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IRB Proposal

Study Title:
Does Utilization of a Home Health Aide Reduce the Risk of Hospitalization in patients with Alzheimer's Disease?

A. Study Purpose and Rationale

Currently, Alzheimer's Disease effects 5.1 million Americans over age 65 and the prevalence is increasing. Healthcare costs of Alzheimer's Disease are estimated at $100 billion per year in the US, making it the third most costly disease1. A large amount of the health care cost incurred by AD patients is due to hospitalizations. Alzheimer's Disease patients are hospitalized 3 times more frequently than age-matched controls2. Hospitalizations also represent a pivotal event for persons with Alzheimer's Disease. Studies demonstrate hospital outcomes for patients with AD are significantly worse than those without AD in terms of delirium, functional losses, prolonged length of stay, institutionalization, and death. Studies have revealed the most frequent reasons for hospitalizations in these patients are syncope or falls, ischemic heart disease, gastrointestinal disease, pneumonia, and delirium1. A subsequent study revealed that patients with AD who are dependent for ADLS are at greater risk for hospitalization3. Given the prevalence, high mortality and morbidity, and high cost of hospitalizations in patients with Alzheimer's Disease research focusing on interventions/treatments to prevent hospitalizations in these patients is of great value to the medical community. One resource used in the management of Alzheimer's Disease is Home Health Aides. Home Health Aides are trained professionals who travel to the homes of community dwelling patients or to long-term care facilities to assist with routine healthcare such as changing bandages and dressing wounds, medication administration, and personal care such as bathing, dressing, and grooming of the patient. They also monitor patients for changes in health status. Patients may be assisted by Home Health Aides anywhere from 1- 24 hours per day.

Home Health Aides represent a resource in assisting AD patients with ADLs and mobility issues as well as general monitoring of the patient. Given that falls and dependence on ADLs increase the risk of hospitalization in Alzheimer's Disease patients, it is reasonable to hypothesize that in patients who utilize Home Health Aides, the incidence of hospitalization will be less than in those who do not use Home Health Aides. Also, we hypothesize there will be a linear decrease in hospitalization rates with increased hours with assistance with home health aides.

B. Study Design and Statistical Analysis

The proposed study is retrospective cohort study involving a chart review of patient's electronic medical records. The electronic medical records of patients with Alzheimer's Disease presenting to neurology clinic at 5 major New York Medical Centers (New York Presbyterian Hospital Columbia and Cornell Campuses, NYU Langone Medical Center, Mt. Sinai Medical Center, Montefiore Medical Center will be reviewed. Information regarding whether the patient has a Home Health Aide and the number of hours the Aide works with the patient is routinely recorded as part of a patient's electronic medical record. The EMR will be reviewed to divide patients into two groups, those with Home Health Care Aides and those without Home Health Care Aides. If a patient has a Home Health Care Aide the number of hours the Aide works with the patient will also be recorded. The patients' EMRs will then be examined to determine if the patient was hospitalized, for any reason or any period of time, within a 1 year period from the start of the study date. The incidence of hospitalizations in patients in each group will then be calculated and compared using a chi-square analysis. The relative risk of being hospitalized in the Home Health Aide group as compared to the non-Home Health Aide group will also be calculated and 95% confidence interval determined.

Previous research has shown Alzheimer's Disease patients to have a yearly hospitalization rate of 18%. In this study a clinically significant reduction in hospitalizations will be 5%. Assuming a difference of 8% (18% hospitalization rate in Non-Home Health Aide utilizing group vs 10% in Home Health Aide group) there would need to be 319 patients in each group to detect this effect size with a power of 80% and a P value of 0.05. This was determined using a chi-square analysis to compare the two proportions.

Within the Home Health Aide group, the number of hours each patient receives care from the HHA will be recorded. A simple linear regression will be performed and the square of the correlation coefficient determined to assess degree of correlation, with the x-axis as number of hours and the y-axis as proportion of patients hospitalized.

In the analysis, the baseline characteristics of the populations, including age, sex, race, number of comorbidities, MMSE score, and number of hospitalizations will be compared using t-tests and chi-square analyses to ensure no differences exist between the two groups. Co-variant adjustment will be used in the analysis to control for the effect of number of co-morbidities and age on the outcome of hospitalizations.

C. Study Procedures
No procedures will be performed during this study.

D. Study Drugs*

There will be no drugs used in this study

E. Medical Device.*

There will be no medical devices in this study.

