The After Discharge Care Management of Low Income Frail Elderly (AD-LIFE) Randomized Trial: Theoretical Framework and Study Design

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Abstract

Interdisciplinary care management is advocated for optimal care of patients with many types of chronic illnesses; however, few models exist that have been tested using randomized trials. The purpose of this report is to describe the theoretical basis for the After Discharge Management of Low Income Frail Elderly (AD-LIFE) trial, which is an ongoing 2-group randomized trial (total $n = 530$) to test a chronic illness management and transitional care intervention. The intervention is based on Wagner's chronic illness care model and involves comprehensive posthospitalization nurse-led interdisciplinary care management for low income frail elders with chronic illnesses, employs evidence-based protocols that were developed using the Assessing Care of Vulnerable Elders (ACOVE) guidelines, emphasizes patient activation, and integrates with community-based long-term care and other community agencies. The primary aim of the AD-LIFE trial is to test a chronic illness management intervention in vulnerable patients who are eligible for Medicare and Medicaid. This model, with its standardized, evidence-based medical and psychosocial intervention protocols, will be easily transportable to other sites interested in optimizing outcomes for chronically ill older adults. If the results of the AD-LIFE trial demonstrate the superiority of the intervention, then this data will be important for health care policy makers. (*Population Health Management* 2011;14:137–142)

Background

THE US HEALTH CARE DELIVERY SYSTEM IS STRUCTURED TO manage episodic acute illnesses. However, older adults, a rapidly expanding proportion of the population, typically suffer from multiple chronic illnesses that are ineffectively managed with episodic care.¹ These patients are often hospitalized with exacerbations of their illnesses and are routinely discharged with insufficient attention to transitional care needs, resulting in potentially avoidable rehospitalizations and institutionalization.^{2–4}

Interdisciplinary care management is advocated for patients with many types of chronic illnesses.^{5–10} Numerous care management programs for frail elders have been reported; however, few have been tested using randomized

trials.^{11–13} In addition, models described in the literature vary substantially in scope (ie, social vs medical models).¹¹ As a result, no single model has emerged that is convincingly superior. Most disease management models focus on medical needs with little, if any, consideration of the psychosocial variables that have a direct impact on medical outcomes. Likewise, many social models fail to integrate important medical information and do not collaborate with the primary care physician (PCP). There are a few successful models that integrate the social and medical models (eg, the Program of All-Inclusive Care of the Elderly [PACE]¹² and the Wisconsin Partnership Program¹³), but they have not been tested using randomized trials and have program elements that restrict their application across large populations. The GRACE (Geriatric Resources for Assessment and Care of Elders) trial

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Presented as a poster at the American Geriatrics Society annual meeting, April 29–May 3, 2009, Chicago, Illinois.

is one randomized trial that reports the effectiveness of care management for low income elderly; however, that model was not linked directly with community resources. It also randomized by physician group within a closed, university-affiliated health care system, limiting the generalizability of the findings.

According to the 2007 National Healthcare Disparities report from the Agency for Healthcare Research and Quality, low income groups have reduced access to high-quality health care,¹⁴ yet these patients, especially those who are dually eligible for Medicare and Medicaid, have the greatest care management needs.¹⁵ According to the Medicare Payment Advisory Commission,¹⁶ this dual eligible population is predominantly female (62%), white (57%), and has at least 1 impairment in activities of daily living (ADL; 55%). Lower income older adults with chronic conditions often have limited social and physiologic reserves for coping with postdischarge complications and are also most likely to lack access to comprehensive care management services.¹⁷ This population experiences worse health and is more likely to die prematurely than their higher income counterparts. In order to meet the changing needs of the aging population, especially those most vulnerable as a result of chronic health, financial, and functional problems, fundamental changes in our health care delivery system are required.

