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Further Application of the Care Transitions Intervention: Results of a Randomized Controlled Trial Conducted in a Fee-For-Service Setting

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The study objective was to test whether a self-care model for transitional care that has been demonstrated to improve outcomes in Medicare Advantage populations—The Care Transitions Intervention—could also improve outcomes in a Medicare fee-for-service population. Intervention patients were less likely to be readmitted to a hospital in general and for the same condition that prompted their index hospitalization at 30, 90, and 180 days versus control patients. Coaching chronically ill older patients and their caregivers to ensure that their needs are met during care transitions may reduce the rate of subsequent rehospitalization in a Medicare fee-for-service population.

KEYWORDS care coordination, care fragmentation, care transitions

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BACKGROUND

Care transitions or "handoffs" represent a particularly vulnerable time during the course of a patient's care episode. Patient safety and quality of care are often compromised as a result of inadequate transfer of critical information, multiple prescribers functioning independently from one another, lack of timely follow-up care, and undefined professional accountability (Beers, Sliwkowski, & Brooks, 1992; Coleman & Berenson, 2004; Coleman, Fox, & on behalf of the HMO Care Management Workgroup, 2004; Coleman, Smith, Raha, & Min, 2005; Cornish et al., 2005; Forster, Murff, Peterson, Gandhi, & Bates, 2003; Moore, Wisnevesky, Williams, & McGinn, 2003; van Walraven, Mamdani, Fang, & Austin, 2004; van Walraven, Seth, Austin, & Laupacis, 2002). Patients and family caregivers consistently report inadequate support and unmet needs during care transitions. They are often unprepared for their self-management role in the next care setting, receive conflicting advice regarding chronic illness management, are often unable to reach an appropriate health care practitioner who has access to their care plan when questions arise, and have minimal input into their care plan (Coleman, 2003; Coleman et al., 2002; Grimmer, Moss, & Gill, 2000; Harrison & Verhoef, 2002; Levine, 1998; vom Eigen, Walker, Edgman-Levitan, Cleary, & Delbanco, 1999; Weaver, Perloff, & Waters, 1998). As a result of inadequate support and guidance offered by the health delivery system, patients and family caregivers are often faced with the task of assuming a substantial role in performing their care coordination activities. While transforming our health delivery system to be more patient centered and less fragmented represents an important long-range solution, there is an immediate need to provide patients and family caregivers with skills, confidence, and tools to assert a more active role in their care.

In a prior published article, the study team reported on the results of a randomized controlled trial of such a self-care empowerment model, the Care Transitions Intervention, in a Medicare Advantage population. Patients and their caregivers who were encouraged to assert a more active role in their care through specific tools and support from a nurse Transition Coach were significantly less likely to experience rehospitalization, a finding that was sustained for at least 6 months (Coleman, Parry, Chalmers, & Min, 2006). This intervention has been widely adopted in leading health care organizations in the United States and Canada.

The randomized controlled trial reported herein was explicitly designed to address whether the intervention could be successfully implemented and reduce rates of rehospitalization in a patient population supported under fee-for-service Medicare, the predominant financing structure serving older adults in the United States. In general, fee-for-service Medicare can be characterized as being less integrated and therefore more fragmented, having less alignment of financial incentives to control costs, and

having fewer mechanisms to coordinate care through case management when compared to Medicare Advantage plans. Because of these contrasting features, there may potentially be even more value to a model designed to ensure greater coordination of care across settings. As the ultimate goal is wide dissemination of the Care Transitions Intervention model, this trial was also conducted to assure greater generalizability of the findings to a broader audience.

