4-21-2017

Evaluation of a Community-based Care Transitions Program to Reduce 30-day Readmissions Using the RE-AIM Framework

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Reducing hospital readmissions has become a national priority to improve the quality of care and lower health care spending. Section 3026 of the Affordable Care Act of 2010 created the Community-based Care Transition Program (CCTP) to reduce 30-day all-cause readmissions in the Medicare FFS population. A CCTP program called the Community Passport 2 Care (ComPass^{2c}) was implemented in nine hospitals in New England. The RE-AIM framework (Reach, Effectiveness, Adoption, Implementation, and Maintenance) was used to evaluate the ComPass^{2c} program in reducing 30-day readmissions in Medicare FFS beneficiaries discharged from one academic hospital in New England.

A retrospective analysis of the ComPass^{2c} program was performed. Eight hundred thirty-two subjects enrolled in the ComPass^{2c} program; 61% were female with a mean age of 79 years (SD = 13). Using linear regression, the unadjusted 30-day all-cause readmission rate decreased by 0.5% each quarter ($p = .03$) for the first eight quarters of the ComPass^{2c} program with a relative risk reduction of 23%. The ComPass^{2c} program reached 32% of eligible Medicare FFS beneficiaries at Hospital X. Implementation for post-discharge phone calls was 89% and 34% for post-discharge home visits. The mean change in patient activation scores was 0.15 (SD = 4.79) without a significant change in activation level (χ^2 (6) = 3.819, $p = .70$).

The data support the conclusion that the ComPass^{2c} program may have been effective in reducing 30-day all-cause readmission rates in Medicare FFS beneficiaries discharged from an academic hospital in New England. The program reached one third of the target Medicare FFS

population. The implementation of post-discharge phone calls was similar to the original research but low for home visit and without change in patient activation. The Doctor of Nursing Practice (DNP) is in a unique leadership position to assess and determine the need for systems change at all levels of care, implement and evaluate evidence-based interventions in clinical practice, and facilitate interprofessional collaboration to improve quality of care. Future research should test transitional care interventions in subjects at risk for readmission who have historically been excluded, difficult to enroll and activate, and in receive care at safety net hospitals.

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B.S.N., Russell Sage College, 1992

M.S.N., University of Pennsylvania, 1996

A Dissertation

Submitted in Partial Fulfillment of the

Requirements for the Degree of

Doctor of Nursing Practice

At the

University of Connecticut

2017

APPROVAL PAGE

Doctor of Nursing Practice Dissertation

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Reduce 30-day Readmissions Using the RE-AIM Framework

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2017

Dedication

To my husband J.D., thank you for your love, support, and belief in me.
I love our life together.

To my daughters Allison and Sydney, I love you so much.
I hope you will pursue your dreams.

Acknowledgements

I would like to thank Dr. Paula McCauley for her support and direction,
Drs. Delaney, Ryan, Molony, and Van Hoof
for their appraisal of my work,
and Dr. Sandra Bellini for creating the DNP program.

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Chapter 1

Introduction

Unplanned hospital readmissions have clinically significant physiological and psychological consequences for patients and are costly to the Medicare program. Reducing hospital readmissions has become a national priority to improve quality of care and lower health care spending. The landmark article by Jencks, Williams, and Coleman (2009) highlighted the problem of 30-day hospital readmissions in Medicare Fee-For-Service (FFS) beneficiaries. The authors found approximately 20% of Medicare FFS beneficiaries hospitalized in the U.S. are readmitted within thirty days of discharge. Equally important, they estimated that 90% of these 30-day readmissions were unplanned and potentially preventable. Recent data suggest that rates of unplanned hospital readmissions are slowly improving. The Centers for Medicare & Medicaid Services (CMS) report that the national readmission rate (i.e., instances when patients return to the same or different hospital within 30 days of discharge) fell to 17.5 percent in 2013, after holding steady at around 19 to 19.5 percent for many years (U.S. Department of Health & Human Services, 2014). However, in spite of these strides, there continues to be a critical need to reduce hospital readmission. Health care reform has pinpointed hospital readmissions as a key area for improving care coordination and achieving potential savings.

Evidence-based transitional care models that address the transition from hospital to home or next setting of care have shown promise in reducing unplanned 30-day readmissions. Section 3026 of the Affordable Care Act of 2010 created the Community-based Care Transition Program (CCTP) for the purpose of testing the effectiveness of these evidence-based transitional care models in reducing 30-day readmissions for high-risk Medicare FFS beneficiaries and to show a cost savings to the Medicare program (https://innovation.cms.gov/initiatives/CCTP/). In New

England, a CCTP program was created called Community Passport 2 Care (ComPass^{2c}) utilizing two evidence-based transitional care models, the Care Transition Intervention® (CTI®) and the Transitional Care Model® (TCM®) to reduce 30-day readmissions in at risk Medicare FFS beneficiaries.

An evaluation of the ComPass^{2c} program is essential to determine if the program has achieved its goals of reducing hospital readmissions. In this chapter the scope of the problem of 30-day readmissions and the research into the interventions to reduce 30-day readmissions are presented. Next, both the CCTP and the ComPass^{2c} program are described. Furthermore, the significance of reducing 30-day readmissions to the profession of nursing, specifically to the Doctor of Nursing Practice (DNP) will be discussed. Finally, a description of the RE-AIM framework (Reach, Effectiveness, Adoption, Implementation, and Maintenance) and how this framework will guide the ComPass^{2c} program evaluation will be illustrated.

Scope of the Problem

Incidence

Since the Jencks article (2009), others have sought to understand the scope of 30-day hospital readmissions. The incidence of 30-day readmissions varies based whether the index admission was for a surgical or medical condition. An index admission is defined as the original hospital admission and live discharge from an acute care hospital that is associated with a 30-day readmission (Horwitz et al., 2012). In general, the 30-day readmission rate for medical admissions is higher than for surgical admissions. For example, in Medicare FFS beneficiaries, the rates of 30-day all-cause readmission ranged from 20.0 - 24.56% for heart failure (Krumholz et al., 2014; Krumholz et al., 2013), 12.3% for ischemic stroke (Krumholz et al., 2014), 18.2-18.3% for pneumonia (Krumholz et al., 2013; Lindenauer et al., 2010), and 18.7-20.8% for acute

myocardial infarction (Brown et al., 2014; Krumholz, Normand, & Wang, 2014; Krumholz et al., 2013). For index admissions due to diabetes mellitus, Medicare FFS beneficiaries had 30-day readmission rates of 16.4% for hyperglycemia and 18.1% in hypoglycemia (Lipska et al., 2014).

Unplanned 30-day readmissions following surgical procedures also differ by type of procedure. In a meta-analysis of common orthopedic procedures in the U.S., the overall 30-day unplanned readmission rate ranged from 4.8-6.0% (Bernatz, Tueting, & Anderson, 2015). More specifically in the Medicare population, the readmission rate was 5.0-8.0% for total knee replacement (Cram, Cai, Lu, Vaughan-Sarrazin, & Miller, 2012; Cram et al., 2012; Vorhies, Wang, Herndon, Maloney, & Huddleston, 2012), and 6.8-10.5% for total hip replacement (Tsai, Joynt, Orav, Gawande, & Jha, 2013; Vorhies, Wang, Herndon, Maloney, & Huddleston, 2011). Following common vascular surgeries, readmission rates for Medicare beneficiaries ranged from 8.0-13.4% for open abdominal aortic repair (Greenblatt et al., 2012; Gupta, Fernandes-Taylor, Ramanan, Engelbert, & Kent, 2014; Tsai et al., 2013) and 7.6-11.0% for endovascular aortic repair (Gupta et al., 2014; Tsai et al., 2013). Thirty-day readmission rates in Medicare FFS beneficiaries following coronary artery bypass surgery ranged from 17.2-17.8% (Tsai et al., 2013), 19.2-20.6% for aortic valve replacement with coronary artery bypass (Barreto-Filho et al., 2013) and 21.0% for mitral valve replacement (Dodson et al., 2012).

Patterns

The timing of unplanned readmissions provides further understanding of patterns associated with 30-day hospital readmissions. In Medicare FFS patients with an index admission diagnosis of heart failure or myocardial infarction, more than two-thirds were readmitted within the first 14 days post hospital discharge (Dharmarajan et al., 2013). Similarly, in patients following surgery for glioblastoma (Dickinson et al., 2014; Nuno et al., 2013), esophageal cancer

(Fernandez et al., 2014), and lung cancer (Hu et al., 2014) readmissions were most frequent in the first 14 days post hospital discharge.

The cause of the index admission is often the same at readmission. Jencks et al. (2009) found that in patients hospitalized for heart failure, pneumonia, chronic obstructive pulmonary disease, psychosis, and gastrointestinal diagnoses, the most frequent reason of readmission was the primary diagnosis at index admission. A more recent study of Medicare FFS beneficiaries found that following an index admission for heart failure or acute myocardial infarction, heart failure was the most common reason for 30-day readmission (Dharmarajan et al., 2013). Similarly, the most common readmission diagnosis following an index hospitalization for pneumonia was pneumonia (Dharmarajan et al., 2013).

Complications related to surgical procedures are the most common reason for unplanned 30-day readmissions following a surgical procedure. Surgical site complications accounted for 46% of readmissions following orthopedic procedures (Bernatz et al., 2015) and were the most frequent cause for unplanned readmission following abdominal aortic repair (Greenblatt et al., 2012).

Risk Factors

Several risk factors have been associated with unplanned 30-day readmissions. Advanced age has been associated with an increased risk for 30-day readmission in medical (Lichtman, Leifheit-Limson, Jones, Wang, & Goldstein, 2013; Hannan et al., 2011; Silverstein et al., 2008) and surgical admissions (Bernatz et al., 2015; Greenblatt et al., 2012). In a large cohort study of 29,292 adults aged 65 or older in the Dallas-Fort Worth, Texas metropolitan area, the risk for readmission significantly increased in individuals age 75 or greater (Silverstein et al., 2008). A similar trend was seen in patients within the Veterans Administration system with a

diagnosis of heart failure, acute myocardial infarction, chronic obstructive pulmonary disease, and pneumonia (Shams et al., 2014), in Medicare FF patients following ischemic stroke, and New York state residents following an index admission where percutaneous coronary intervention was performed (Hannan et al., 2011). In a meta-analysis of patients who had orthopedic procedures, age was statistically and positively correlated with increased 30-day readmissions (Bernatz et al., 2015).

Co-morbid conditions and complications increase the risk of an unplanned hospital readmission (Van Walraven et al., 2010). In a single institution study of medical admissions, patients with the co-morbidities of neoplasms, heart failure, and chronic kidney disease had the highest risk of potentially avoidable 30-day readmissions (Donze, Lipsitz, Bates, & Schnipper, 2013). Following endovascular or open abdominal aneurysm surgery, wound complications such as infection or bleeding were responsible for approximately half of the 30-day readmissions whereas medical comorbidities such as pneumonia, heart failure, and gastrointestinal obstruction were the cause for the other half (Greenblatt et al., 2012).

A history of prior hospitalization is also a strong predictor of 30-day readmission. Hospitalization within 6-12 month prior to index admission has been significantly associated with an increased risk of 30-day readmission in multiple studies (Albrecht et al., 2014; Donze, Aujesky, Williams, & Schnipper, 2013; Hasan et al., 2009; Taha, Pal, Mahnken, & Rigler, 2014).

Polypharmacy has been associated with 30-day readmissions. In general medicine subjects 18 years and older, 10 or more medications upon discharge was predictive of 30-day readmission (Taha et al., 2014). Gildersleeve and Cooper (2013) found a mean number of 14 medications two days prior to discharge were predictive of 30-day readmission on multivariate

analysis. In a separate study, the addition of each home medication increased the risk of 30-day readmission by 4% (Dugger et al., 2014).

Health literacy and numeracy are factors that have been found to influence hospital readmissions within 30 days. It is estimated that 46% of Americans have low or marginal health literacy (Paasche-Orlow, Parker, Gazmararian, Nielsen-Bohlman, & Rudd, 2005). Health literacy is "defined as the degree to which an individual can obtain, process, and understand basic health information and services needed to make health decisions" (Institute of Medicine [IOM], 2004, p. 1). Numeracy is defined as the "ability to use and understand numbers in daily life" (Rothman et al., 2006, p. 392). Lower health literacy has been associated with poor health outcomes including increased hospitalizations, increased use of emergency care, and decreased ability understand and follow health related instructions (Berkman, Sheridan, Donahue, Halpern, & Crotty, 2011). Low health literacy (Mitchell, Sadikova, & Jack, 2012) and low numeracy in heart failure patients (McNaughton et al., 2013) have been found to increase the risk of 30-day hospital readmission and emergency room visits.

Poor coordination of care has been associated with 30-day hospital readmissions (MedPAC, 2007). Coordination of care includes timely follow-up with community providers following hospital discharge. Approximately half of patients readmitted within 30-days did not have a claim filed for an outpatient physician visit within 30 day of their index admission (Jencks et al., 2009). Hernandez et al. (2010) studied the relationship between 7-day physicians follow up and 30-day readmission among Medicare beneficiaries hospitalized with heart failure. The median percentage of patients who had 7-day follow-up after discharge following index hospitalization was 38.3% (Hernandez et al., 2010). Those patients who received early follow-up had lower rates of all-cause 30-day readmission. Similarly, the rate of timely provider

follow-up in general medicine patients was 49% with 10-fold increased odds of 30-day hospital readmission in patients lacking timely provider follow-up (Misky, Wald, & Coleman, 2010).