Purpose

The purpose of this report is to describe the theoretical basis for the After Discharge Management of Low Income Frail Elderly (AD-LIFE) trial, an ongoing randomized trial of an intervention designed to improve chronic illness management and transitional care. The study will evaluate the effectiveness of a year-long intervention of comprehensive posthospitalization nurse-led interdisciplinary care management for low income frail elders with multiple chronic illnesses. The intervention promotes patient activation through health coaching, uses evidence-based protocols, and integrates with community-based agencies.¹⁸ The primary aim of the AD-LIFE trial is to test the effectiveness of the intervention at improving a profile of outcomes measuring health and well-being for chronically ill elderly patients who are eligible for Medicare and Medicaid.

Theoretical Framework

The AD-LIFE trial incorporates elements of a number of chronic illness care models.^{3,5,19–21} These models assert that optimal care for patients with chronic illnesses is not possible in a traditional health care system that emphasizes disease treatment over illness prevention. Patients in these traditional systems pass from one care setting to another with little or no communication between providers or follow-up to ensure that patient needs are addressed. Furthermore, PCPs do not have the time and often feel ill-prepared to provide the systematic assessments, preventive interventions, patient education, health coaching, and psychosocial follow-up required for effective chronic illness care.^{11,21–24} As a result, PCPs often refer patients with chronic illnesses to multiple providers; fragmentation of care ensues when there is inadequate communication between providers, typically because no single provider coordinates care to ensure that evidence-based guidelines are used to enhance health outcomes.

Wagner's Chronic Care Model,²⁵ for example, proposes that improvement in the care of patients with chronic conditions can occur only when the following changes occur in the health care delivery system: (1) delivery system redesign, (2) community linkages, (3) effective self-management support, (4) organizational structure, leadership, incentives, and resources, (5) evidence-based decision support, and (6) improved information systems. According to Wagner, implementation of these changes should result in more productive interactions between patients and providers that assure the delivery of services that improve functional and clinical outcomes.²¹

Setting

The AD-LIFE trial is being conducted at Summa Health System in Akron, Ohio. Summa is an integrated health delivery system with 2060 licensed beds on 6 campuses. In addition to these acute care hospitals, this integrated system comprises a physicians group, a health insurance arm, an acute rehabilitation hospital, home care, a physician house calls program, palliative care and hospice services, postacute and senior services, and the Summa Foundation. The AD-LIFE trial will measure the additional effect of comprehensive care management superimposed on this environment because half of the participants are randomized to usual care. There may be several advantages to conducting a trial of this nature within an integrated delivery system. For example, interdisciplinary care models that cross care settings are already ingrained in the culture, making it easier, perhaps, for the AD-LIFE interdisciplinary team to interact with the PCP. In addition, many community linkages already existed, so new working relationships did not have to be forged for the trial. However, patients were not recruited from the health insurance plan arm that provides care management services.

Methods

Overview of the AD-LIFE Care Management Intervention

The AD-LIFE trial targets functionally impaired, low income, frail elderly, a group with the least access to high-quality health care and the worst health outcomes.¹⁴ The intervention incorporates the 6 elements of Wagner's Chronic Care Model to create a comprehensive, patient-centered intervention that redesigns health care delivery for chronically ill, low income, frail elderly patients after discharge from an acute care facility. A brief description of the intervention will assist with seeing how the elements of the model have been used to build this comprehensive care management intervention.

The AD-LIFE intervention targets patients with the following characteristics: ≥ 65 years old, confirmed or probable dual eligible (Medicare and Medicaid), have at least 1 chronic illness (ie, chronic obstructive pulmonary disease, diabetes, cerebrovascular accident, coronary artery disease, hypertension, congestive heart failure, osteoporosis, osteoarthritis), and at least 1 impaired ADL or 2 impaired instrumental activities of daily living (IADL), and must be discharged home. Eligible patients are enrolled at the time of discharge and randomized into either the intervention ($n = 265$) or usual care groups ($n = 265$) after baseline mea-