METHODS

Study Setting and Dates

The intervention was conducted in collaboration with a not-for-profit senior care clinic that cares for over 5,500 patients age 65 years and older in Colorado. When patients require acute care, they are predominantly hospitalized in two community-based hospitals that are operated by the same parent company. These hospitals rely on a hospital-based physician model (i.e., hospitalists) to care for patients. Older patients who require post-hospital subacute services primarily receive care in one of six skilled nursing facilities located in the vicinity of the two hospitals or from one of four distinct home health care agencies. Study participants randomized to the control received usual care that consisted of standard discharge planning offered by the hospital. Control subjects did not receive post-hospital outreach such as follow-up phone calls. The study began September 1, 2002, and concluded August 31, 2003. The institutional review board and Health Insurance Portability and Accountability Act (HIPAA) authorities of the participating health care system, contract hospital, and the University of Colorado Health Sciences Center approved the study protocol.

Participants and Inclusion Criteria

To be eligible for this study, patients from the participating delivery system had to (a) be age 65 years and older, (b) be admitted to the participating delivery system's contract hospital during the study period to a nonpsychiatric ward of the hospital, (c) be community-dwelling (i.e., not from a long-term care facility), (d) reside within a predefined geographic radius of the hospital (thereby making a home visit feasible), (e) have a working telephone, (f) be English-speaking, (g) show no documentation of dementia in the medical record, (h) have no plans to enter hospice, (i) not be participating in another research protocol, and (j) have documented in their medical record at least one of 11 diagnoses, including stroke, congestive heart failure, coronary artery disease, cardiac arrhythmias, chronic obstructive pulmonary disease, diabetes, spinal stenosis, hip fracture, peripheral vascular disease, deep venous thrombosis, or pulmonary embolism. The rationale for selecting

these conditions was based on either the high likelihood that patients would require a stay in a post-hospital skilled nursing facility or home health care services (and thus experience additional care transitions) or because of the need for intensive anticoagulation management (Gage B, 1999).

Trained study nurses identified eligible patients at the time of hospital admission and approached them to obtain informed consent. At this time, they also administered a four-item cognitive screening test that included the patient's current age, today's date, the name of the facility, and the patient's telephone number. Patients who answered less than three questions correctly could still participate in the study if they could identify an able and willing proxy. The study nurses used a random number generator to produce a random allocation sequence. Blinding of participants was not possible during the study protocol.

Essential Features of the Care Transitions Intervention

The Care Transitions Intervention was designed to address potential threats to quality and safety during care transitions by providing patients and their caregivers with tools and support to encourage them to more actively participate in their care transitions. The Care Transitions Intervention promotes self-management of chronic conditions via a coaching model aimed at helping patients understand how to get their needs met and how to more effectively communicate during health care interactions. The essential features of the intervention are described herein and are summarized in Table 1. The Care Transitions Intervention is in the public domain. A more comprehensive description of the intervention, the tools, and a training DVD and manual are available free of charge on the Internet (http://www.caretransitions.org) and in prior publications (Coleman et al., 2004; Parry, Coleman, Smith, Frank, & Kramer, 2003).

The intervention was built on four pillars or conceptual domains that were derived from patient and caregiver feedback obtained from earlier qualitative studies regarding those factors that would be most valuable to them during care transitions (Coleman, et al., 2002). The four pillars include (a) a reliable medication self-management system, (b) a patient-centered record owned and maintained by the patient to facilitate cross-site information transfer, (c) timely follow-up with primary or specialty care, and (d) an unambiguous list of "red flags" indicative of a worsening condition and instructions on how to respond to them. The four pillars were operationalized through two mechanisms designed to encourage older patients and their caregivers to assert a more active role during care transitions as well as to foster care coordination and continuity across settings: (a) a Personal Health Record (PHR) and (b) a series of visits and phone calls with a Transition Coach.