Solutions

Interventions that target high risk individuals, improve coordination of care and communication with community providers have the potential to reduce unplanned 30-day readmissions. Transitional care delivery models have focused on improving the coordination of care and communication as a patient transition from the hospital to the next setting of care. Transitional care has been defined as "a broad range of time-limited services designed to ensure health care continuity, avoid preventable poor outcomes among at-risk populations, and promote the safe and timely transfer of patients from one level of care to another or from one type of setting to another"(Naylor, Aiken, Kurtzman, Olds, & Hirschman, 2011, p. 747). The Care Transition Intervention® and the Transitional Care Model® are two evidence-based transitional care delivery models that have demonstrated the efficacy and effectiveness in reducing 30 day hospital readmissions.

The Care Transition Intervention®. The CTI® is a four week intervention that utilizes a transition coach to build patient and caregiver self-care management skills (Parry, Coleman, Smith, Frank, & Kramer, 2003). The transition coach is a registered nurse or a social worker whose role is to impart self-care skills. The CTI® is based on four pillars of self-care: (1) medication self-management; (2) timely follow-up with primary care provider or specialist; (3) disease specific knowledge and management, "Red Flag" symptom identification and an action plan; and (4) the patient-centered health record (PHR) (http://caretransitions.org/). The CTI® consists of one hospital visit, one home visit, and three weekly phone calls by the transition coach. At the hospital visit, the coach focuses on an explanation of the intervention including

introduction of the PHR, patient/caregiver knowledge of medications, 7-day post-discharge follow-up appointment with primary care provider or specialist, patient/caregiver recognition of symptoms indicating worsening health, and patient/caregiver recognition of medication side effects. At the home visit, the coach facilitates patient identification of 30-day health goals, medication reconciliation and correction of discrepancies, review of discharge summary, update to PHR, encourages sharing of PHR with other providers, reinforces follow-up with providers, role play questions to ask at follow-up visits, and discuss symptoms of worsening health condition or medication side effects. The coach conducts weekly follow-up phone calls to assess progress on patient-identified health goals, patient progress on each of the four pillars, provide active coaching, and ensuring patient's needs are being met.

The Transitional Care Model®. The TCM® is a 90-day intervention that uses the transitional care nurse to deliver the intervention. The transitional care nurse is an advanced practice registered nurse. The intervention starts with a hospital visit from the transitional care nurse to assess the patient and caregiver's discharge needs and development of an individualized discharge plan in collaboration with the patient's providers. Upon discharge, the patient receives two home visits from the transitional care nurse; the first visit within 48 hours of discharge, the second visit 7-10 days following discharge. Home visits include physical and environmental assessments, empowering patients' and caregivers' self-management, medication reconciliation, symptom self-management, diet, activity, sleep, emotional wellbeing, and medical follow-up. The transitional care nurse makes weekly telephone follow-up calls to monitor progress. Patients and caregivers can also call the transitional care nurses with questions and concerns. The transitional care nurse is available by phone 7-days a week. At the completion of the intervention, the transitional care nurse provides a discharge summary to the patient, caregivers,

and providers which detail the care plan, progress, and ongoing concern (http://www.nursing.upenn.edu/ncth/transitional-care-model/).

Community-based Care Transitions Program

In an effort to address both the human and financial consequences of 30-day readmissions to Medicare beneficiaries, the Affordable Care Act (ACA) of 2010 (Section 3026) created the Community-based Care Transitions Program. The CCTP was a national initiative created by the public-private organization called Partnership for Patients (https://partnershipforpatients.cms.gov/). The Partnership for Patients strives to improve quality, safety and affordability of health care for all Americans. The Partnership set a goal in 2010 of reducing readmissions by 20% in four years. The purpose of the CCTP was to test the effectiveness of evidence-based transitional care models in improving quality of care, reducing 30-day readmissions for high-risk Medicare beneficiaries, and show a cost savings to the Medicare program. These improvements should not be accompanied by unintended consequences such as an increase in 30-day mortality or increase utilization of 30-day emergency department or observation stay visits.

Through the ACA, CMS initially provided $500 million to fund the CCTP but reduced the funding to $300 million in 2013. Community-based Organizations (CBOs) who provided transitional care services were eligible to participate in the CCTP as well as hospitals with high 30-day readmission rates who partnered with CBOs. CBOs submitted written proposals to CMS and CMS award 2-year agreements to successful CBO applicants. Applications were accepted on a rolling basis and awarded on a first come, first served basis as funding permitted.

The Community Passport 2 Care (ComPass^{2c}). In New England, a CBO with over 30 years of experience in providing care management services to elders and adults with disabilities

created a CCTP called the Community Passport 2 Care (ComPass^{2c}). The ComPass^{2c} program was implemented May 1st, 2012 with the goal of reducing 30-day hospital readmissions in Medicare FFS beneficiaries. The program was free to hospitals and subjects who enrolled in the program. Nine New England hospitals partnered with the CBO who administered the ComPass^{2c} program. ComPass^{2c} program utilized the CTI® and the TCM® care delivery models. The ComPass^{2c} program was a voluntary program offered to Medicare FFS beneficiaries prior to hospital discharge.

The ComPass^{2c} program utilized transition coaches and nurses to deliver the ComPass^{2c} intervention. Transition coaches were social workers or community health workers while transition nurses were registered nurses all of which were employees of the CBO. All coaches and nurses had at least a bachelor's degree or higher. All transition coaches and nurses were trained in CTI® however transition nurses were also trained in TCM®.

The ComPass^{2c} program included an in-hospital risk assessment and planning, enhanced teaching and learning, facilitation of communication across settings, and tailored transitional care and coaching based on an individual's needs. Eligible subjects were assessed for their risk of 30-day hospital readmission using ComPass^{2c} Intervention Determination Instrument. The ComPass^{2c} Intervention Determination Instrument included Project BOOST® Risk Assessment, subject self-reported health (SRH), the Brief Health Literacy Screen (BHLS), and the Patient Health Questionnaire-2 (PHQ-2).

Enhanced teaching and learning began at hospitalization, continued at home visits, and was reinforced during telephone contact with subjects and/or their caregivers. Enhanced teaching and learn included early identification of learners and the use of "Teach-Back" methods to determine understanding and self-care capacity. Coaching and motivational interviewing

principles were used to enable the subject and caregiver engagement and self-care capacity. Educational materials used were appropriate to language, reading and health literacy level.

The ComPass^{2c} program also focused on improved communication across settings. Activities to improve communication across settings included medication reconciliation prior to transition and timely transfer of critical health information to post-hospital providers (primary care provider, home health nurse, post-acute care facilities). The ComPass^{2c} staff participated in community forums with representatives from hospitals, home health care agencies, skilled nursing facilities, and community-based services. Facilitators and barriers, best practices, clinical processes, outcomes, and opportunities for improvement were shared among participants of the forums.

Transitional care and coaching was tailored to the subject's individual risk level. Subjects were categorized as low, medium, and high risk for 30-day readmission and assigned to interventions based on their risk assessment. The three levels of the ComPass^{2c} program are described below:

Low-risk subjects. Low-risk subjects were defined as having few or no logistical or psychosocial barriers, high levels of activation and self-care capacity, high levels of social support, and few changes in medication, function, or post-discharge needs upon transition. The intervention for this group of subjects included:

- In-hospital assessment of needs
- Enhanced teaching/learning
    - PHR
    - Condition-specific self-management
    - "Red flag" symptom identification with action plan

  - Medication self-management
  - Timely post-discharge follow-up with primary care provider or specialist
- Telephone follow up days 1 -3 post-hospitalization with follow-up calls as needed to:
  - Reinforce teaching
  - Assess medication self-management
    - medication understanding and adherence
    - adverse drug effects
  - Identify barriers to:
    - filling prescriptions
    - attending medical appointments
    - self-care
  - Identify new concerns
  - Referral to community resources

Moderate-risk subjects. Moderate-risk subjects were defined as having logistical or psychosocial barriers identified, low to moderate levels of activation, gaps in knowledge or self-care capacity, and/or significant changes in health, function, medications, or care needs. The intervention for this group of subjects included:

- All interventions used for low-risk subjects
- Care Transition Intervention (CTI®) a four week intervention that utilized the transition coach or nurse to deliver the four transition pillars defined as:
  - PHR
  - Medication self-management

- Condition-specific self-management, "Red Flag" symptom recognition with action plan
- Timely post-discharge follow-up with primary care provider or specialist

High-risk subjects. High-risk subjects were defined as having cognitive impairment with inadequate in-home support, history of multiple readmissions, multiple logistical and/or psychological barriers, and/or low activation, knowledge or self-care capacity. The intervention for this group of subjects included:

- All interventions used for low-risk subjects
- Transitional Care Model (TCM®), an eight week intervention utilizing the transitional care nurse (TCN) to delivered the following:
  - TCN home visits weeks 1-4 post-transition
  - TNN home visits/telephone contact include health monitoring, health education, skill acquisition to enhance self-care for subjects and their caregivers
  - TCN accompanies subject to primary care provider or specialist follow-up
  - TCN on-call 7-days a week (8 am to 8 pm on weekdays, 4 hours on weekend)
  - TCN telephone contact at least once per month after first month

The ComPass^{2c} program began at Hospital X on May 1st, 2012 and enrolled its last patient on November 30th, 2014. The efficacy of these transitional care interventions in the research setting is known. It is not known whether the application of these evidence-based transitional care interventions as described in the ComPass^{2c} program impacts 30-day readmission rates. A knowledge gap exists regarding the effectiveness of the ComPass^{2c} program in reducing all-cause 30-day readmission rates in Medicare FFS beneficiaries. An evaluation of the ComPass^{2c} program will address this knowledge gap.

Significance to Nursing

Reducing 30-day hospital readmissions is important to the profession of nursing because unplanned 30-day readmissions to the hospital impact the quality and safety of health care. Nurses at all level of practice are responsible for and have the capacity to improve the quality and safety of care transitions. Nurses educated at the bachelor and masters' levels are prepared to deliver direct patient care. The Doctor of Nursing Practice (DNP) however takes a broader view of healthcare. Excessive 30-day hospital readmissions are a population health outcome and the DNP is prepared to affect patient care at the population level.

The eight DNP Essentials articulate the specific actions that demonstrate how the DNP works to improve the health of populations (American Association of Colleges of Nursing [AACN], 2006). The DNP identifies a gap in quality and safety of care within their organization. Next, the scope of the problem and evidence-based solutions are critically evaluated. The DNP brings the problem and potential solutions to leadership and policymakers to gain support for the need for organizational change. The DNP also raises awareness about the problem to nursing and other health care professionals. Working collaboratively, the DNP designs, implements, and evaluates an evidence-based improvement program. Finally, the DNP disseminates the results of the program to leadership, stakeholders, and health care professionals at large through presentation and publishing.

A program evaluation is an example of the contributions the DNP can make to population health. The Institution of Medicine's Report on the Future of Nursing recommends nurses lead collaborative improvement efforts such as transitional care to provide safe, high quality health care (Institute of Medicine [IOM], 2011). The DNP is uniquely prepared to meet this recommendation and challenge.

Purpose

The purpose of this project is to evaluate the ComPass^{2c} on three aspects; (1) the effectiveness of the ComPass^{2c} program in reducing 30-day readmissions rates for Medicare FFS beneficiaries; (2) the reach of the ComPass^{2c} program in targeting at-risk Medicare beneficiaries; and (3) the consistency in implementation of key ComPass^{2c} program elements.

Evaluation Framework

RE-AIM is a framework for planning, evaluating, reporting, and reviewing evidence-based interventions in clinical practice. RE-AIM is an acronym for Reach, Efficacy/Effectiveness, Adoption, Implementation, and Maintenance (see Appendix A). The RE-AIM framework was developed to address methods for evaluating the impact of evidence-based health behavioral interventions on public and population health. The initial literature about the RE-AIM model was published in 1999 (Glasgow, Vogt, & Boles, 1999). The authors of the framework challenged the thinking that randomized controlled trials (RCTs), with motivated patient populations, highly trained staff, and optimal conditions should be the "goal standard" for determining the usefulness of an intervention. They argued, while efficacy-based research methods are necessary to enhance internal validity of an intervention, the results create non-representative samples and settings. Second, interventions often are intensive of time and effort by patients, providers, and staff. A RCT testing an intensive intervention will have the staff and resources to support the intervention however when applied to the clinical practice setting, staff and resources are lacking and results are less than robust. Third, the cost of the intervention is not a factor in the RCT setting but may be prohibitive in the clinical setting if there is an absence of financial reimbursement to cover cost. Finally, efficacy-based research has a beginning and end point and does not address how to maintain and intervention and its

effects over time. The authors suggest that the lack of attention to the external validity, few trained staff and resources, money, and long-term planning for maintaining the intervention all influence the effectiveness in the clinical practice setting (Glasgow, Vogt, & Boles, 1999).

The RE-AIM framework is compatible with Social-Ecological Theory, Systems Thinking Theory (Glasgow et al., 1999), as well as the PRECEDE-PROCEED model of planning and evaluation. In the Social-Ecological Theory, spheres of influence effect behavior including individual, peer/family, local community, and society at-large influences. Glasgow (1999) described how (1) individual patient factors; (2) close relationship factors such as family, friends, and health care providers; (3) community/organizational contextual factors such as worksites, health care systems, and neighborhoods; and (4) society/cultural factors such as policy, media, and regional factors can influence health outcomes. Systems Theory acknowledges health and health care systems as complex, unpredictable, and influenced by both interacting and multilevel variables (Holmes, Finegood, Riley, & Best, 2012). The acronym PRECEDE which was developed in the 1970s stands for Predisposing, Reinforcing, and Enabling Constructs in Educational/Environmental Diagnosis and Evaluation; while PROCEED added in the 1990s stands for Policy, Regulatory, and Organizational Constructs in Educational and Environmental Development (Gaglio & Glasgow, 2012). For interventions to have an impact on health outcomes, the RE-AIM authors emphasized the need for these variables to be included in efficacy/effectiveness research.

