assess gait speed, and, with inputs of age and gender, predict median life expectancy and % 5-year and 10-year survival. The second-generation, advanced smart phone app will have the functions described for the first generation app, but, in addition to providing gait speed, will also: a) require input of the gender and age of the patient; and b) provide median life-expectancy, expected % 5-year and % 10-year survival (adjusting for gait speed, gender, and age). Calculations and output from the app would be validated against the standardized survival map for 100 cases. The equations for generation of these curves have been provided by Subashan

Perera, Ph.D., Associate Professor, Division of Geriatric Medicine (**Appendix A**), and were validated in nine large multiple epidemiological studies with over 34,485 participants. The investigative team recognizes that this enhanced app possibly could, but not likely, be judged a medical device as per FDA final guidance on mobile medical apps [15]. These rules would not apply to the testing of the device, but would be relevant to considerations of release of the app for sale. The investigative group holds an approved PCORI LOI for patient communication and understanding around prognostication in surgical and prevention decision making.

C.3. Methods Used to Address Specific Aim 3:

In the third and final phase of the project, the Aware Home Research Initiative will use information from the workflow analysis to develop a fixed, easily installed, deployable device to be used in a variety of outpatient and inpatient settings for determination of gait speed as per the aim. The course will be laid out with a fixed, folding, articulated measure that will span a four meter length with a start and finish gate at either end. The prototype will have directionality and will be able to be mounted (start to finish) within standard attachments within hallway handrails. Ideally, the gates will detect the passage of the trunk of the body (as opposed to swinging legs or arms, which might break the plane earlier), but this difference in timing based upon different body parts breaking the plane will be addressed and weighed against the protection that being near the handrail would afford.

There will be a display on the end gate that will display both elapsed time as well as gait speed. While an electric eye device would likely be accurate, this would mean that the installation would require calibration of the device upon installation. Other circuit completion signaling approaches will be considered, including ultrasonic range finder, PIR motion sensor, and RFID (radio-frequency identification) tagging. The target price for unit cost will be $75, with a target price for the prototype of $125. This prototype will be assessed against a gold-standard device for gait speed, such as the Gait-Rite analysis system or videotaped, timed analysis. This testing will be conducted in the Aware Home Research Initiative, under the direction of Mr. Jones. Discussions with Emory EHR leaders about the appropriate location and applicability of a discrete data element will inform the desirability of placement of these data in the Medicare AWV PowerForm.

E. Next Steps

The development of a reliable and facile way of measuring gait speed will improve clinical effectiveness and have the following outcomes: integration of these data into the Cerner EMR system for use in clinical care and prediction for adverse events; integration of these data into the TEC Health Prevention module/AWV PowerForm; use in research proposals on measurement of frailty in surgical populations as part of pre-operative assessment; and development of two commercially available products−gait speed measurement device and mobile application (mobile app would be subject to final FDA guidelines, expected by August 2013). The opportunity to predict increasing frailty and decreasing life expectancy may prove to decrease costs to Medicare as interventions develop to care for the frail elder outside of the acute care setting. Providing primary care providers with predictive tools to guide decision making, and potentially including these data in Medicare annual wellness visits, also may enable patient centered decision making at a much earlier point in time.

F. Resources

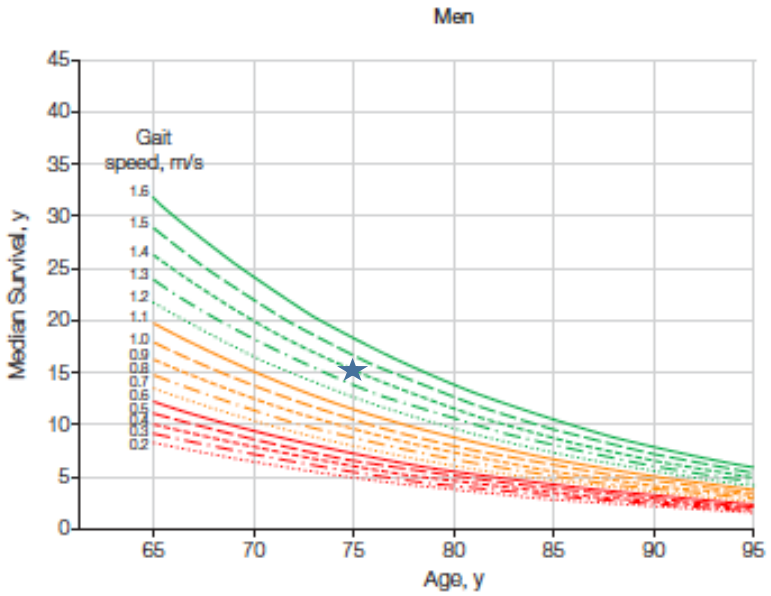
Resources for this protocol include those available through Aware Home Research Initiative and the Center for Assistive Technology and Environmental Access (CATEA), through the Birmingham/Atlanta VA Geriatric Research Education and Clinical Center, and through the Emory Center for Health in Aging, and the Nell Hodgson Woodruff School of Nursing.