asures are taken. Intervention patients receive a phone call from a geriatrics-certified advanced practice nurse (APN) within 48 hours of discharge to ensure that immediate needs are being met. The APN and a nurse care manager (CM) perform a comprehensive in-home assessment and delineate patient goals of care within 7 days of discharge. These findings are shared with an interdisciplinary team that generates individualized care plans that are structured around the Assessing Care of Vulnerable Elders (ACOVE) guidelines.¹⁸ The core team includes a geriatrician, a nurse care manager, an APN, a social worker from the Area Agency on Aging (AAoA), and a geriatrics-certified pharmacist. Extended team experts, who participate as needed, include a psychologist, cardiologist, pulmonologist, endocrinologist, and occupational therapist. The nurse CM presents the care plan to the patient and PCP in a paid face-to-face office visit during which plans for implementation are finalized. The nurse CM facilitates implementation of the plan over the following year during frequent scheduled and as needed follow-up contacts.

Study outcomes, measured at 6 and 12 months, will include: cognitive function, physical function, emergency department visits, hospitalizations, nursing home admission, quality of life, ADLs, IADLs, quality of medical management, medications, blood pressure, depression, falls, nutrition, pain, exercise, smoking, patient involvement in decision making, access to care, satisfaction, caregiver strain, completion of advanced directives, incontinence, knowledge of personal health risk factors, medication organization, and disease management knowledge. To compare the two groups on these multiple end points, a global hypothesis testing strategy will be used that strongly controls Type I error while optimizing power for consistent intervention effects.

How the AD-LIFE intervention is consistent with Wagner's chronic illness care model

Delivery system redesign. Interdisciplinary care management is advocated to optimize the care of patients with a variety of chronic illnesses and is central to operationalizing Wagner's model. The redesign implemented in the AD-LIFE trial integrates the medical and social models of care by creating an interdisciplinary care management team that utilizes nurse CMs and coordinates care with the AAoA, other community agencies, and the PCP. The presence of this CM ensures coordination of care across all providers and enhances adherence to evidence-based protocols in a way that is generally not possible for a single PCP.

The interdisciplinary team provides the leadership, incentives, and resources for PCPs who are managing chronically ill patients. Because PCPs are reimbursed for their participation in the trial, there is an incentive for the PCP to participate in the patient's chronic illness management. The PCP is also provided with added resources via the academic detailing that accompanies all team recommendations.

In addition to the interdisciplinary team, a major feature of delivery system redesign incorporated into the AD-LIFE trial is the geriatric APN, who assists with initial assessments and care planning and oversees the activities of the nurse CMs who ultimately implement the care plans. The APN also reassesses patients when they are readmitted to the hospital and assists with discharge planning. Issues beyond the

APN's expertise are referred to the team geriatrician. The use of an APN in this role is one way to expand the reach of the relatively few geriatricians and geriatrics expertise to a larger portion of the population.

Another important aspect of delivery system redesign is the regular and frequent follow-up by the nurse CMs. This provides professional assistance during care transitions, a time when patients are typically on their own to navigate the complex system of social and medical resources they may need to ensure optimal recovery. The in-home visits also improve health care delivery by allowing the CMs a first-hand look at the patient's environment and potential barriers to optimal health recovery. The frequent follow-up also allows the CMs to identify potential problems at an early stage so that treatment can be initiated promptly.

Community linkages. To ensure the most comprehensive access to community resources, an AAoA social worker is a regular member of the interdisciplinary team to provide referrals for psychosocial needs and to assist with gaining access to those services while the nurse CM provides referrals to available community resources for medical needs. The CM also provides patients with information on community-based disease-specific education, prevention programs, and physical activity.