RE-AIM is a framework for improving the likelihood that an efficacy-based intervention will be successfully implemented and sustained in populations and in a large number of health care settings (Gaglio & Glasgow, 2012). Initially the impact of an intervention was conceptualized as the Reach, which was defined as percent penetration of an intervention into a

defined population, multiplied by the Efficacy (Abrams et al., 1996). These original concepts were expanded upon to address the settings to which interventions would be implemented and sustained. RE-AIM in its current form is made up of five domains: (1) Reach, (2) Efficacy/Effectiveness, (3) Adoption, (4) Implementation, and (5) Maintenance. Together, these five domains determine the impact of an intervention. Virginia Polytechnic Institute, School of Science and Agriculture hosts the RE-AIM website (http://re-aim.org/).

Reach

The reach of an intervention is defined by the number and proportion of subjects willing to participate compared to those eligible and the representativeness of those subjects to the target population (http://re-aim.org/). Representativeness is determined by evaluating basic demographic variables of those subjects who agree to participate compared to those who are eligible and choose not to participate or the general target population. When these two groups are similar, then the outcomes are more generalizable. If these groups are not similar, then a case can be made that the intervention outcomes are different based on these demographic variables. The reach domain addresses whether the intervention attracts participants most in need of the intervention (Gaglio & Glasgow, 2012).

Efficacy/Effectiveness

The outcomes of an intervention including benefits and harms, patient related outcomes such as quality of life, and cost associated with an intervention are how efficacy/effectiveness is measured (Glasgow et al., 1999; http://re-aim.org/). Efficacy research is the "initial testing of an intervention on an outcome under controlled conditions that typically uses randomization of participants in an effort to establish a causal relationship between the intervention and the outcome and internal validity" (Rabin & Brownson, 2012, p. 30) Effectiveness research

"determines the impact of an intervention that has been previously subjected to scientific study by randomized clinical trials and applies this intervention to the wider general population in everyday clinical practice with a focus on external validity or generalizability" (Rabin & Brownson, 2012, p. 31). The efficacy/effectiveness domain asks if the intervention effect is robust, with minimal harm, and with positive effect on quality of life and other health-related outcomes (Gaglio & Glasgow, 2012).

Adoption

Adoption is the evaluation of the willingness of organizations to participate and the representativeness of these organizations the others (Green & Glasgow, 2006). It is recommended that the availability of resources, expertise of the interventionists, and setting size or location are factors that should be compared to sites who do not participate in an intervention (http://re-aim.org/). The adoption domain raises the question of feasibility of the intervention in the clinical setting in regards to time, cost, expertise, and resources (Gaglio & Glasgow, 2012).

Implementation

Implementation refers to the intervention being delivered as it was designed (http://re-aim.org/). Implementation interacts with efficacy to produce effectiveness in the clinical setting (Glasgow et al., 1999). Implementation is evaluated at the setting level. The implementation domain addresses whether the intervention can be implemented as intended by staff, the time commitment of staff, and if costs are reasonable when compared to the effectiveness of the intervention (Gaglio & Glasgow, 2012). The creators of RE-AIM recommend evaluation of implementation at a minimum of six to 12 months with repeated measurements providing a better understanding of the effects of an intervention (Glasgow et al., 1999).

Maintenance

Maintenance is a measure of how enduring the intervention effect is on both the individual participants and the organization (Glasgow et al., 1999; Green & Glasgow, 2006). Evaluation of maintenance should occur at a minimum of two years post implementation with ongoing measurement to determine the sustainability of the intervention (Glasgow et al., 1999).

The RE-AIM framework guides the evaluation of evidence-based interventions in clinical practice. This framework will support the evaluation of the ComPass^{2c} program implemented at one of the nine partnering hospitals in New England. The Reach, Effectiveness, and Implementation domains will be addressed.

Research Questions

1. What is the effectiveness of the ComPass^{2c} program in reducing 30-day all-cause readmission rates in Medicare FFS beneficiaries discharged from an academic hospital in New England?
2. What is the reach of the ComPass^{2c} program in Medicare FFS beneficiaries discharged from an academic hospital in New England?
3. What is the consistency of implementation of key ComPass^{2c} program elements in Medicare FFS beneficiaries discharged from an academic hospital in New England?

Definitions of Key Terms and Variables

Index admission/discharge. An index admission is the original hospital admission and live discharge from an acute care hospital that is associated with a 30-day readmission and does not include patients transferred to another acute care hospital or those patients who leave the hospital against medical advice (Horwitz et al., 2012).

All-cause readmission. An all-cause readmission is an unplanned acute clinical event of any cause experienced by the patient following an index hospitalization leading to an urgent rehospitalization (Horwitz et al., 2012).

Observation stay. An observation stay is defined by Medicare as hospital outpatient services provided to a beneficiary either in the ED or another area of the hospital while a physician determines whether the beneficiaries requires inpatient services (*Medicare Benefit Policy Manual*, 2015).

Variables

Thirty-day readmission. A thirty-day readmission is an unplanned admission to the hospital within 30 days following an index admission to the same or different hospital (Stone & Hoffman, 2010). Thirty-day all-cause readmission rate is defined as the number of Medicare FFS beneficiaries readmitted within 30-days of index discharge from Hospital X (numerator) divided by the total number of index discharges from Hospital X during the reporting period (denominator). The numerator includes all hospital readmissions that occurred within 30-days of index discharge, including those to other hospitals. Beneficiaries who died during their index hospital stay were excluded (Centers for Medicare and Medicaid Services [CMS], 2014, p. 10)

Seven and 14-day follow-up rate. Seven and 14-day follow-up rate is defined as the number of Medicare FFS beneficiaries with an ambulatory visit within 7-14 days of index discharge from Hospital X (numerator) divided by the total number of index discharges from Hospital X (CMS, 2014, p. 13).

Thirty-day emergency department (ED) visit rate. Thirty-day ED visit rate is defined as the number of Medicare FFS beneficiaries who experience an ED visits within 30-days of an index discharge from Hospital X (numerator) divided by total number of index discharges from

Hospital X (denominator) including and ED visit to any hospital except those resulting in same-day or next-day inpatient admission or observation stay (CMS, 2014, p. 15).

Thirty-day observation stay rate. Thirty-day observation stay rate is defined as the number of Medicare FFS beneficiaries who experience an observation stay within 30-days of an index discharge from Hospital X (numerator) divided by the total number of index discharges from Hospital X (denominator) (CMS, 2014, p. 16).

Thirty-day mortality rate. Thirty-day mortality rate is defined as the number of Medicare FFS beneficiaries with an index discharge from Hospital X who died within 30-days of discharge (numerator) divided by the total number of index discharges form Hospital X (denominator) excluding those beneficiaries who received hospice care anytime during the 365-days prior to index discharge (CMS, 2014, p. 17).

Summary

Healthcare reform has pinpointed 30-day hospital readmissions as an area for improving care and achieving savings to the Medicare program. Thirty-day readmissions are common in both medical and surgical populations with most readmissions occurring within the first 14 days post-hospital discharge. Reasons for unplanned 30-day readmissions include worsening of the index admission condition and complications from surgical procedures. Risk factors for 30-day readmission are many and include advanced age, comorbid conditions, polypharmacy, inadequate health literacy and numeracy, prior hospitalization in the preceding 6-12 months, lack of care coordination, and breakdowns in communication as patients' transitions from the one setting of care to another.

Evidence has demonstrated the efficacy and effectiveness of transitional care interventions in reducing 30-day readmissions. The CTI® and TCM® are examples of evidence-

based intervention that have been effective in reducing 30-day readmissions. The ACA created and Medicare funded the CCTP, a national demonstration project aimed at addressing the human and financial consequences of 30-day readmissions in Medicare beneficiaries. In New England, a CCTP called ComPass^{2c} was designed utilizing CTI® and the TCM® and implemented in nine hospitals.

Reducing 30-day hospital readmissions is important to the profession of nursing because unplanned 30-day readmissions to the hospital impact the quality and safety of health care. Nurses can have a direct influence on the quality and safety of care they provide through their direct contact with patients and participation in transitional care interventions. The Doctor of Nursing Practice (DNP) however takes a broader view of healthcare. Excessive 30-day hospital readmissions are a population health outcome and the DNP is prepared to affect patient care at the population level.

The purpose of this project is to evaluate the effectiveness of the evidence-based ComPass^{2c} program in reducing 30-day readmissions rates for Medicare FFS beneficiaries using the RE-AIM framework. The domains of the RE-AIM framework guide the three research questions including, the effectiveness of the ComPass^{2c} program, the reach of the ComPass^{2c} program, and the implementation fidelity of the ComPass^{2c} program. As the ComPass^{2c} program has ended, the evaluation is timely.

Chapter 2

Integrated Review of the Literature

The Community Passport 2 Care (ComPass^{2c}) program was designed and implemented to reduce 30-day readmissions in Medicare fee-for-service (FFS) beneficiaries. The ComPass^{2c} program utilized two evidence-based transitional care models including the Care Transition Intervention® (CTI®) and the Transitional Care Model® (TCM®). The CTI® and the TCM® have been evaluated in randomized controlled trials (RCTs) and replicated in other settings and populations in effectiveness trials. In efforts to reduce 30-day readmissions within the U.S. and abroad, several organizations have implemented programs applying the CTI® or TCM® in clinical practice. The evaluation of a program differs from that of a RCT or and effectiveness trial. A program evaluation appraises the process, implementation, outcomes, net impact, and cost in order to inform decision or policy makers about whether to adopt, modify or abandon the program (Polit & Beck, 2012). The RE-AIM framework, an acronym for Reach, Effectiveness, Adoption, Implementation, and Maintenance, addresses these five domains which collectively determine the effectiveness/impact of a program in clinical practice. The effectiveness/impact of a program is influenced by the ability to reach the intended population, the adoption of the program by organizations and staff, the consistent delivery of key program elements as intended, and the maintenance of the program and its outcomes over time.

This chapter will present the application of the RE-AIM framework which will be used to evaluate the reach, effectiveness, and implementation of the ComPass^{2c} program.

An integrated review of the literature of the original trials testing the CTI® and TCM® interventions, effectiveness trials of CTI® and TCM®, and programs that utilized the CTI® and

TCM® delivery models will follow. The chapter will conclude with the review of the first annual report of the Community-based Care Transitions Program (CCTP).

Integrated Review of the Evaluation Literature: RE-AIM Framework

The gold standard for evaluating the efficacy of an intervention is the randomized control trial (RCT). This research design is often impractical in the clinical practice setting however. For example, is often not possible to control for factors which may affect participation in an intervention, expertise of staff, availability of resources, and maintenance of the intervention over time. In short, the focus of the RCTs on internal validity is at the expense of external validity (Green & Glasgow, 2006). The RE-AIM framework addresses this imbalance by focusing on factors that affect external validity and the overall effectiveness of an evidenced-based intervention. The following integrated review of the literature will describe the evidence supporting use of the RE-AIM framework in program evaluations.

A literature search to identify evidence regarding program evaluation using the RE-AIM framework was conducted between 2005 and present. A combination of key terms including program evaluation, and RE-AIM, the Boolean modifier AND, were use in identifying program evaluations in PubMed and CINAHL. Limits of English language were used. The RE-AIM website (http://re-aim.org/) was also searched for scholarly articles. The search yielded 121 articles. These articles were reviewed at the titles and abstracts level first and then at the text level. Articles were selected for review if they included programs that addressed secondary or tertiary interventions in adults age 18 or older and included at least two of the five RE-AIM domains. Articles were excluded if there focus was on primary prevention or systematic reviews as the ComPass^{2c} program was a tertiary intervention. Ultimately, a total of five journal articles were used to inform the integrative review on the RE-AIM framework. The ComPass^{2c} program

was a combination of a hospital and community-based intervention, therefore hospital-based or community-based program evaluations were chosen. In all, three hospital-based and two community-based programs will be reviewed for their application of the RE-AIM framework.

Hospital-based Programs

Ottawa Model. The Ottawa Model is an evidence-based smoking cessation program for hospitalized smokers implemented in nine Ontario hospitals (Reid et al., 2010). The overall aim of the Ottawa Model was to increase the number of smokers who achieve long-term abstinence following hospitalization. The Ottawa model's program components include identifying hospitalized smokers, providing inpatient smoking cessation counseling, pharmacotherapy, and outpatient telephone follow-up using an interactive voice response system.

Outcomes of interest included reach, effectiveness, adoption, and implementation. The intervention had a wide reach across all nine hospitals with 69% (29-79%) of hospitalized smokers receiving the intervention. In terms of effectiveness, subjects who received the Ottawa Model intervention had a higher abstinence rate at six months compared to controls. When controlling for hospital, the abstinence rate was 29.4% vs. 18.3% (OR = 1.71, 95% CI [1.11–2.64] Z = 2.43; I 2 =0%; p = .02), similar to that found in other studies (Reid et al., 2006). Overall, 34% of hospital units adopted the intervention with smaller hospitals having greater adoption of the intervention. At the hospital level, implementation indicators varied. Seventy percent of subjects received inpatient counseling, 30% of subjects were prescribed smoking cessation medications, and 23% were enrolled in outpatient telephone follow-up. Of those subjects referred for telephone follow-up, half of the calls were completed. Nurses provided counseling to 415 subjects with each call lasting approximately 10 minutes.

There are several important strengths to this study. First, this study was guided by an evidence-based smoking cessation model, the Ottawa Model. Second, this study addressed the reach, adoption and implementation of the program and its impact abstinence rates. The effectiveness of the program was dependent on the intervention reaching smokers, adoption of the program by hospitals, and the consistency of program implementation. The evaluation found that more than two-thirds of smokers were reached however smaller hospitals adopted the program more often than larger hospitals and prescribing of smoking cessation medication was less frequent. Future success of the program depends on targeting adoption efforts on large hospitals and implementation efforts on prescribers to facilitate smoking cessation medication ordering to improve and maintain the effect on abstinence rates. The information from this study is meaningful for the planners of this program and to other organizations planning to implement similar evidence-based smoking cessation interventions.