Ted Johnson, MD, MPH, is a health-services research trained geriatrician with 10 years of research experience in nocturia. He is the Atlanta Site Director of the Birmingham / Atlanta GRECC, a Professor of Medicine and Epidemiology at Emory University. Through Emory Healthcare, he is charged as a co-lead of the Primary Care Expansion Strategy and charged to develop The Emory Clinic strategy on prevention. **Molly Perkins, PhD**, is a doctorally-trained sociologist with federally funded grants in mixed-methods (qualitative and quantitative). **Camille Vaughan, MD, MS**, is a geriatrician researcher and Assistant Professor of Medicine who is funded through a 5-year VA Career Development Award with a focus on the frail elderly, particularly those with Parkinson Disease. **Viraj Master, MD,** is an Associate Professor of Urology who has been conducting studies of frailty in older populations undergoing surgical intervention, and has past experience working with health literacy and numeracy in these populations. **Jon Sanford, MS,** is a full-time faculty member at GA Tech in the college of architecture, the Director of CATEA, and a member of the Atlanta VA Rehabilitation Research and Development Center. **Brian Jones, MS**, is a Senior Research Engineer at GA Tech, and the Director of the Aware Home Research Initiative. **Carolyn Clevenger, DNP**, is the Assistant Dean for Masters Nursing at the Nell Hodgson Woodruff School of Nursing and a lead faculty in the VA Quality Scholars program at the Atlanta VA Medical Center, one of eight such Centers in the US. **Phyllis Wright, DNP**, is a faculty member at the Nell Hodgson Woodruff School of Nursing and previously served as health care consultant with Price-Waterhouse Coopers.

G. Timeline of Tasks by Months

Task / Months	1	2	3	4	5	6	7	8	9	10	11	12
Project start up and pilot instruments	X	X										
Aim 1												
Integrate existing smartphone app into two clinic settings			X	X								
Conduct workflow analysis				X	X							
Aim 2												
Develop and test a new deployable, easily installed low-cost fixed gait speed device			X	X	X	X	X	X	X	X		
Aim 3												
Create advanced, second-generation smart-phone application									X	X	X	X

Figure 2. Predicted Median Life Expectancy by Age and Gait Speed



The above equations generate a point on the above graph, allowing a smart phone application to give the "point on the curve" ★ where age, gender, and calculated gait speed offer a number that is median survival. In this case, a 75 year old male with a gait speed of 1.4 meters/second has a median survival of 15 years.

Shared under agreement for the purposes of development of a hand-held mobile application by Stephanie Studenski, MD, Director; and Subashan Perera, Ph.D.; Associate Professor; National Institute on Aging Claude D. Pepper Older Americans Independence Center; Division of Geriatric Medicine; University of Pittsburgh; 3471 Fifth Avenue, Suite 500; Pittsburgh, PA 15213

HUMAN STUDIES SECTION

A. Risk to Subjects

1. Human Subjects Involvement and Characteristics: Research subjects will include patients, providers, and administrators who will participate in focus groups and semi-structured interviews regarding the use of gait speed and other measures of frailty and their potential roles in clinical decision making. Other participants will be younger and older adults who will walk beginning from a standing position and at a comfortable pace over a short distance (4-5 meters) in a controlled setting in the absence of trip hazards.

2. Potential Risks: Participation in this protocol is believed to have little physical health risk to the participant. This protocol will be performed in the clinic settings of the Wesley Woods Center, the Aware Home, and the Center for Assistive Technology and Environmental Assistance.

B. Adequacy of Protection from Risks

1. Recruitment and Informed Consent: Recruitment will be through community flyers and subject registries.

2. Protection against Risk: There are several features of this current protocol that will protect the risks to the participants, including confidentiality. We do not anticipate collecting protected health information through the course of the formal research proposed here. The potential risk to the participant's health, as mentioned, is from falling while walking.

C. Potential Benefit of the Proposed Research to the Subject and Others

The potential benefit to participants is that they will receive an evaluation of gait speed.

D. Importance of the Knowledge to be Gained

These results are likely to improve our understanding the use of gait speed in clinical decision making and the ability to more easily gather this information from older adults. The risks to the participants are minimal.

E. Statement of Disclosure

The PI and investigators have no financial or contractual relationship with any organization or individuals involved in the study that might constitute a conflict of interest.

F. Acknowledgement to Include Women and Minorities in Research

By design, this study addresses how to evaluate gait speed in older adults. We will likely find populations enriched with older women. Our past research recruitments have demonstrated high proportions of typically underrepresented minority groups (in this case African-American populations).

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