The PHR is a patient-centered document that consists of the core data elements needed to facilitate continuity of the care plan across settings. In

TABLE 1 Care Transitions Intervention Activities by Pillar and Stage of Intervention

Stage of intervention	Four pillars			
	Medication self-management	Patient-centered record	Follow-up	Red flags
Goal	• Patient is knowledgeable about medications and has a medication management system.	• Patient understands and utilizes a Personal Health Record (PHR) to facilitate communication and ensure continuity of care plan across providers and settings. The patient manages the PHR.	• Patient schedules and completes follow-up visit with primary care provider/specialist and is prepared to be an active participant in these interactions.	• Patient is knowledgeable about indications that condition is worsening and how to respond.
Hospital visit	• Discuss importance of knowing medications and having a system in place to ensure adherence to the regimen.	• Explain PHR.	• Recommend primary care provider follow-up visit.	• Discuss symptoms and drug reactions.
Home visit	• Reconcile pre- and post-hospitalization medication lists. • Identify and correct any discrepancies. • Model for patient steps to take to seek professional advice.	• Review and update PHR. • Review discharge instructions. • Encourage patient to update and share the PHR with primary care provider/or specialist at follow-up visits.	• Emphasize importance of the follow-up visit and need to provide primary care provider with recent hospitalization information. • Practice and role-play questions for primary care provider.	• Assess condition. • Discuss symptoms and side effects of medications.
Follow-upcalls	• Answer any remaining medication questions.	• Remind patient to share PHR with primary care provider/specialist. • Discuss outcome of visit with primary care provider/specialist.	• Provide advocacy in getting earlier appointment, if necessary.	• Reinforce when/if primary care provider should be called.

this study, the core data elements included an active problem list, medications and allergies, whether advance care directives had been completed, and a list of red flags or warning signs that corresponded to the patient's chronic illness(es). A transfer checklist was also included to prepare the patient for an impending discharge and to give him or her permission to speak up if his or her health care professionals had not attended to these areas. Finally, the PHR included space for the patient to record questions and concerns in preparation for his or her next encounter. The patient and caregiver were encouraged to maintain and continually update the PHR and to share this document with practitioners across health care settings.

These same qualitative studies also led to the introduction of the Transitions Coach as the vehicle by which to impart the self-management skills. The primary role of the Transition Coach was to encourage the patient and caregiver to assert a more active role during care transitions, provide continuity across settings, and ensure that the patient's needs were being met irrespective of the care setting. Transition Coaches were registered nurses; however, rather than functioning as another care provider, the Transition Coaches facilitated the patient and caregiver's role in self-care. Thus, key attributes of Transition Coaches included the ability to shift from doing things for the patient to encouraging him or her to do as much as possible for him or herself, competence in medication review and reconciliation, and experience helping patients to communicate their needs to a variety of health care professionals.

The Transition Coach first met with the patient in the hospital prior to discharge to establish initial rapport, introduce the PHR, and arrange a home visit ideally within 48 to 72 hours after hospital discharge. For those patients transferred to a skilled nursing facility, the Transition Coach telephoned or visited at least weekly to maintain continuity, facilitate preparation for discharge with attention to self-care, and arrange for a home visit. The home visit involved the Transition Coach, the patient, and the caregiver (where applicable). A primary goal of the home visit was to reconcile all of the patient's medication regimens using the Medication Discrepancy Tool (Smith, Coleman, & Min, 2004). The Transition Coach and patient reviewed each medication to ensure the patient understood its purpose, instructions, and potential side effects. When a medication discrepancy was identified, the Transition Coach and the patient made a plan for how to resolve the problem, such as having the patient telephone the appropriate health care professional (e.g., principal physician, specialist, home care nurse, community pharmacy) for more urgent matters or write a question on the PHR as a reminder to raise the concern with the health care professional at the appropriate follow-up appointment. Transition Coaches routinely worked with patients to identify contributing factors to their recent hospitalization and would coach them on alternative ways they may respond when these same factors presented in the future.

In addition, the Transition Coach imparted skills for effectively communicating care needs during subsequent encounters with health care professionals. The patient and Transition Coach rehearsed or role-played effective communication strategies so that the patient would be prepared to clearly articulate his or her needs. The Transition Coach also reviewed with the patient any red flags, warning symptoms, or signs that a condition was worsening and provided education about the initial steps to take to manage the red flags and when to contact the appropriate health care professional.