There are several important limitations to this study. First, demographic data was not collected for the control group so there is no way of knowing if the intervention group was similar to the control group. Second, each hospital had an expert facilitator to assist with adoption and implementation of the intervention. It is unlikely that other organizations will have the benefit of expert facilitators assisting them with adoption and implementation of the intervention. Facilitators may play an important role in the adoption and implementation of the Ottawa model. Lastly, the post-hospital follow-up phone calls were done using an automated telephone activated voice recognition system (AVR). Other institutions may not have the AVR system available in their communities and would need to substitute live staff to operate post-hospital follow-up phone calls. Some organizations may not have the resources to implement and maintain the follow-up calls.

Tobacco Tactics and RN-SBIRT. Two other hospital-based program evaluations are presented together because of their similarities in objectives. Tobacco Tactics is an evidence-based smoking cessation program (Vick, Duffy, Ewing, Rugen, & Zak, 2012) while RN-SBIRT (Screening, Brief Intervention, and Referral to Treatment) is an alcohol training program modified for registered nurses (Broyles et al., 2013). The aim of these two evaluations were to determine the effectiveness of these training programs on staff self-reported attitudes, knowledge, and behaviors,. A secondary aim of the Tobacco Tactics study was the reach and effectiveness of the intervention on smoking cessation rates 30-day post hospitalization.

Using the RE-AIM framework to evaluate both programs, the authors found that the education programs could reach a moderate to large proportion of nursing staff, be consistently implemented, and significantly increased the knowledge and skill of staff. The Tobacco Tactics training reached 67% of eligible nurse while the RN-SBIRT reached 42% of eligible nurses. Five out of six RN-SBIRT training sessions and all booster sessions were implementation in their entirety. The Tobacco Tactics training had a positive effect of on nurses' self-reported confidence in their ability to deliver smoking cessation services (39.1% vs 60.8%, $p = .001$) and an increase in the delivery of smoking cessation services to inpatients following the training sessions (54% vs 70.5%, $p = .015$). In the RN-SBIRT program, nurses reported a significant increase in Role Adequacy ($p = .032$), frequency of performance ($p = .011$) and competence ($p = .001$) for a greater number of alcohol-related care tasks compared to the control unit nurses.

The secondary aim of the Tobacco Tactic program was to evaluate the intervention's reached and effectiveness in reducing 30-day cessation rates. Patients reported increase in smoking cessation services provided to them while hospitalized post the Tobacco Tactics training (51.9% vs 61.1%, $p = 0.5$) and high levels of satisfaction with these services (52% vs

68.4%, p = 0.2) however neither was significant. Similarly, there were higher 30-day quit rates among smokers post the Tobacco Tactics training however the authors did not have a large enough sample size to detect a difference in quit rates.

Utilization of the RE-AIM framework strengthened the evaluation of these programs with similar barriers to implementation identified. The demands of clinical care and variable staff schedules created obstacles to full implementation of these programs. Staff in both studies reported they were not consistently relieved of their inpatient care responsibilities to allow them to attend either the Tobacco Tactics or RN-SBIRT training sessions.

There are several limitations to these studies. First, the Tobacco Tactics did not evaluate the characteristics of the sample of nurses who participated in the training compared to the other nurses the hospital who did not participate. Nurses who completed the Tobacco Tactics training may not be representative of the whole population of nurses at this hospital. Next, the sample size of nurses enrolled in the RN-SBIRT training was small which may bias results. Lastly, the Tobacco Tactics program measured the effectiveness of the training by 30-day cessation rates however the study was not powered to detect a difference.

Community-based Programs

Ask Advise Connect (AAC). This study evaluated two different approaches to delivering the Quitline smoking cessation intervention to 10 family practice clinics in the Houston metro area (Vidrine et al., 2013). "Ask Advise Refer (AAR)" is a passive recruitment approach where patients' smoking status is assessed, brief quit advice is delivered, and a referral card with information on how the patient can contact the Quitline is provided. "Ask Advise Connect (AAC)" is an active approach where all the steps in the AAR are performed however patients are referred to quit-lines via their electronic health record and are proactively contacted

by the Quitline. The authors hypothesized: (1) AAC would have a greater reach; (2) the efficacy of AAR would be greater than AAC; (3) the impact of AAC would greatly exceed the impact of AAR.

The findings of the study supported each of the three hypotheses. The AAC approached reached more patients (11.4% versus 0.6%, p =.001, OR 17.38, 95% CI, 8.08-37.36). The Quitline enrollment rate, was greater in the AAR group than the AAC group (100% versus 68.7% enrollment rate, Z = 2.01, p = .045). Impact was defined as reach X efficacy. In the case of the AAC approach, the impact was 7.8% (11.4% x 68.7%). For the AAR approach, the impact was 0.6% (0.6% x 100%). The impact of the AAC approach was clinically more meaningful than the AAR approach (t(4) = 9.19, p = .001, OR 11.60, 95% CI[5.53,24.32]).

There are several strengths of this study. The active AAC approach reduces many patient related barriers to smoking cessation treatment. The evaluation using RE-AIM highlights the importance of reach of an intervention rather than just its efficacy. The setting of the study is representative of clinical practice. It is feasible that the AAC approach could be implemented in other settings with an electronic medical record and increase the impact of smoking cessation interventions.

There are also some limitations of this study. In order to minimize the disruption a study can have in clinical practice, data such as demographics and other smoking related patient data were not collected. Without this data we are blind to the characteristics of the subjects which might influence outcomes. The generalizability and representativeness is limited by the fact that only subjects that had health insurance were eligible. Finally, the authors make note that without state funding of the Quitline, implementation could not occur. State-level politics and budget cuts could impact fund for Quitline programs.

Diabetes Self-management Education Program (DSME). A second outpatient-based program evaluation was performed for a diabetes self-management education (DSME) program (Glasgow et al., 2009). Using a unique hybrid preference/randomized study design, the authors' compared the reach, effectiveness, and implementation of a DVD-based DSME to classroom DSME. The secondary purposes was to (1) determine if allowing patients to choose the DSME modality compared to being randomly assigned a modality affected outcomes; (2) determine if combining classroom and DVD DSME compared to classroom DSME alone affected outcomes.

The authors found a greater reach with the DVD-based DSME and equivalent effectiveness compared to classroom DSME. The participation rate was higher in the group that was able to choose the modality of the DSME (48% vs 37%, $p = .02$). Subjects in the choice group overwhelmingly preferred the DVD-based DSME over classroom education (38% vs 9.4%, $p < 0.001$). In terms of effectiveness, there was not difference in self-management behaviors, self-efficacy, patient activation, diabetes related problem solving skills, hemoglobin A1c, or blood pressure from baseline to six months post intervention between the DVD or classroom groups. Adding the DVD to the classroom DSME had no significant benefit.

Implementation measures from the DVD group provide useful information. A little more than two thirds of subjects said they watched all or most of the DVD content. Action plans creation was completed in half of the subjects who viewed the DVD. About 20% of subjects reported that they found the DVD extremely helpful whereas 46% of subjects who received classroom DSME reported the classroom instruction as extremely helpful.

There are several strengths of this study. First, unlike most practice-based research, this study used randomization of the modality of DSME helping to reduce bias. Second, this study measured the difference in the reach of the two DSME modalities and determined that the DVD-

based diabetes education reached more patients than classroom-based education. Third, effectiveness of DSME was measured at the behavioral level as well as the biological level both of which are clinically meaningful. The researchers found similar change in subject's diabetes self-management behaviors and hemoglobin A1c to between the two interventions modalities. Lastly, implementation of the DSME was measured. This provides feedback to creators of the DVS-based DSME as to how much of the DSME was completed by participants.

A few limitations are worth noting from this study. The design of the study did not include a control group therefore the absolute level of change is unknown. What is clear is that the DVD-based DSME is equivalent to in-person classroom DSME and subjects preferred this modality. Another limitation is the high attrition rate between 75-80% for both arms of the study. It raises questions as to why the subjects were not interested in participating in the study.

Summary

Three hospital-based programs and two outpatient-based programs utilized the RE-AIM framework to appraise their programs. The evaluation of the Ottawa Model smoking cessation program in nine hospitals illustrates how a research-based intervention is adopted and implemented across a variety of hospital settings (Reid et al., 2010). The Ask Advise Connect (AAC) Quitline study is an excellent example of how important reach is to the effectiveness of an intervention (Vidrine et al., 2013). Similarly, if only effectiveness was measured in the DSME study, it would not be known if the subjects preferred the DVD-based modality over classroom DSME which has similar outcomes (Glasgow et al., 2009). These studies demonstrate the benefit of the RE-AIM framework in program evaluation. The use of the RE-AIM framework to evaluation the ComPass^{2c} program will provide meaningful information about effectiveness but will also give insight on the penetration of the intervention to the target

population of at-risk Medicare beneficiaries and the consistency of the intervention which impacts effectiveness.

Integrated Review of the Empiric Literature: Transitional Care Interventions

For over twenty years, researchers have been testing transitional care interventions to address the gaps in care that occur as people transition from hospital to home. This section will focus on the two evidence-based transitional care models; the Care Transition Intervention®, and the Transitional Care Model®. The integrated review of the literature on transitional care interventions is divided into efficacy/effectiveness studies that tested the original interventions CTI® and TCM® or replicate these interventions and program evaluations that utilized these interventions in clinical practice.

A literature search for the CTI® and TCM® was performed in PubMed and CINAHL databases from 2005 to present. A combination of key terms including thirty-day readmissions or rehospitalizations, 30-day readmissions or rehospitalization, transitional care, care transitions, Care Transitions Intervention, Transitional Care Model, and program evaluations along with the Boolean modifiers (OR, AND) was used. The limits of English language and adult populations were applied. The websites for CTI® (http://caretransitions.org/) and TCM® (http://www.nursing.upenn.edu/ncth/transitional-care-model/) were reviewed for scholarly articles. A total of 249 articles were found. These articles were first reviewed at the title level and duplicates removed. Abstracts were then reviewed for populations with at least one chronic disease, discharged from acute care hospital, readmission as an outcome, and interventions that used either the CTI® or TCM® care delivery models. The reference lists of journal articles were reviewed for additional pertinent sources of evidence. The studies were then categorized into efficacy/effectiveness trials and program evaluations.

Efficacy/effectiveness trials

Care Transitions Intervention. Three studies were conducted to test the efficacy/effectiveness of the CTI® intervention by the original creators of the intervention. The first study was a small (n = 158) quasi-experimental study (Coleman et al., 2004), the second was a larger (n = 750) RCT (Coleman et al., 2006) and the third a smaller (n = 98) RCT (Parry, Min, Chugh, Chalmers, & Coleman, 2009). All three studies evaluated rates of rehospitalization at 30, 90, and 180 days post index hospitalization. One study also measured 30-day emergency department and observational stay utilization (Coleman et al., 2004). All three studies reported on the consistency of implementation of the CTI® intervention.

The CTI® intervention was the same across all three studies with one exception; the Transition Coach was an Advanced Practice Nurse (APNs) in the first two studies whereas in the smaller RCT, the Transition Coach was a registered nurse (RN) or social worker. The settings and samples differed across these trials. The setting for the first two CTI® trials was a large not-for-profit group-model of the Medicare Advantage delivery system in Colorado (Coleman et al., 2004; Coleman et al., 2006). This managed care delivery system contracted with one acute care hospital, eight skilled nursing facilities and one home health care agency. The smaller RCT (Parry et al., 2009) was conducted in collaboration with a not-for-profit senior care clinic in Colorado with Medicare FFS beneficiaries. Patients were hospitalized in one of two community hospitals operated by the same parent company, utilized one of six skilled nursing facilities located near the hospitals, and one of four home health care agencies.

In all three studies eligible patients were community dwelling adults aged 65 and older, hospitalized in participating hospitals, had non-psychiatric related admission, English speaking, lived within a predefined geographic area of the hospital, had a phone, and had no plans to enter

hospice. Subjects had to have one of the following diagnoses congestive heart failure, chronic obstructive pulmonary disease, coronary artery disease, diabetes mellitus, and stroke, medical and surgical back conditions, hip fracture, peripheral vascular disease, deep vein thrombosis, pulmonary embolism, and cardiac arrhythmias. These diagnoses were chosen because of the likelihood subjects would require post-hospital care at a skill nursing facility or home health care and therefore need multiple transitions.

Integrity of the CTI® intervention was determined by the number of subjects who completed a home visit and follow-up telephone calls from a transition coach. Across all three studies, the majority of subjects received a home visit and telephone follow up. In two of the studies, approximately 90% of subject received a home visit while between 72-93.8% completed 3 or more follow up phone calls (Coleman et al., 2004; Parry et al., 2009). Eighty-six percent of subjects in the second study had a home visit and at least one follow up call (Coleman et al., 2006).

Rehospitalization across all three studies was less in the intervention groups than the control groups. In the quasi-experimental study, the adjusted odds ratio comparing readmission of intervention subjects to controls was 0.52 ($p = .04$, 95% CI [0.28, 0.96]) at 30 days, 0.43 ($p = .002$, 95% CI [.25, .72]) at 90 days, and 0.57 ($p = .02$, 95% CI [.36, .92]) at 180 days (Coleman et al., 2004). In the larger RCT, the adjusted odds ratio was 0.59 ($p = .048$, 95% CI [.35, 1.00]) at 30 days and 0.64 ($p = .04$, 95% CI [.42, .99]) at 90 days, and 0.80 ($p = .28$, 95% CI [.54, 1.19]) at 180 days (Coleman et al., 2006). Rehospitalization rates for the Medicare FFS RCT were 6.8% in the intervention group versus 16.7% in controls ($p = .15$) at 30 days, 9.3% versus 31% ($p = .01$) at 90 days, and 20.9% versus 38.1% ($p = .08$) at 180 days (Parry et al., 2009).