Effective self-management support. The first step in effective care management is to have the patient state his or her goals of care. Care plans are then devised to help the patient achieve those goals. The first 6 months of the AD-LIFE intervention provides for frequent postdischarge follow-up so the CM can provide assistance, skills training, coaching, and help with problem solving. The CM promotes self-directed care by providing the patient with a written summary of the care plans devised by the team as well as with educational resources, and accompanies the patient to PCP visits as needed to provide role modeling and coaching. In addition, the CM maximizes patients' psychosocial support to optimize their ability to self-manage. Advance care planning is also incorporated into the intervention to ensure that patients maintain as much control over their care as they desire and to improve communication with the PCP. The first 6 months of the intervention involves intensive care management; during the second 6 months the CM steps back and allows the patient to practice self-management.

Organizational structure, leadership, incentives, and resources. The AD-LIFE intervention would not have been possible without the cooperation between our health system's Senior Services leadership and high-level administrators at the AAoA. Leadership from both organizations realized that optimal outcomes for patients with chronic conditions could not be achieved without breaching professional "silos." It was agreed that only through a collaborative team process involving professionals who represent the complete biopsychosocial sphere could the goals of both health care and social service providers be met. This resulted in the inclusion of an AAoA social worker as a permanent member of the interdisciplinary team.

Evidence-based decision support. Evidence-based recommendations for effective management of many chronic

conditions are numerous and continually changing.²¹ The ACOVE¹⁸ project was undertaken to provide an objective measure of the quality of care that health systems provide to community-dwelling elderly patients who are at risk for functional decline or death.²⁸ The project involved the generation of a set of quality indicators that are being used in the AD-LIFE trial. Although ACOVE was constructed using the best available evidence that relates process to patient outcomes, no trials have been conducted to test the effectiveness of adherence to ACOVE's processes on improving patient outcomes.

AD-LIFE also utilizes evidence-based geriatric syndrome treatment protocols developed by our research team after an exhaustive review of the literature. All of these best practice guidelines have been incorporated into the intervention to guide the team recommendations. PCPs are provided with a copy of the guidelines along with pertinent references and short paragraphs providing academic detailing to enhance decision support. A detailed pharmacological review by a geriatrics-certified pharmacist is also provided to the PCP to promote optimal prescribing.

Improved information systems. The intervention uses our hospital database to retrieve inpatient records and ongoing outpatient charting. The hospital database is also linked to AAoA's database, which greatly enhances communication across providers. In-hospital findings and discharge instructions are communicated by fax to the PCP at the time of the patient's discharge to ensure that the PCP is aware of the patient's status and treatment plan. Team assessment findings and computerized care plans are also communicated to the PCP by fax, phone, and during a dedicated office visit. All of these elements of the intervention improve the communication of clinical information.

Results

Baseline characteristics of the AD-LIFE population

AD-LIFE enrollment is complete and, because the care management intervention lasts 1 year, we will not know the results of the hypothesis test until that time. However, because the study intervention was designed based on our knowledge of the published characteristics of the dual eligible population, it is of interest to know whether the AD-LIFE population drawn from people living in northeastern Ohio matches the characteristics of the dual eligible population as a whole. Table 1 shows that the AD-LIFE population has a higher proportion of people with at least 1 impairment in ADLs than dual eligibles in general¹⁵ (66% vs 55%, respectively); however, inclusion criteria for the trial mandated impairment in either 1 ADL or at least 2 IADLs. The AD-LIFE population also has substantially more females than the national average (85% vs 62%, respectively); however, this mimics the population in Ohio's Medicaid waiver program, PASSPORT, which is 78% female.²⁷ Similarly, the AD-LIFE population also has a higher proportion of whites (72% vs 57%), but a similar proportion to the PASSPORT program (71%). The AD-LIFE and PASSPORT populations also have higher proportions of patients who live in the community (99% and 96%, respectively) compared to the general dual eligible population (78%); however, institutionalized patients are ineligible for both the AD-LIFE trial

TABLE 1. CHARACTERISTICS OF THE NATIONAL DUAL ELIGIBLE POPULATION VS THE AD-LIFE DUAL ELIGIBLE POPULATION

<i>Characteristics</i>	<i>National dual eligible population</i>	<i>AD-LIFE dual eligible population</i>
Impaired in at least 1 Activity of Daily Living	55%	66%
Demographics		
Percentage female	62%	85%
White, non-Hispanic	57%	72%
African American	21%	27.9%
Other	7%	0.6%
Lives alone	31%	63%
Lives with relative or nonrelative	47%	36%