Following the home visit, the Transition Coach maintained continuity with the patient and caregiver by phoning three times over a 28-day post-hospital discharge time period. The first call generally focused on determining whether the patient had received appropriate services (e.g., were new medications obtained, was durable medical equipment delivered). The Transition Coach also asked whether the patient had experienced any of the red flags and reinforced the appropriate response should these signs or symptoms manifest. In the two subsequent calls, the Transition Coach reviewed the patient's progress toward goals established during the home visit, discussed any encounters that took place with other health care professionals, reinforced the importance of maintaining and sharing the PHR, and supported the patient's role in chronic illness self-management. On average, Transition Coaches could manage approximately 26 to 28 patients, all of whom were recently discharged from the hospital. Table 1 illustrates the relationship between the four pillars on which the intervention was based and the specific goals and tasks for each stage of the intervention.

Main Outcome Measures

The primary target outcome measure was to determine whether the intervention reduced nonelective rehospitalization (inclusive of both the study and any nonstudy hospitals) at 30, 90, and 180 days post-discharge from the index hospitalization. An additional outcome measure established a priori was to determine whether the intervention reduced rehospitalization for the same condition that prompted the index hospitalization. Measures of rehospitalization at any given time interval were cumulative and inclusive of rehospitalizations that occurred in the earlier time interval. Rehospitalization data were obtained directly from the Centers for Medicare and Medicaid Services. Data on patient demographics and diagnoses were abstracted from the hospital chart or directly from the patient at the time of initial recruitment.

Upon enrollment, intervention and control participants were asked to self-identify a personal or health goal that they would like to achieve within the next 30 days, the time period that coincided with the end of the intervention. After 30 days a research assistant, blinded to study group assignment, telephoned participants to remind them of their goal and ask them

about their progress toward achieving their goal. Participants were asked to select the response that best characterized their progress: (a) I have not worked on my goal; (b) I have not met my goal but I am working on it; (c) I have met my goal as well as I expected; and (d) I have met my goal better than I expected.

Statistical Analysis

Initial two-sample comparisons of the intervention and control groups were conducted using appropriate statistical tests (e.g., chi-square test for dichotomous variables). Fisher's exact test was used for dichotomous outcomes with small cell counts testing statistical significance between the intervention and control groups. Consented patients were analyzed as originally assigned during randomization (i.e., intent-to-treat) and were included in all of the analyses provided that data were available. All analyses were completed using SAS for Windows version 8.02 (SAS Institute, Cary, NC).

RESULTS

The participant flow is illustrated in Figure 1. Among the 329 patients approached to participate in the study, 142 (43.2%) did not meet the study eligibility criteria, 89 (27.1%) refused to participate, and 98 (29.8%) consented. Forty-four (89.8%) of the intervention patients and 42 (85.7%) of the control patients were included in the analyses. Mortality did not differ by study group. Overall, 44 (89.8%) of the intervention patients received a home visit and 46 (93.8%) received all three telephone calls.

Table 2 compares the demographic, diagnostic, and hospital utilization characteristics of the study subjects. Overall, the random allocation produced highly comparable intervention and control study groups with no significant differences in demographic or clinical characteristics. In general, advanced age, a large burden of chronic illness, and a high rate of prior hospital and emergency department utilization characterized the study population. Overall, 40 (41.8%) of the 98 study subjects rated their health status as fair or poor.

Table 3 presents rates of rehospitalization among the intervention and control subjects at 30, 90, and 180 days. Intervention patients had lower hospital readmission rates than control patients at each time interval. The differences were statistically significant at 90 days. Intervention patients were significantly less likely to be rehospitalized at 90 and 180 days for the same condition that precipitated the index hospitalizations.