F. Study Questionnaires
There will be no questionnaires used in this study.

G. Study Subjects

Patients will be eligible in the study if they are 65 years and older, with a diagnosis of probable or possible Alzheimer's disease documented in their chart and seen in neurology clinic at one of 5 major New York Medical Centers (New York Presbyterian Hospital Columbia and Cornell Campuses, NYU Langone Medical Center, Mt. Sinai Medical Center, Montefiore Medical Center). To ensure that patients have a similar level of baseline characteristic in the two groups (ie to control for the possibility that those with more advanced disease may be more likely to have Home Health Aides) only those with mild or moderate disease as defined by an MMSE evaluation with a score of 10-24 will be included in the study.

Patients will be excluded if they have a diagnosis of severe Alzheimer's disease based on an MMSE score of <10, live in a care facility such as a skilled nursing facility or assisted living facility.

This study will involve a vulnerable population, as it will include elderly patients as well as patients who are unable to give informed consent. Their inclusion in the study is necessary as Alzheimer's Disease is a disease of the elderly population. However, this study involves minimal risks to the patients. The study involves a review of the patient's electronic medical record. This always has a small risk of breach of patient confidentiality. However the data will be protected and de-indentified prior to analysis. They will continue to have their care as they normally would and will be receiving no experimental treatments.

H. Recruitment of Subjects

This analysis will be a retrospective cohort study and will be performed as a chart review. Patients will be identified for inclusion in this study by presenting to Neurology Clinic at one of 5 major medical New York Medical Centers (New York Presbyterian Hospital Columbia and Cornell Campuses, NYU Langone Medical Center, Mt. Sinai Medical Center, Montefiore Medical Center).

Informed consent will not be obtained from study subjects. A waiver of informed consent is attached. The study meets the criteria for waiver of informed consent as it involves no greater than minimal risk to the subjects, the waiver will not adversely effect the rights and welfare of the subjects, and the research project could not practically be carried out without the waiver of informed consent as it is retrospective chart review study.

I. Confidentiality of Study Data

Only the investigators will have access to the study materials. Data will be stored on a encrypted, password protected computer. Once subjects are chosen, no personal identifiers (such as hospital unit number, SSN, subject name, date of birth, address) will be collected from the medical record. A unique code will be generated for each subject and the code key will be kept on a password-encrypted computer accessible only to the conductors of the study. The code key will be destroyed 1 month after the completion of data analysis.

J. Potential Conflict of Interest
There are no potential conflicts of interested with this proposed study.

K. Location of the Study

To achieve the required number of study participants to power the study to detect small differences in hospitalization rates, the study will involve multiple large medical centers within the New York area. This will include NY Presbyterian Hospital (Columbia and Cornell Campuses), NYU Langone Medical Center, Mt. Sinai Medical Center, Montefiore Medical Center. The proposal will be presented to the IRB for the various institutions involved.

L. Potential Risks:
There will be limited risks for the participant of this study. Given that this is a retrospective chart review, patient's electronic medical records will be accessed to determine if they have a home health aide and hospitalization rates. With all retrospective chart review studies studies there is an inherent risk of breach of confidentiality. However, as described above, the data will be protected to ensure confidentiality. Otherwise, the patients will incur no additional risks or discomfort. They will continue to receive care as they normally would and will be receiving no experimental treatments.

M. Potential Benefits

There several potential benefits of the study. It is unlikely the subjects themselves will benefit directly as a consequence of the study, however society and investigators will benefit from the knowledge gained. As described in the study rationale, hospitalizations for patients with Alzheimer's Disease are 3 times more frequent than that of the general population, lead to devastating outcomes, and lead to large health care expenditures. Thus, studies examining interventions that may potentially decrease the hospitalization rates of AD patients are necessary and of value to the medical community. The study may reveal important data about whether the use of home health aides is associated with lower risk of hospitalization. While this is not a randomized controlled trial and causality cannot be determined from this study, it will given investigators insight into whether larger controlled trials on interventions with home health aides would be useful. This

would be of financial benefit, to help determine where to target funding for interventions for AD.

N. Alternative Therapies
This study does not involve an experimental therapy, thus no alternative therapies are available.

0. Compensation to Subjects
No compensation will be provided for the subjects

P. Costs to Subjects
The subject will incur no additional costs as a result of participating in the study.

Q. Minors as Research Subjects
This study will not involve minors.

R. Radiation or Radioactive Substances
No radiation or radioactive substances will be used.

Works Cited:
1. Rudolph JL, Zanin NM, Jones RN, et al. Hospitalization in community-dwelling persons with Alzheimer's disease: frequency and causes. *J Am Geriatr Soc*. 2010;58(8):1542-1548
2. 2009 Alzheimer's disease facts and figures. Alzheimers Dement. 2009; 5:234–270. [PubMed:19426951
3. Voisin T, Andrieu S, Cantet C, Vellas B; REAL.FR Group. Predictive factors of hospitalizations in Alzheimer's disease: a two-year prospective study in 686 patients of the REAL.FR study. J Nutr Health Aging. 2010 Apr;14(4):288-91