In addition to rehospitalization rates, emergency department (ED) or observational stay utilization was measured in one of the three CTI® studies. Coleman et al. (2004) measured ED or observation stay rates 30-days post index hospitalization in control and intervention subjects. There was no difference in ED or observational stay utilization at 30-days between groups, 11% in the intervention group versus 14% in controls ($p = .27$) with an adjusted odds ratio of 0.76 (95% CI .44-1.30, $p = .40$).

Two trials replicated CTI® in the clinical setting to test the effectiveness, generalizability, and feasibility of the interventions in different settings and populations (Ohuabunwa, Jordan, Shah, Frost, & Flacker, 2013; (Voss et al., 2011)). These quasi-experimental prospective cohort studies were performed in a large academically affiliated 953-bed urban safety net hospital (Ohuabunwa et al., 2013) and in three regional academic hospitals, two community hospitals, and one tertiary-care hospital (Voss et al., 2011). Ohuabunwa et al. (2013) used hospital-based RNs to implement CTI® while Voss et al. (2011) partnered with the local Quality Improvement Organization (QIO) and utilized community-based RNs and social workers to implement the CTI®. The populations included adults over the age of 60 with medical conditions as the primary diagnosis at index admission and at least one co-morbid condition. One study enrolled Medicare FFS beneficiaries only (Voss et al., 2011) while the other targeted low-income populations (Ohuabunwa et al., 2013).

The reach and integrity of the intervention was reported in these studies. Sixteen percent of eligible subjects at the safety net hospital enrolled (Ohuabunwa et al., 2013), while 55% of Medicare FFS subjects' enrolled (Voss et al., 2011). Integrity of implementing the CTI® intervention was addressed in one study (Voss et al., 2011). Almost three quarters of

intervention subjects received a home visit and two follow up telephone calls from transition coaches.

The outcome of 30-day hospital readmission was mixed between the studies. In the study by Voss et al. (2011) in which hospitals partnered with the state QIO to administer CTI® to Medicare FFS beneficiaries, the absolute readmission rate was 12.8% in the intervention group versus 20% in the control group (OR 0.61, p = .05, 95% CI [0.42, 0.88]). There was no reduction in 30-day hospital readmission rates in the population of low-income, high-risk elders who received the intervention compared to controls (9.6% vs 17.3%, p > .05) (Ohuabunwa et al., 2013).

Thirty-day post-discharge ED utilization and primary care follow-up visits were secondary outcomes evaluated by Ohuabunwa et al. (2013). There was not difference in 30-day post discharge ED utilization rates between the intervention and control groups (17.3% versus 15.4%, p = .81). Pre and post intervention group 30-day ED visits rates were similar as well (42% versus 43.5%, p = .69). Primary care follow-up rates within 30-days was significantly higher in the intervention group compared to the control group (40.4% versus 19.2%, p < .001) but no different pre and post in the intervention group (59.4% versus 66.7%, p = .82).

There were several strengths to this body of evidence on the CTI®. First, two of the original studies used an experimental design with a control group (Coleman et al., 2006; Parry et al., 2009) while the other studies were quasi-experimental, all included a control group. Second, populations studied were not condition specific enrolling subjects with a wide range diagnoses, strengthening generalizability. Third, the consistency of delivery of the intervention was high across all of these studies.

The limitations of these studies testing the CTI® included small sample size, a single health system as the study setting, high attrition, and a large number of subjects declining the intervention. A small sample size limited power to detect differences in 30-day hospital readmission rates for the Medicare RCT (Parry et al., 2009) and the trial of low-income elders (Ohuabunwa et al., 2013). Two of the original CTI® trials were conducted in a single health system in Colorado and may not be feasible or obtain similar results in other settings (Coleman et al., 2004; Coleman et al., 2006). The study by Voss et al. (2011) reported a 75% attrition rate as well as a difference between subjects who enrolled in the intervention and those who declined. Subjects who declined the intervention were older, had longer hospital stays, and had been hospitalized more often in the year prior to index admission. Finally, the refusal rate was high in the Medicare FFS RCT at 27% (Parry et al., 2009) as well as in one of the replication studies at 48% (Voss et al., 2011).

Transitional Care Model (TCM®). Five studies were conducted by the creators of TCM® to test the efficacy/effectiveness of the intervention. The earliest study to test the TCM® intervention (Naylor et al., 1994) did not include home visits but was strictly comprehensive discharge planning therefore will not be included in this review. Two of the four studies were RCTs (Naylor et al., 1999; Naylor et al., 2004) with the two most recent quasi-experimental studies testing the effectiveness of the intervention in different populations and settings (Naylor et al., 2013; Naylor et al., 2014). One of the quasi-experimental studies prospectively enrolled willing Aetna Medicare Advantage members prior to an index hospitalization and compared them with matched controls (Naylor et al., 2013) while the other randomly assigned three different evidence-based interventions to three separate hospitals (Naylor et al., 2014). All four studies measured rehospitalization rates, while two studies measured mortality, and three studies

measured ED utilization. Consistency of the implementation of the TCM® intervention was not reported.

The target population across the four studies was elders at high risk for readmission. Eligible subjects were age 65 years or more, community dwelling, lived within the geographic service area, English speakers, and could be reached by telephone following discharge. The first three studies enrolled subjects who were cognitively intact (Naylor et al., 1999; Naylor et al., 2004; Naylor et al., 2013) however the most recent study targeted elders with cognitive impairment (Naylor et al., 2014). The first TCM® trial included patients with select medical and surgical cardiac conditions including congested heart failure, myocardial infarction, angina, coronary artery bypass grafting, or valve replacement as well as respiratory tract infection, major small and large bowel procedures, and orthopedic procedures of the lower extremities (Naylor et al., 1999). The next TCM® RCT included patients with heart failure only (Naylor et al., 2004). The quasi-experimental studies included many common chronic medical illnesses but excluded neurological disorders, cancer, end-stage renal disease, and untreated psychiatric disorders (Naylor et al., 2013; Naylor et al., 2014).

The settings for these fours studies varied. The earliest study took place at two urban academic medical centers (Naylor et al., 1999) while the most recent study was performed at three hospitals that were part of an academic system (Naylor et al., 2014). The study of subjects with heart failure occurred at six hospitals which were either academic or community hospitals (Naylor et al., 2004). The setting for the Aetna Medicare Advantage members was hospitals in the mid-Atlantic region (Naylor et al., 2013).

In an effort to test the TCM® intervention on rehospitalization outcomes in high-risk elders, patients had to have risk factors for readmission. In two of the studies the criteria for

eligibility included inadequate home supports, multiple, active chronic health conditions, history of depression, moderate-to-severe functional impairment, multiple hospitalizations in the prior six months, hospitalization within the past 30 days, fair to poor self-rating of health, or history of non-adherence to medical therapies (Naylor et al., 1999; Naylor et al., 2013). The earlier RCT required subjects to meet at least one of the criteria (Naylor et al., 1999) whereas the Aetna Medicare Advantage study required subjects to have two or more of these risk factors (Naylor et al., 2013). To enroll subjects with cognitive impairment, subjects needed to have a history of dementia or demonstrate evidence of cognitive impairment assessed by Six-Item Screener and CLOX1, a clock drawing task (Naylor et al., 2014).

The TCM® intervention and the use of the APN remained constant throughout all four studies. A modification to the TCM® protocol was made in the Aetna Medicare Advantage study due to perceived regulatory and legal constraints (Naylor et al., 2013). The advanced practice transitional care nurses were not allowed to interact with the Aetna members during their acute hospital stay. Instead the transitional care nurses began the TCM® intervention with Aetna members enrolled in the study that had not been hospitalized and continued the intervention with home visits only after a hospitalization occurred.

The findings from these studies support a reduction in readmission rates in high-risk elders who received the TCM® intervention. The first TCM® RCT (Naylor et al., 1999) found significantly fewer readmissions in the intervention group at six weeks (17 versus 47, $p < .001$) and 24 weeks (49 versus 107, $p < .001$). At 24 weeks, there was an absolute risk reduction of 16.8% and a relative risk reduction of 45% in patients who received the TCM® intervention. The heart failure RCT (Naylor et al., 2004) found fewer readmissions at 52 weeks in the intervention group (104 versus 162, $p = .047$). The quasi-experimental study of Aetna Medicare Advantage

members (Naylor et al., 2013) found a significant reduction in readmissions at 90 days (45 versus 60, $p < .04$) but not at 180 (104 versus 112) or 365 days (184 versus 203). In the study of cognitively impaired elders, 30-day readmissions rates were lower in the TCM® group 9% (6/66) compared to the low intensity 22% (15/66) and moderate intensity19% (14/71) groups (Naylor et al., 2014). Time to rehospitalization or death was longer in in the TCM group (83 days) compared to low intensity group (33 days) or moderate intensity group (58 days). The total number of all-cause rehospitalization days for the low intensity group was 6.23-times higher than the TCM® group and 3.35-times higher in the moderate intensity group than the TCM® group (Naylor et al., 2014).

There was no difference in deaths between control and interventions groups for the two studies that reported mortality following an index hospital admission. In heart failure subjects, 13 control subjects versus 11 intervention subjects died by week 52 ($p = .83$) (Naylor et al., 2004). For subjects with cognitive dysfunction, 3% in the low intensity group, 5% in the moderate intensity group, and 2% in the TCM® died by 180 days (unweighted Fisher's exact test, $p = .25$) (Naylor et al., 2014).

Of the three studies that measured ED utilization as an outcome, there was not significant difference in the number of ED visits following the index hospitalization between groups. At 24 weeks post discharge, fail elders in the control group had a similar mean number of ED visits compared to intervention group (0.2 ± 0.4 versus 0.1 ± 0.5, $p = .21$) (Naylor et al., 1999). Mean number of ED visits were no different following discharge for subjects with heart failure at 52 weeks for controls and intervention groups (0.3 ± 1.2 versus 0.1 ± 0.4, $p = .116$) (Naylor et al., 2004). Finally, no statistical difference was demonstrated in ED visits for elders in the Aetna Medicare Advantage members (Naylor et al., 2013).

The TCM® was replicated by Stauffer et al. (2011) in a quasi-experimental pilot study of adults 65 years or older with heart failure hospitalized within one health system. A separate hospital within the health system that did not implement TCM® was used as a concurrent control. In this study a hospital-based APNs delivered the TCM® intervention. The intervention reached 40% of the 140 eligible heart failure subjects. The adjusted all-cause 30-day readmission rates was 48% lower following the TCM®intervention at the intervention hospital however there was no difference in 30-day readmission rates between the intervention and controls.

There are several strengths and weaknesses of these TCM® trials worth mentioning. The main strength of the studies presented is the rigorous design of the trials conducted by the original creators of TCM®. Two studies employed an RCT design but all had a control or comparison group. Generalizability of the two h is limited because it is condition specific however heart failure is a common reason for hospital admission and readmission in adults over 65 years old. The of results in the quasi-experimental study (Naylor et al., 2013) can be generalized to Medicare Advantage beneficiaries only but adds to the body of knowledge on transitional care interventions in this group (Coleman et al., 2004; Coleman et al., 2006). Finally, an increase in ED visits could be seen as an unintended consequence of the TCM®, therefore a lack of a difference in mean number of ED visits between groups can be seen as an additional strength of the intervention.

Summary

Both the CTI® and TCM® have demonstrated success in reducing rehospitalization in adults over the age of 65 with common medical and surgical conditions in both the Medicare FFS and Medicare Advantage populations and in urban and community hospitals. Six of the 10 studies presented utilized the APN to deliver the intervention. The consistency of

implementation of the interventions as intended was high in the CTI® trials indicating the feasibility of the intervention components and the acceptability of the components to subjects who enrolled. Emergency department visits, observation stays, and morality are unintended negative consequences of these interventions. Both care delivery models did not show an increase in utilization of other services or mortality due to the intervention. Overall, these findings demonstrate that supporting subjects and their caregivers in assuming an active role in self-care during transitions reduces readmission rates.

Program Evaluations

Three transitional care programs utilizing either CTI® or TCM® were developed, implemented, and reported in the literature. The first program called the Transitional Care (TLC) Partners, was based on the TCM® and developed for elderly veterans at the Durham Veterans Affairs Medical Center, an academic teaching hospital (Hendrix et al., 2013). The second program was developed by the Singapore Ministry of Health called the Aged Care Transition (ACTION) national demonstration project. The ACTION program was based on CTI® and targeted elders with complex health needs and implemented by the Agency for Integrated Care (AIC) in five hospitals. The third program was a CCTP created in Arizona called Sun Health Care Transitions Program (Logue & Drago, 2013).

The fourth program evaluation was reported in the gray literature and addresses the first year of the Community-based Care Transitions Program (CCTP). The ComPass^{2c} program was one of 47 CCTPs included in this national program evaluation. Despite the lack of peer review, the CCTP evaluation is included because its content is relevant.

Transitional Care (TLC) Partners Program. The primary goal of the TLC Partners program was to reduce hospital readmissions and emergency department (ED) use at 30 and 60

days post index hospitalization (Hendrix et al., 2013). The evaluation described the development of the nurse practitioner (NP)-led program based on the TCM® framework. The TLC Partners program modified the TCM® by adding an occupational therapist and social worker to address the unique medical and socioeconomic needs of veterans. Patient eligibility, referrals, and program description were provided. Data collection on hospital and ED visits was tracked for 90 days following index hospital discharge for both TLC-enrolled veterans and veterans referred to TLC but not enrolled. Caregiver outcomes were collect by the Preparedness in Caregiving and Short Zarit Burden Scale at week one and end of program.

The evaluation was performed on the first five months of the TLC program. A total of 80 referrals were received; 67% met criteria and enrolled; 32.5% were ineligible because they were discharged to a facility, lived outside the geographic 35-mile radius, too young, too ill, or discharged before seen by the TLC NP. In the first month, almost half of the referrals who were veterans did not meet eligibility criteria due to living outside the 35-mile radius or age less than 60 years. Monthly meetings with physicians, case managers, and the circulation of a brochure summarizing the program helped to re-educate staff about eligibility criteria. No information regarding enrollment rate was presented.