The analysis of the goal achievement question showed a trend in favor of intervention patients. Among intervention patients, 37.5% reported

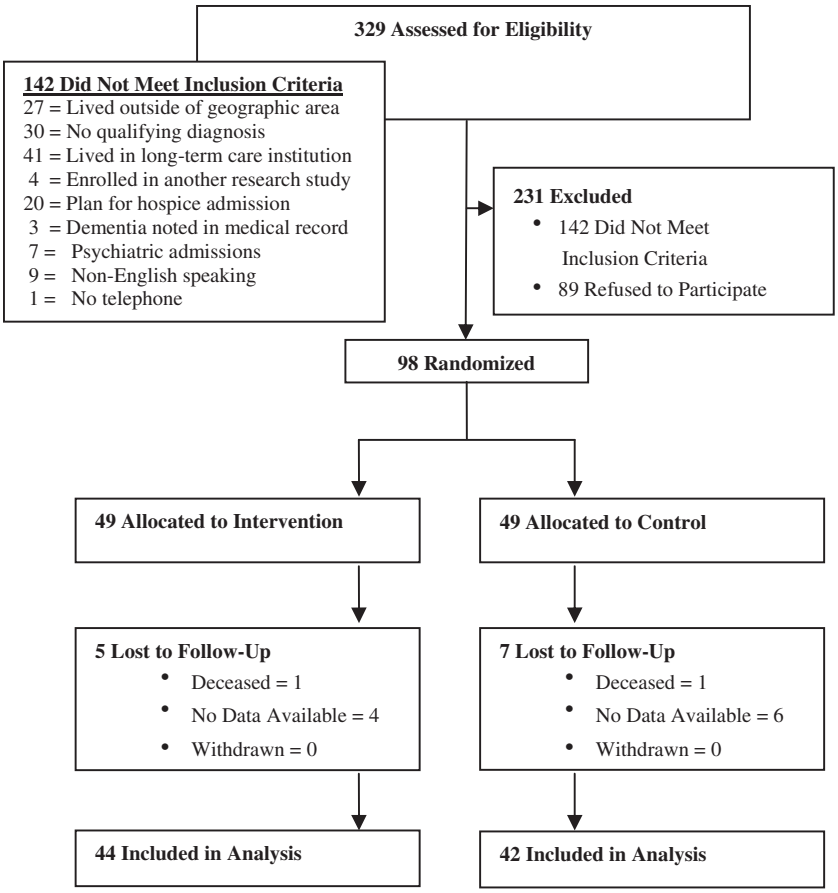

FIGURE 1 Participant Flow.

achieving or exceeding their self-identified goal as compared with 30.8% in control patients (p = .59).

DISCUSSION

Summary of Key Findings

Overall, the findings from this study conducted in a traditional Medicare fee-for-service setting appear to confirm the findings from the earlier study conducted in a Medicare Advantage (capitated) setting (Coleman et al., 2006). The Care Transitions Intervention was designed to provide patients and caregivers with tools and skills that would encourage them to assert a more active role in their care. As a self-care model, it not only was intended to positively influence the care experience during the impending transition but also during subsequent transitions. The results suggest that the benefits of

TABLE 2 Description of Study Sample (Reported as %, Unless Otherwise Noted)[1]

Variable	Intervention (n = 49)	Control group (n = 49)	P-value
Age (years)	80.5	82.8	0.21
Female	75.5	61.2	0.13
Married	28.6	35.4	0.47
Lives alone	55.1	59.2	0.68
Education			
Less than high school	28.6	18.4	0.07
High school diploma	32.6	24.5	
Some college	10.2	12.2	
College degree	28.6	44.9	
Self-identified race			
White	87.8	89.8	0.49
African American	0.0	2.0	
Hispanic	12.2	8.2	
Self-reported health status			
Poor	14.3	16.3	0.71
Fair	24.5	26.5	
Good	38.8	38.8	
Very good	16.3	10.2	
Excellent	6.1	8.2	
Selected hospital discharge diagnoses			
Stroke	2.2	0.0	0.33
Congestive heart failure	20.0	14.0	0.45
Coronary artery disease	6.7	11.6	0.42
Cardiac arrhythmia	13.3	14.0	0.93
Chronic obstruct pulmonary disease	15.6	23.3	0.36
Diabetes	0.0	2.3	0.30
Hip fracture	11.1	7.0	0.50
Dehydration	6.7	9.3	0.65
Pneumonia	15.6	11.6	0.59
Hospitalized in the 6 months prior to enrollment	31.1	48.8	0.09
Emergency department visit in the 6 months prior to enrollment	60.0	48.8	0.29
Length of stay of index hospitalization (days)	6.2	7.2	0.40