AD-LIFE, After Discharge Care Management of Low-Income Frail Elderly.

and PASSPORT. A subanalysis of a sample of the population eligible for the AD-LIFE trial suggests that people who are enrolled in a program such as PASSPORT are also more likely to enroll in a care management trial such as AD-LIFE because 69% of those enrolled in AD-LIFE also have PASSPORT.

Discussion

The current structure of the US health care system requires redesign if it is to meet the needs of the upcoming avalanche of older adults. Policy makers are becoming more aware of this as the health care reform debate includes more language about preventive care, patient self-management, and payment and delivery system redesign (eg, Accountable Care Organizations²⁸). The increasingly popular medical home model incorporates these concepts and makes the PCP the epicenter of all patient care needs; however, empirical evidence regarding the effectiveness of this model is lacking. Nonetheless, it is generally agreed that the greatest promise for optimizing outcomes for chronically ill patients is to strengthen the partnership between patients and their PCPs and to improve patient activation for chronic illness self-management.

Few randomized trials have been conducted that test the superiority of a care management model that incorporates medical and psychosocial interventions. An exception is the GRACE trial already described. A recent report by Mathematica Policy Research, Inc.²⁹ evaluated 15 care coordination programs administered by Medicare between April 2002 and June 2005. These programs used nurses to provide patient education and monitoring, mostly by telephone, twice per month on average. None of the programs showed net savings or improved adherence measures and just a few showed improvement on quality indicators.

Our intervention more fully integrates the elements described as essential for delivering chronic illness care when compared to previous care management studies. These elements include delivery system redesign; links to community resources; self-management support; organizational leadership, incentives, and resources; decision support; and improved clinical information systems.²⁵ Our study uses

standardized assessments and evidence-based intervention protocols to enhance decision support for the team and the PCP. Assisting patients with self-management skills and empowering them through coaching is a major emphasis of this intervention. We maximized links to community resources by integrating an AAoA social worker into the interdisciplinary team. We use nurses as CMs because they have the skills to interface with the patient's PCP and other specialists, having an impact on delivery system redesign and improving the flow of clinical information. The intervention, however, could be enhanced through better use of health information technology.

AD-LIFE is more of a "consult and support" model in which patients keep their own PCP rather than switching to a closed staff model or clinic as is done in the PACE model and other programs.^{11,12} Our model may have greater appeal to patients and providers and may be more generalizable across the country where the majority of care is delivered in the community setting in the patient-physician dyad model.

If the results of the AD-LIFE trial show superiority of the intervention, then this data will be important for health-care policy makers. In addition, our model, with its standardized evidence based medical and psychosocial intervention protocols, will be easily transportable to other sites interested in optimizing outcomes for chronically ill older adults.

Acknowledgments

The authors would like to thank Michele Gareri, RN, and Linda Mussey, RN, for serving as care managers for this study, Susan Sikora, RN, for patient recruitment, and Kim Peterson for her assistance with study protocols and manuscript preparation. We would like to thank James Salem, MD, Charles Fuenning, MD, Cathy Torcasio, PhD, and Roger Chaffe, MD, for their participation on the interdisciplinary team. We would also like to thank the Area Agency on Aging 10B Inc., especially Brandy Veal and Sandee Ferguson.

Author Disclosure Statement

Drs. Allen, Jarjoura, and Pfister, and Ms Hazelett, Ms Wright, Ms Fosnight, Ms Kropp, and Ms Hua disclosed no financial or personal conflicts of interest related to this study.

Financial Support: Agency for Healthcare Research and Quality grant #1 R01 HS014539-01A1 and the Summa Foundation. The sponsors of this study were not involved in the design or implementation of this study.

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