Demographic characteristics of TLC and non-TLC veterans were presented. Not surprisingly, the majority (96%) of enrolled subjects were men, a little less than half (47%) were white, a third African-American (38%), and two-thirds were 75 years and older. A little more than half of TLC-enrolled veterans had one or more ED visit and 45% had been hospitalized in the 90 days prior to index hospitalization.

The evaluation of primary outcomes included the proportion of veterans with 30-day readmission and 30-day ED visits between TLC and non-TLC veterans. The evaluation also

measured caregiver outcomes including preparedness and burden as secondary outcomes. Due to low sample size and preliminary nature of the data, no statistical tests were performed. TLC enrolled veterans were readmitted less often than non-TLC veterans at both 30 (23% versus 36%) and 60 days (23% versus 64%). Similarly, TLC-veterans were less likely to visit the ED at 30 (20% versus 27%) and 60 days (27% versus 36%). Of the 14 caregivers that completed the Preparedness in Caregiving survey and the 15 caregivers who completed the Zarit Burden Scale, 43% reported increase in caregiver preparedness scores and 53% had a decrease in caregiver burden. There was not difference in overall mean scores for caregiver preparedness or burden before or after TLC program. Narrative feedback was overwhelmingly positive with themes of easy access to a provider and not having to travel back and forth to the VA identified.

Aged Care Transition Program. The Singapore Ministry of Health Aged Care Transition (ACTION) program was a national demonstration project to reduce unplanned hospital readmissions, ED visits, and reduce cost (Wee et al., 2014). The evaluation of the ACTION program measured unplanned hospital readmissions at 15, 30, and 180 days, ED visits at 30 and 180 days post index discharge, and patient experience and quality of life surveys at 1-week and 4-6 weeks using the Care Transition Measure-15 (CMT-15) and the EuroQOL (EQ-5D) scale. The CMT-15 was reported as locally validated. The cohort of 4,132 ACTION subjects enrolled during an 18-month time period was matched to a comparison group based on administrative data from the Ministry's Case-mix database for the same time period. The nonequivalence of the comparison group was adjusted using propensity score weighting with multiple logistic regressions. No information regarding enrollment or implementation was presented.

Criteria for enrollment into the ACTION program were similar to other studies and programs with the goal of enrolling high risk subjects. Individuals met one or more of the following criteria including admission to government-subsidized hospital ward, ≥65 years old, multiple diagnoses and comorbidities, >5 medications, impaired function, impaired self-care skills, cognitive impairment, catastrophic injury or illness, chronic illness, lived alone or with poor social support, and history of multiple hospital admissions or ED visits in past six months. A little more than half of ACTION-enrolled subjects were women with a mean age of 79 years. Almost all ACTION-enrolled subjects (97.4%) had an ED visit and 40.7% had a hospitalization within six months prior to enrollment in the program.

Unplanned readmissions were significantly lower in ACTION subject at 15 days (10% versus 21.3%, OR 0.5, $p < .001$, 95% CI [0.4, 0.5]), 30 days (15.6% versus 27.8%, OR 0.5, $p < .001$, 95% CI [0.5, 0.6]), and 180 days (37.9% versus 51.6%, OR 0.6, $p < .001$, 95% CI [0.6, 0.7]). Emergency room visits were significantly less likely in ACTION subject at 30 days (19.3% versus 32.0%, OR 0.81, $p < .001$, 95% CI [0.72, 0.90]) and 180 days (46.3% versus 57.9%, OR 0.9, $p = .03$, 95% CI [0.82, 0.99]). Mortality however was higher in the ACTION group than the comparison group at 15, 30 and 180-days post discharge. Within 30-days post index discharge, 7% of ACTION subjects died compared to 3.1%.

Eighty-four percent of subjects completed both the EQ-5D scale and the CMT-15 patient satisfaction questionnaires with 70% of caregivers filling out the surveys. The overall mean score on CTM-15 at week four was 63.8 out of a possible100 points. On the EQ-5D, there was a significant improvement across all domains from week one to weeks four through six for mobility, self-care, usual activity, pain, and anxiety/depression. Finally, mean scores for self-rated health improved from week one to week four through six (60.4 versus 64.1, $p = .03$).

Sun Health Care Transitions Program. The Sun Health Care Transitions Program was a CCTP based on CTI® and TCM® and implemented by the community-based organization called Sun Health in two area hospitals that were part of a large non-profit health system (Logue & Drago, 2013). An all-registered nurse (RN) model was deemed cost-prohibitive; therefore licensed practical nurses (LPN) enrolled patients and coordinated care and RNs made home visits. The program evaluated whether the Sun Health CCTP was implemented as planned, improved outcomes, and whether participants were satisfied with the program.

The implementation of the Sun Health CCTP was measured by frequency of subject encounters, medication reconciliation, education on medicines, disease specific information, and red flags, and completed depression and mobility screening by transition coaches for the first 24 subjects. Seventy-nine percent of subject had between one and six follow-up phone calls and three to eight home visits with coaches. Eighty-seven percent of subjects received medication reconciliation and medication education. Education on red flags and disease specific education occurred 91.7% of the time. Depression and mobility screen was completed only 41.7% of the time.

The outcome evaluation was measured by number of medication discrepancies identified, number of assisted appointments, averted care visits, and 30-day readmission rates. A total of 300 medication discrepancies were found with an average of 2.1 discrepancies per subject. Thirty-five percent of subjects required assistance with post-hospital discharge follow-up appointments. Unplanned readmission was averted in 20.8% of subjects and ED visits in12.5% of subjects due to coaches' intervention. Finally, 4% of subjects were rehospitalized within 30-days of discharge. This is compared to historical 30-day readmission rates of 14.7% and 15.4% in 2010 at each of the two hospitals.

Subject satisfaction and change in level of confidence with knowledge and skill in self-care was measured by questionnaire. The questionnaire consisted of 22-items, 13 using a 5-point Likert scale for satisfaction, 8 using a 4-point Likert scale for confidence, and one open-ended question about what subjects liked least and best about the program. The questionnaire was developed and administered by Sun Health. Sixty-two subjects completed the questionnaire. The overall rating for the program was 4.82 (scale 1-5). The change in subject's confidence levels pre and post intervention were all significant (p=.001).

Community-based Care Transitions Program. The First Annual Report of the CCTP is an evaluation of the initial progress of the program during the 12-months ("CCTP Evaluation," 2014). The Centers for Medicare and Medicaid Services (CMS) awarded a contract to Econometrica, Incorporated and IMPAQ International to design and conduct the CCTP evaluation. Econometrica, Inc. is a research and management organization that performs cost-effective analyses, modeling, and economic evaluations for the public and private sectors (http://econometricainc.com/). IMPAQ International is an organization that conducts program evaluations, research, surveys, technology, and policy analysis for governments, businesses, foundations, non-profits, and universities (http://www.impaqint.com/). The design of the program evaluation includes characteristics of CCTPs throughout the U.S., implementation of these programs, and outcomes. The report was made public May 30th, 2014.

CCTP Characteristics. The annual report characterizes the first 47 approved CCTP sites through the end of 2012. The details include the characteristics of the participating community-based organizations (CBOs), the partnering hospitals, CCTP design, and market areas serviced by participating hospitals. Data is based on CCTP applications submitted to CMS, American

Hospital Association Annual Survey of Hospitals, 2012 Census data, and Dartmouth Atlas Hospital Referral Region data sources.

The evaluation sought to answer two questions, the first of which was to describe the characteristics of the CCTP sites. Over 70% of CBOs were either Area on Aging Agencies (AAA), Aging and Disability Resource Centers (ADRC), or a combination of both. Most CBOs coordinated care and were direct service providers with 93.6% providing two or more elder services. Over 90% of partnering hospitals were short-term general hospitals, 81% were small to moderate sized, and 62.8% had higher than the national average of Medicare discharges. Over 80% of CCTP sites selected the CTI® or CTI® plus another model, half of the programs utilized a combination of social workers and nurses, and another 25% utilized a combination of community health workers, pharmacists, pharmacy technicians, social workers, and nurses. Forty percent of CCTP sites targeted Medicare age beneficiaries only while another 40% enrolled all Medicare beneficiaries regardless of age and those dually eligible for Medicaid. The majority of CBOs (78.7%) partnered with other community agencies such as skilled nursing facilities, Meals on Wheels, and home healthcare agencies. There was little variation or patterns found across CCTP market sites.

The second question asked which CCTP characteristics are associated with early success. Implementing the program within 3 months of CCTP award and meeting average monthly enrollment goals at least once by April 30th, 2013 were process measures deemed indicative of program success. Fifty-three percent of sites were able to implement the CCTP within three months of their award and 23% of sites met average monthly enrollment targets. Nine out of 47 CCTP sites met both process measures. Targeting all Medicare beneficiaries, using CTI® with

another model, CBOs that provided both care coordination and direct support services, and CBOs partnering with 1-5 hospitals were characteristics of CCTP sites meeting both measures.

CCTP implementation. The evaluation of program implementation was based on scripted phone interviews with CBO staff and managers. Facilitators and barriers to program implementation as well as changes made during the program were the focus of these interviews. Facilitators identified included a good relationship with partnering hospitals, robust information technology infrastructure, and access to partnering hospitals' electronic health record (EHR). Internal hospital factors such as mergers, new EHR systems, competing initiatives, and changes in leadership and key hospital staff were frequent barriers cited. Medicare beneficiaries with active mental health issues and active caregivers were the most difficult to enroll and provide services for. Most CCTP sites made changes during the first year of implementation including expanding enrollment criteria, adding more staff with skills in coaching that were bilingual, and adding additional hospitals or community partners such as skilled nursing facilities.

CCTP outcomes. Thirty-day readmissions, 30-day emergency department (ED) visits, and 30-day hospital observation use were the outcomes of interest for this evaluation. The analysis of the impact of the CCTP on outcomes was performed using Medicare claims data. CCTP sites that began implementation and submitted a claim to Medicare for 2012 were included in this analysis. First, 30-day unadjusted readmission rates for 48 CCTP sites and 212 partner hospitals were analyzed and compared to hospitals internal to the CBO's market area but not participating in the CCTP and hospitals external to the CBO's market area. Second, the overall impact of CCTP on adjusted 30-day readmissions, 30-day ED visits, and 30-day observation use were compared to internal and external hospitals both prior to the CCTP implementation (2010) and post implementation.

Overall there was a decline in unadjusted and adjusted 30-day readmission rates however neither analysis was statistically significant. Four CCTP sites individually had significant reductions in unadjusted 30-day readmissions. One of the four sites had lower 30-day readmission rate compared to both internal and external comparison hospitals, another site had lower readmission rates compare to hospitals within the CBO's market area, and two sites had lower readmission rates compared to external hospitals. CBOs with a significant reduction in 30-day readmission rates were more likely to be AAA/ADRCs, have prior experience with providing direct services to beneficiaries, and offer six or more elder services. With so few CCTPs achieving a reduction in 30-day readmission rates, predictions about what CCTP characteristics indicate success are speculative.

The trends were similar across all groups for the outcomes of 30-day ED visits and 30-day observation use. The rates of 30-day ED visits remained constant from 2010 baseline to 2012 for CCTP hospitals as well as internal and external comparison hospitals. Thirty-day observation utilization increased for all groups from 2010 to 2012 however these rates were 18% higher in the CCTP hospitals. It was noted that programs that had been operating longer saw a decline in observation utilization over time.

Summary

All four program evaluations appraised the application of transitional care delivery models in clinical practice with the goal of reducing 30-day hospital readmissions. The programs assessed implementation, characteristics of subjects, 30-day healthcare utilization, and subject experience. Three of the four programs, TLC, Sun Health, CCTP, were early evaluations while ACTION assessed outcomes for 18 months. Two programs were local evaluations and ACTION and CCTP were national demonstration projects. Three of the four evaluations looked

at implementation outcomes. The TLC program assessed the initial referrals finding many subject not meeting criteria leading to re-education of hospital staff about eligibility criteria. Sun Health looked at the frequency of key process components to determine the fidelity of their intervention. The CCTP evaluation addressed key implementation components as time from award to start of the program and meeting average monthly enrollment numbers as successful implementation. Three programs evaluated characteristics of subjects who enrolled to determine if the targeted population enrolled in the program.

All of the programs reported on outcomes of 30-day health care utilization. Only the ACTION program reported significant reductions in 30-day readmission rates. Three of the studies addressed 30-day ED visit rates while the TLC and CCTP evaluations found no difference in ED utilization at 30-days, the ACTION program found significant reductions. Only the CCTP looked at 30-day observation rates. This is important to examine as it may be a negative consequence of the pressure to keep 30-day readmit rates low. Mortality was analyzed in the CCTP and ACTION evaluations with no difference for the CCTP evaluation however increased mortality at 6 months for ACTION enrolled subjects.

Finally, subject experience/satisfaction was appraised. The CCTP evaluation did not look at subject experience however the other programs did address these outcomes. TLC looked at caregiver burden and preparedness, Sun Health measured confidence with self-care skills and knowledge, and quality of life was assessed in the ACTION program.

These program evaluations were all missing a framework to guide the evaluation. The RE-AIM framework could be used for the planning, development, implementation, and evaluation of these programs. The proposed evaluation of the ComPass^{2c} program will close the gap found in the literature by including a conceptual framework, address the reach of the

intervention to the target population, provide 24 months of key program implementation processes, and contribute additional knowledge of health care utilization following these transitional care delivery models.