[1]A chi-square test was used for categorical variables; a t test was used for continuous variables to test significance across the intervention and control groups.

coaching are sustained for months after the conclusion of the intervention. Patients who received the Care Transitions Intervention were less likely to be readmitted across all time periods, with statistically significant differences at 90 days. Transition Coaches directly addressed the conditions and contributing factors that prompted the index hospitalization, and consequently, these patients were significantly less likely to be rehospitalized at 90 and 180 days for the same condition that prompted the index hospitalization. This readmission rate for the intervention group reached a plateau of 2.4% over the 6-month duration of the study. In contrast, the readmission rate for the control group continued to increase over the 6-month duration of the study, eventually reaching a nearly tenfold difference (2.4% vs. 23.8%).

TABLE 3 Utilization Outcomes[1]

Variable	Intervention (n = 49) (%)	Control group (n = 49) (%)	P-value
Rehospitalized within 30 days	6.8	16.7	0.15
Rehospitalized within 90 days	9.3	31.0	0.01
Rehospitalized within 180 days	20.9	38.1	0.08
Rehospitalized for same diagnosis as index hospitalization within 30 days	2.3	9.5	0.20
Rehospitalized for same diagnosis as index hospitalization within 90 days	2.4	19.0	0.03
Rehospitalized for same diagnosis as index hospitalization within 180 days	2.4	23.8	0.008

[1]Chi-square test (or Fisher's exact test for rehospitalized for the same diagnosis outcomes) was used to test statistical significance between the intervention and control groups.

Finally, a nonstatistically significant though higher proportion of intervention patients reported achieving or exceeding their self-identified goal compared with control patients. The Care Transitions Intervention was designed to be an effective and relatively low-cost and low-intensity intervention that could be implemented in a variety of delivery systems under different financing structures. The intervention was implemented with equal ease in the fee-for-service Medicare population as it was in the Medicare Advantage population, despite the fact that patients in the former setting were older, less educated, more likely to be Hispanic, and more likely to live alone than those in the latter study setting. At a minimum, the trial reported herein demonstrated that the intervention could be successfully implemented in a less integrated, more representative health care delivery environment. The prior study performed in the Medicare Advantage population relied on advanced practice nurses, whereas this study, performed in a traditional Medicare fee-for-service setting, employed registered nurses. In aggregate, these findings have important implications for translating this model into practice (Greenhalgh, Robert, Macfarlane, Bate, & Kyriakidou, 2004).

Comparison With Published Studies

A comprehensive review the literature is beyond the scope of this article. Prior studies have demonstrated reductions in rehospitalization rates for older chronically ill adults and patients with specific conditions, such as congestive heart failure, through advanced practice nurse- and pharmacist-led interventions (Naylor et al., 1999; Rich et al., 1995; Stewart, Pearson, & Horowitz, 2000; Townsend et al., 1988). A Cochrane Collaboration systematic review concluded that the impact of discharge planning on readmission, rates, hospital length of stay, health outcomes, and cost to patients and health care providers is uncertain (Shepperd, Parkes, McClaren, & Phillips,

2004). The results of the Medicare Care Coordination Demonstration reported on 15 randomized controlled trials performed by leading health care delivery systems. These interventions largely emphasized assessment, care planning, and patient education (Peikes, Chen, Schore, & Brown, 2009) with little emphasis on self-management, coaching, or an explicit focus on the care delivered during transitions. None of these trials demonstrated cost savings, and the vast majority (13 out of 15) of trials showed no difference in reducing hospitalizations. The authors concluded that viable care coordination programs need to have a strong transitional care component in order to yield net cost savings. The Care Transitions Intervention was designed to be different from these studies in three important ways. First, it was designed to be a self-care model that encouraged patients and family caregivers to assert a more active role in their care. Second, it was designed to be relatively low intensity with a single home visit and follow-up phone calls. Third, it was designed not only to improve the immediate transitions that patients and their caregivers faced but also to provide them with confidence, skills, and tools that could be used to improve their experience during future care transitions.