Conclusion

The RE-AIM framework for program evaluation addresses the effectiveness of an evidence-based intervention in the clinical setting but also factors that affect external validity such as reach of the intervention to the target population, representativeness of the enrolled population to the target population, consistency of implementation, adoption of the program by the organizational and/or staff, and maintenance of the intervention over time. Each program evaluation presented demonstrated how the RE-AIM domains impact the overall effectiveness of the intervention. The studies presented in this chapter illustrate the rational for choosing the CTI® and TCM® care delivery models in the ComPass^{2c} program. These models have been tested and applied to high risk elderly populations in a variety of clinical settings. However the experience of translating these care delivery models into clinical practice has had varying success as noted in the program evaluation section. Indeed, the evaluation of the application of evidence-based care delivery models into clinical care as in the CCTP is incomplete. The ComPass^{2c} program evaluation will address the gap in knowledge about the ability of the two evidence-based transitional care models to reach the high-risk Medicare population, the ability of the program to be delivered as intended, and the effect of the program on 30-day readmission rates.

Chapter 3

Methodology

The aims of this project were to evaluate the Community Passport 2 Care (ComPass^{2c}) program guided by the Reach, Effectiveness, Adoption, Implementation, and Maintenance framework (RE-AIM). The ComPass^{2c} program evaluation addressed the effectiveness of the program to reduce 30-day readmissions at Hospital X, the reach of the program into the target population, and the implementation of key program elements. In this chapter, the methods for evaluating the ComPass^{2c} program are described including: study design, sample, setting, and protection of human subjects, instruments, procedures, treatment of the data, study questions, analysis, and limitations of the data.

Design

A retrospective observational design was used to address the aims of this program evaluation. This design was appropriate because of the lack of randomization of subjects. In addition, there was no manipulation of the independent variable, the ComPass^{2c} program.

Specific Aims:

1. Determine the effectiveness of the ComPass^{2c} program in reducing 30-day all-cause readmission rates for Medicare FFS beneficiaries discharged from an academic hospital in New England.
2. Determine the reach of the ComPass^{2c} program in Medicare FFS beneficiaries discharged from an academic hospital in New England.
3. Determine the consistency of implementation of key ComPass^{2c} program elements in Medicare FFS beneficiaries discharged from an academic hospital in New England.

The primary aim was to determine the effectiveness of the ComPass^{2c} program in reducing 30-day all-cause readmissions for Medicare FFS beneficiaries discharged from Hospital X. Thirty-day all-cause readmission rates for Medicare FFS beneficiaries discharged from Hospital X were measured at the aggregate level. Aggregate data was provided by the Centers for Medicare and Medicaid Services (CMS), based on Medicare reimbursement claims, and defined by CMS in the Community-based Care Transitions Program (CCTP) Quarterly Monitoring Report. Thirty-day all-cause readmission rates were defined as the number of Medicare FFS beneficiaries readmitted within thirty days of index discharge from Hospital X (numerator). The numerator is divided by the total number of index discharges from Hospital X during the reporting period (denominator). The numerator includes all hospital readmissions that occurred within 30-days of index discharge, including those to other hospitals. Beneficiaries who died during their index hospital stay were excluded (CMS, 2014, p. 10).

Thirty-day all-cause readmission rates for ComPass^{2c} participants discharged from Hospital X were also measured at the subject level. This data was provided by the Community-based Organization (CBO) and is based on Medicare billing data. Thirty-day readmission rates were calculated by the number of ComPass^{2c} subjects readmitted within thirty days of index discharge from Hospital X (numerator) divided by total number of ComPass^{2c} subjects (denominator).

Effectiveness was also measured by other post-discharge events including 7-day and 14-day physician follow up rates, 30-day emergency department (ED) visit rates, 30-day observation stay rates, and 30-day mortality rates for any Medicare FFS subject discharged from Hospital X. The 30-day post-discharge events were measured at the aggregate level, based on Medicare reimbursement claims, and defined by CMS in the CCTP Quarterly Monitoring Report. The

denominator for all 30-day post-discharge utilization events was total number of index discharges from Hospital X during a reporting period. Seven and 14-day post-discharge physician follow-up visits rate was defined as the number of Medicare beneficiaries with an index discharge during the reporting period who had an ambulatory visit with a physician within seven and 14 days of an index discharge from Hospital X (numerator). Thirty-day post-discharge hospital ED visit rates were defined as the number of ED visits that occurred within 30-days of index discharge during the reporting period, including those to other hospitals, except for those visits that resulted in same-day or next-day inpatient admission or observation stays (numerator). Thirty-day post-discharge hospital observation stay rates were defined as the number of observation stays that occurred within 30-days of index discharge during the reporting period, including those to other hospitals, but excludes observation stays that resulted in same-day or next-day inpatient admission (numerator). Thirty-day post-discharge mortality rates were defined as the number of Medicare beneficiaries with an index discharge from Hospital X during the reporting period that died within 30 days of discharge (numerator).

The pre-program outcomes for 30-day readmission rates, seven and 14-day physician follow up visits, 30-day ED visits, 30-day observation visits, and 30- mortality for Medicare FFS beneficiaries discharged from Hospital X were compared to quarterly post-program outcomes of Medicare FFS beneficiaries discharged from Hospital X from May 1, 2012 through November 30, 2014. The pre-program time frame was January 1, 2010 – December 31, 2010. Pre-program groups were used rather than concurrent groups because other initiatives occurred simultaneously to the ComPass^{2c} program that could affect these outcomes. CMS did not provide data on outcomes from comparison hospitals.

The second aim of the program evaluation was to determine the reach of the ComPass^{2c} program into the Medicare FFS population at Hospital X. The participation rate was determined by the counts of subjects enrolled in the ComPass^{2c} program at Hospital X (numerator) over the number of subjects eligible to participate (denominator). Demographic data described eligible and enrolled subjects. Representativeness was determined by comparing the demographic data of eligible subjects and enrolled ComPass^{2c} subjects. Data on eligible subjects from May 1, 2012 through November 30, 2014 was provided by Hospital X from the Admissions, Discharges, and Transfers (ADT) database. Data on enrolled ComPass^{2c} subjects was provided by the CBO.

The third aim of the program evaluation aim was to determine if the essential program elements of ComPass^{2c} program were implemented as planned. The essential program elements included post discharge home visits and telephone calls. Post discharge home visits and telephone calls are defined as documentation within the ComPass^{2c} chart of an encounter. Implementation was evaluated by the number and percentage of essential program elements that were delivered. Implementation was also evaluated by the change in patient activation at completion of the program. Activation was measured by the Patient Activation Measure® (PAM®), a 13-item survey administered pre and post the program. Data on the delivery of program elements and patient activation was provided by the CBO.

Sample

Eligibility Criteria

The target population was Medicare FFS beneficiaries hospitalized at Hospital X between May 1st, 2012 and November 30th, 2014 who were age 18 years or older. In the initial stages of the program, CMS limited enrollment into the ComPass^{2c} program to subjects with the principal diagnoses of congestive heart failure, myocardial infarction, stroke, transient ischemic attack,

pneumonia, chronic obstructive pulmonary disease, or asthma based on the International Classification of Disease, Ninth Revisions (ICD-9) codes (see Appendix B). Subjects dually eligible for Medicare/Medicaid with multiple chronic conditions and a history of multiple readmissions were also eligible. On June 10th, 2013, CMS expanded enrollment to subjects with the principle diagnosis of diabetes mellitus, renal disease (without hemodialysis), two or more readmissions within past six months, subjects with depressive symptoms, cognitive impairment, and those discharged to skilled nursing facilities. In February of 2014 enrollment was expanded to include any subject with any diagnosis who was designated at risk for readmission by utilization of a risk assessment instrument.

Exclusions

There were several criteria that excluded subjects from participating in the ComPass^{2c} program. Subjects could not participate in the ComPass^{2c} program if enrolled in Medicare Advantage plans, private insurance, a clinical trial, or hospice. Subjects transferred to other hospitals within 24 hours of admission lived outside of Compass^{2c} service area, or left against medical advice were not eligible to participate in the Compass^{2c} program. Finally, individuals with major trauma, unstable mental illness, active substance abuse, long-term hyper-alimentation, active cancer treatment (chemotherapy and/or radiation), or hemodialysis were considered beyond the scope of the ComPass^{2c} program and therefore not eligible to participate.

Subject Referral

Subjects hospitalized at Hospital X were referred to the ComPass^{2c} program coaches and nurses through several mechanisms. The transition coaches and nurses received inpatient census list each weekday morning from Hospital X's ADT department. In addition, staff from the Office of Clinical Effectiveness and Patient Safety produced a list of hospitalized subjects based on

primary admission diagnosis including pneumonia, chronic obstructive pulmonary disease, acute myocardial infarction, and congestive heart failure. This second list was compiled from hospital pharmacy provider orders for intravenous steroids and diuretics, laboratory medicine provider orders for troponin levels, as well as manual review of emergency department documentation. The census and admission lists were sent by secure email to transition coaches and nurses. Based on the census and admission lists, the transition coaches and nurses assessed subject eligibility for the ComPass^{2c} program. Transition coaches had access to electronic health records, electronic registration information and demographics, and in-patient medical charts from Hospital X. A convenience sample of consecutive subjects was approached.

Setting

Hospital X is a small not-for-profit academic hospital in New England. Data describing Hospital X's service was provided by the state hospital association. Hospital X's service area covers 69 zip codes. Fifteen percent of the service area is aged 65 years or older. Approximately two-thirds (67%) are white, 12% are black, 15% Hispanic, 4% are Asian, and 2% are other. Fifty-two percent of the population in Hospital X's service area is female. Eleven percent live below the poverty line and 35% have a bachelor's degree or higher.

Protection of Human Subjects

Request to conduct this program evaluation was requested by the research from the Institutional Review Boards (IRB) at Hospital X and the state university. All subject protected health information (PHI) was de-identified prior to receipt by the investigator. Data did not include any identifying information such as names, dates of birth, addresses, zip codes, phone numbers, fax numbers, email addresses, IP addresses, URL, serial numbers, medical record numbers, driver's license numbers, vehicle identification numbers, social security numbers,

insurance identification numbers, biometric identification numbers, or device numbers. All dates except the year were removed according to Health Insurance Portability and Accountability Act (HIPAA) policy.

Instruments

Eligible subjects were assessed for their risk of 30-day hospital readmission and level of intervention by the Project BOOST® Risk Assessment; subject self-reported health (SRH), and the Brief Health Literacy Screen (BHLS). The risk assessment was performed by ComPass^{2c} transition coaches and nurses using inpatient electronic medical records and through subject interview.

The Patient Activation Measure® (PAM®) was used to evaluate patient activation (see Appendix D). The PAM® was administered twice for each subject by transition coach or nurse. The first administration occurred within four days following hospital discharge either at the initial home visit or by phone. The second administration occurred at the final home visit or by phone.

Project Boost Risk Assessment

The determine level of transitional care intervention. The creators of the Project BOOST® "8P" Risk Assessment intended its use as a checklist rather than a risk scoring instrument, therefore psychometric testing has not been performed ("Project BOOST," 2014). The Project BOOST® "8P" Risk Assessment considers eight risk factors; (1) problem medications defined in the ComPass^{2c} program as anticoagulants, insulin, oral hypoglycemic, combination of aspirin and clopidogrel, digoxin, amiodarone, narcotics, ≥2 cardiac or psychoactive medicines, or ≥3 new medicines, (2) psychological history of depression or positive screen for depression via the PHQ-2, (3) principle diagnoses of cancer, stroke, diabetic

complications, COPD, or CHF,(4) polypharmacy defined as ≥5 routine medications, (5) poor health literacy assessed by subjects' inability to repeat back key health information taught by nurses and coaches or BHLS, (6) patient support defined as absence of caregivers to assist with post-discharge home care, (7) prior non-elective hospitalizations within past 6 months, and (8) palliative care defined by advanced or progressive disease.

Self-reported Health

The ComPass^{2c} readmission risk determination included self-reported health status. Self-reported health has been found to be a predictor of future hospitalizations (Gold, Franks, & Erickson, 1996), and mortality (Idler & Benyamini, 1997). Subjects rate their current health on a 5-point Likert scale of excellent (1), very good (2), good (3), fair (4), or poor (5), with higher scores indicating poor health. Psychometric testing of 1,129 subjects with chronic disease from the Stanford Chronic Disease Self-Management Study revealed a test-retest reliability score of .92 and a standard deviation of .91 (Lorig et al., 1996, p. 25).

Brief Health Literacy Screening

The 3-question Brief Health Literacy Screen (BHLS) was used to assess subjects' health literacy. The first question was "How often do you have someone (like a family member, friend, hospital/clinic worker or other caregiver) help you read hospital materials?" Subjects could respond, all of the time (1), most of the time (2), some of the time (3), a little of the time (4), none of the time (5). The second question was "How confident are you in filling out forms by yourself?" Subjects could respond, extremely (5), quite a bit (4), somewhat (3), a little bit (2), not at all (1) to the question. The third question was, "How often do you have difficulties learning about your medical condition because of difficulty understanding written instructions?" Subjects could respond, all of the time (1), most of the time (2), some of the time (3), a little of

the time (4), none of the time (5). After reverse-scoring the item addressing confidence with forms, responses to the three items were summed, scores ranged from 3-15. Scores less than or equal to nine indicated inadequate health literacy.

The BHLS was validated in the both the inpatient and outpatient setting when administered by nursing staff (RN) or by research assistants (RA) and to the short Test of Functional Health Literacy in Adults (S-TOFHLA) (Wallston et al., 2014). The internal consistency reliability was high with Cronbach alpha's for hospitalized patients of 0.80 and 0.76 for BHLS-RN. Intraclass correlation between the BHLS-RN and BHLS-RA among outpatients was 0.77 (95 % CI 0.71–0.82) and 0.49 (95 % CI 0.40–0.58) among hospital patients. In both the hospital and outpatient settings, BHLS-RN and BHLS-RA scores correlated significantly with the reference standard S-TOFHLA. In the hospital setting, the S-TOFHLA compared with BHLS-RN had an $r = 0.35$ [95% CI, (0.27–0.43), $p < 0.001$], while in the outpatient setting an $r = 0.35$ [95% CI, (0.19–0.50), $p < 0.001$]. In the hospital setting, the S-TOFHLA compared with BHLS-RA had an $r = 0.48$ [95% CI, (0.40–0.55), $p < 0.001$] and an $r = 0.42$ [95% CI, (0.29–0.55), $p < 0.001$] for outpatient setting. Finally, area under the receiver operating characteristic curve for BHLS-RN to predict adequate health literacy on the S-TOFHLA was 0.71 [95% CI, (0.65–0.77)] in the hospital and 0.76 [95% CI, (0.64–0.87)] in the clinic. The area under the receiver operating characteristic curve for BHLS-RA to predict adequate health literacy on the S-TOFHLA was 0.75 [95% CI, (0.70–0.80)] in the hospital and 0.84 [95% CI, (0.76–0.92)] in the clinic.