Costs of Intervention and Productivity

The annualized cost for the Care Transitions Intervention was $68,830 and included the following itemized costs: salary and benefits for the Transition Coach ($65,500), cell phone and pager ($650), mileage for the Transition Coach ($2500), and reproduction of the PHR and other supplies ($180). A more general detailed cost analysis based on a different study is available at http://caretransitions.org/documents/Colorado_Business_Plan_2009.pdf (accessed May 15, 2009).

Study Limitations

As with many multicomponent interventions, it can be challenging to determine which elements of the model made the greatest contributions to the reported findings. In a qualitative study reported earlier (Parry, Kramer, & Coleman, 2006), the authors explored this question further. The key factors driving the success of the intervention appeared to be the continuity of the relationship with the Transition Coach across settings, the resultant sense of being cared, gaining self-confidence in how to manage one's condition, and the trust that was established face-to-face during the home visit. This study was explicitly conducted to further demonstrate the generalizability of the Care Transitions Intervention. However, despite this deliberate intent, study participants were recruited from a single setting and thus may or may not be generalizable to the broader Medicare fee-for-service beneficiary population. Further, when compared to the Medicare Advantage population studied in

an earlier trial (Coleman et al., 2006), the subjects in the trial reported herein had lower levels of education, lower socioeconomic status, and greater racial diversity. These factors may have contributed to the observed differences in the rate of refusal to participate in the intervention trial. In the Medicare Advantage population, 10% of subjects refused compared to 27% in the Traditional Medicare fee-for-service population. Initially, some of the Hispanic patients were reluctant to consent to the study as the consent form and the HIPAA form intimidated them. Others expressed concerns about the Transition Coach making a home visit. The study team later learned that some Hispanic patients had undocumented individuals living in their household and feared that the Transition Coach might be collaborating with the Immigration and Naturalization Services. Once the study team received endorsement from local physician groups for the value of the study and this was shared with all potential patients including Hispanic patients, the willingness of eligible patients to participate in the study increased considerably. As an additional indicator of generalizability, the 30-day hospital readmission rate in the control group was 16.7%, which compared favorably to the national average of 17.6% (Medicare Payment Advisory Commission [MEDPAC], 2007). Finally, this study may not have had adequate power to detect true differences in utilization and goal achievement outcomes.

Convergence of National Attention

The findings of this study need to be considered within the context of national efforts to improve care transitions. A convergence of national activities has identified transitions out of the hospital as a priority area in need of action. These esteemed organizations include the Joint Commission, the Centers for Medicare and Medicaid Services and their accompanying Quality Improvement Organizations, the Institute for Healthcare Improvement, the Institute of Medicine, the National Quality Forum, the Medicare Payment Advisory Committee, the American Board of Internal Medicine Foundation, the National Transitions of Care Coalition, the American College of Physicians, the Society for General Medicine, and the Society for Hospital Medicine. Hospital 30-day risk-adjusted readmission rates will soon become a publicly reported performance measure (MEDPAC, 2007). Each of these efforts emphasize the importance of a patient-centered focus toward improving quality and safety during this vulnerable time and call for evidence-based models to accomplish this objective. The Care Transitions Intervention represents an important innovation that has been developed and tested in multiple settings with the explicit purpose of helping health delivery systems achieve this goal.

CONCLUSIONS

National attention to improving the quality of transitional care is expanding. Evidence-based models of care are needed that promote greater cross-setting collaboration between health care professionals and also between health care professionals and patients along with their family caregivers. The Care Transitions Intervention is a patient-centered self-care model that is designed to help patients ensure that their needs are met as they transition across settings. By ensuring that patients' needs are met, this model may potentially reduce rates of subsequent hospital readmissions when employed in a variety of care settings and under different financing mechanisms.

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