Patient Activation Measure®

The PAM® is a 13-item instrument which assesses subject's perceptions of self-efficacy (knowledge, confidence, and skills) for managing their own health behaviors and health care

(Hibbard, Mahoney, Stockard, & Tusler, 2005). Subjects were presented with statements and asked to answer "strongly disagree" (1), "disagree" (2), "agree" (3), or "strongly agree" (4) to each statement (Appendix C). Each item is scored on a Likert-scale from 1-4, with "not applicable" or a blank item scored as not answered. The total raw points are converted to a score ranging from 0-100 by dividing the total raw points by the number of items answered. PAM® scores are divided into four levels of activation (see Appendix D); level one subjects are defined as passive recipients of health care (score ≤ 47), level two subjects lack knowledge of health-related facts or do not connect these facts to their own health (score 47.1- 55.1), level three subjects are beginning to taking action related to their health (score 55.1-67.0), and level four subjects have adopted new health behaviors but may struggle to maintain these behaviors in times of health crisis (score ≥ (Hibbard, 2008). The PAM® assessed ComPass2c subjects' perceptions of self-efficacy for managing their own health care following the most recent hospital stay.

Psychometric testing of the PAM® was performed by telephone survey of 1,515 randomly selected adults in the U.S. for the original 22-item instrument (Hibbard, Stockard, Mahoney, & Tusler, 2004). This same data was used again to reduce the PAM® to 13 items (Hibbard, Mahoney, Stockard, & Tusler, 2005). Rasch analysis was used to identify items from the original PAM® that could be eliminated without loss of significant precision and reliability. Item reduction was considered complete when further deletions resulted in unacceptably low levels of reliability and precision. The performance of the 13-item PAM® in various subgroups was compared to the original PAM®. Construct validity assessment on the 13-item PAM® was conducted and compared with the 22-item PAM®. The 13-item PAM® has a calibrated scale range from 38.6 to 53.0), compared with 38.3–54.5 for the 22 items. Lower reliability was found

for subgroups with no chronic illness, age 85 years or greater, poor self-rate health, and lower income and education between the 13-item PAM® and original 22-item PAM® however, but still within an acceptable range. To assess the construct validity of the 13-item PAM®, preventive behaviors, disease-specific self-management behaviors, and consumeristic behaviors are all strongly linked with activation scores using the 13-item PAM® with little difference compared to the original 22-item PAM®.

Procedures

Prior to beginning the ComPass^{2c} program evaluation, approval was obtained from both Hospital X and the state university Institutional Review Boards (see Appendix E). The investigator submitted a written request for data on subjects enrolled in the ComPass^{2c} program from the Director of Quality Improvement at the CBO. All subject level data from the CBO was requested in an electronic spreadsheet format. The investigator requested the following ComPass^{2c} subject data from the CBO: age, gender, BOOST "8P" risk assessment, subject SRH, BHLS, ComPass^{2c} model assignment, 30-day all-cause readmissions of ComPass^{2c} subjects, PAM®, home visits, and telephone contacts.

CMS provided the CBO with program monitoring data on a quarterly basis. The data included percentage of ComPass^{2c} subjects rehospitalized within 30 days of discharge from Hospital X. Additionally, CMS reports 30-day all-cause readmission rates, 30-day mortality rates, 30-day ED rates, 30-day observation stay rates, 7-day and 14-day physician follow up rates for all Medicare FFS beneficiaries discharged from Hospital X. The investigator requested the data mentioned above from the Director of Quality Improvement at the CBO from May 1, 2012 to most current quarterly report.

To determine the number of subjects eligible to enroll in the ComPass^{2c} program at Hospital X, the investigator submitted a written request for data on Medicare FFS subjects discharged alive from Hospital X from May 1, 2012 through November 30, 2014. Subjects eligible for enrollment in the ComPass^{2c} program were based on ComPass^{2c} eligibility and exclusion criteria. The following subject level demographic data was requested using the Patient Data Request form, age, gender, and history of admission to Hospital X in past six months. Subject level data was requested in an electronic spreadsheet format.

Treatment of Data

Data management

Data were obtained in spreadsheets using either comma separated values (.csv) or Excel (.xlxs) format. These spreadsheets were imported into SPSS for statistical analysis (SPSS Statistics GradPack Version 23 and SPSS Statistics Version 24). The data was stored on the investigator's password protected personal computer (PC) and maintained in a cloud storage account called OneDrive.

The investigator became familiarize with the datasets including how the data were collected and measured. A codebook was developed for each variable and included a variable label, variable value, level of measure, data source, and statistical test. The symbol of a period (".") was assigned for missing data. The codebook file was stored on the researcher's password protected personal laptop computer and maintained in the cloud storage account, OneDrive.

A preliminary assessment of the data files was performed to detect missing values, outliers, and wild codes. Missing data determination was performed using the Missing Value Analysis (MVA) module within SPSS. Scatterplot displays were performed to identify outliers and wild codes.

Planned Analysis

1. What is the effectiveness of the ComPass^{2c} program on reducing 30-day all-cause readmission rates in Medicare FFS beneficiaries at an academic hospital in New England?

Research Question 1 was answered at the aggregate level using summary statistics obtained from CMS Quarterly Reports. Summary statistics are presented in a combination of tabular and graphical formats for 30-day readmission rates in ComPass^{2c} participants discharged from Hospital X, 30-day all-cause readmission rates for Medicare FFS subject discharged from Hospital X, 30-day mortality rates for Medicare FFS subject discharged from Hospital X, 30-day emergency department (ED) visit rates for Medicare FFS subject discharged from Hospital X, 30-day post discharge observation stay rates for Medicare FFS subject discharged from Hospital X, and 7-day and 14-day post discharge follow up rates for Medicare FFS subject discharged from Hospital X. Linear regression modeling was utilized to determine trends, direction of trends, and significance. Statistical results for Research Question 1 based on CMS Quarterly Reports were validated, in part, by using subject level data obtained from the CBO to create frequency tabulations in SPSS of the counts of ComPass^{2c} subjects who were and were not readmitted within 30-days following discharge from Hospital X. Absolute risk reduction, relative risk, relative risk reduction, and numbers needed to treat were calculated.

2. What is the reach of the ComPass^{2c} program in Medicare FFS beneficiaries discharged from an academic medical center in New England?

Research Question 2 was answered by creating frequency tabulations in SPSS of the counts of subjects eligible to participate in the program and the count of subjects who agreed to participate in the program. Next, frequency tabulations were created of the counts of enrolled

subjects by age, gender, problem medications, principle diagnosis, and prior non-elective hospitalization in last six months, palliative stage of illness, self-reported health, BHLS, and ComPass^{2c} model assignment. Last, frequency tabulations were created of the counts of eligible subjects by age, gender, and history of non-elective admission in past six months at Hospital X.

SPSS was used to calculate descriptive statistics for characteristics pertaining to enrolled and non-enrolled subjects. Age, number of days enrolled, self-reported health, and ComPass^{2c} model assignment were measured at the ordinal level. Gender, problem medications, BHLS, principle diagnosis, prior hospitalizations, and palliative stage of illness were measured at the nominal level.

3. What is the consistency of implementation of key ComPass^{2c} program elements in Medicare FFS beneficiaries discharged from an academic hospital in New England?

Research Question 3 was answered by creating frequency tabulations in SPSS for the overall counts of documented post discharge home visits, documented follow up telephone calls, and PAM® scores and level at the start and the completion of the ComPass^{2c} program. The counts of home visits and telephone calls were tabulated by ComPass^{2c} intervention level which includes the low risk level intervention, the moderate risk level intervention, and the high risk level intervention. The means, medians, modes, and ranges of documented home visits and telephone calls were determined.

Rates of 30-day readmissions were determined relative to the documented of home visits. Home visits were grouped to create nominal level a variable. The dependent variable of subject level 30-day readmissions was measured at the nominal level. Chi-square analysis was applied to identify potential differences in rates of 30-day readmissions relative to the completion of home visits.

Differences in PAM® scores and level at the start and completion of the ComPass^{2c} program were calculated. PAM® levels were measure at an ordinal level. Chi-square analysis was performed to determine if there was a difference in PAM® level from pre and post measurement.

Summary

The purpose of this retrospective program evaluation was to determine the effectiveness of the program in reducing 30-day hospital readmissions in the Medicare FFS population at Hospital X, the reach of the ComPass^{2c} program into the Medicare FFS population at Hospital X, and the consistency of implementation of key program elements. The methods for achieving these three objectives included comparing baseline 30-day readmission rates to quarterly program rates in Medicare FFS subjects hospitalized at Hospital X. An evaluation of other post-discharge outcomes of the ComPass^{2c} program including seven and 14-day outpatient physician follow-up visits rates, 30-day mortality rates, 30-day ED visits rates, and 30-day observation stay rates added to the full impact of the program. Comparing the number of subject willing to enroll in the program to those eligible estimated the ability of the program to reach subjects at risk for readmission. Demographic data, information from the Project BOOST® Risk Assessment, SRH, and BHLS allowed for more complete description of the characteristics of enrolled and eligible subjects. Finally, the fidelity of the program was determined by the number of key program elements that were documented and the impact of the intervention on patient activation. This analysis supports the determination of the success of the ComPass^{2c} program at Hospital X.

Chapter 4

Results

This chapter presents the results from the analysis performed in the evaluation of the Community Passport 2 Care (ComPass^{2c}) program at an academic medical center in New England. First, a description of the subjects who enrolled in the ComPass^{2c} program at Hospital X is presented. Next, each research question and its results are given. Finally, additional analyses are offered. This chapter concludes with a summary of the results of the ComPass^{2c} program evaluation.

Description of Subjects

A total of 832 subjects enrolled in the ComPass^{2c} program at Hospital X from May 1, 2012 to November 30, 2014. Table 2 presents demographic data of subjects enrolled in the ComPass^{2c} program. The mean age was 79 years (SD = 13) with 19% of subjects 90 years of age or older. The majority of subjects (61%) were female. A little over half (55%) of enrolled subjects were assigned the moderate risk level intervention. The 30-day readmission rate for this cohort of patients was 15%.

Table 1

Characteristics of Enrolled and Eligible ComPass^{2c} Subjects at Hospital X

Characteristics	Enrolled (n = 832)	Eligible (n = 2643)
Age years, mean (SD)	79 (13)	77 (14)
< 65 (%)	90 (11)	440 (17)
65-74	165 (20)	575 (22)
75-89	416 (50)	1184 (45)
≥90	161 (19)	444 (17)
Gender, female (%)	505 (61)	1430 (54)
30-day readmission rate (%)	125 (15)	-
Intervention level (%)		
Low risk	247(30)	-
Moderate risk	454(55)	-

High	118(14)	-
Self-rated health (%)		
Excellent	1 (.2)	-
Very good	29 (5)	-
Good	296 (51)	-
Fair	239 (41)	-
Poor	18 (3)	-
BHLS Score		
≤9 Inadequate	111 (47)	-
Project BOOST® Risk Assessment (%)		
Problem Medications[a]	209 (39)	-
Prior Hospitalization History[b]	147 (28)	217 (8)

Note. SD = standard deviation. BHLS = Brief Health Literacy Screen.
[a] Anticoagulants, insulin, oral hypoglycemic, aspirin & clopidogrel, digoxin, amiodarone, narcotics or ≥2 cardiac or psychoactive drugs, or ≥3 new medicines taken at least daily [b] ≥2 readmissions in past 6 months or any readmission in past 30 days

Analysis of Research Questions

Research question number 1: What is the effectiveness of the ComPass^{2c} program on reducing 30-day all-cause readmission rates in Medicare FFS beneficiaries discharged an academic hospital in New England?

The effectiveness of the ComPass^{2c} program on 30-day all-cause readmission rates was observed at the hospital (aggregate) level. Baseline rates are from January 1, 2010 through December 31, 2010. Quarterly provisional rates are provided but due to lag time in Medicare claims reporting only final quarterly rates are used for analysis reflecting a total of eight quarters from May 1, 2012 through April 30, 2014.

At the hospital level, the 30-day all-cause readmission rate for Medicare fee-for-service (FFS) beneficiaries at Hospital X decreased over the first eight quarters (see Appendix F). Simple linear regression was calculated to predict 30-day readmission rate based on time. A significant regression equation was found ($F(1,7) = 7.709$, $p = .027$), with an R^2 of .524. Thirty-day readmission rate is equal to 20.767 + -.500 (time) percentage when time is measured in quarters. Thirty-day readmission rates decreased -0.5% for each quarter of time. The 2010 pre-

program 30-day all-cause readmission rate for Medicare FFS beneficiaries at Hospital X was 21%. Over the course of the ComPass^{2c} program ending April 30, 2014, the unadjusted quarterly 30-day all-cause readmission rate to Hospital X decreased to16.2%. There is a relative risk reduction of 23% with 21 beneficiaries needing to be enrolled in the ComPass^{2c} program to prevent one 30-day readmission.

Still using aggregate level data, the 30-day readmission rate of ComPass^{2c} subjects discharged from Hospital X for quarters four through eight showed a similar trend to the Medicare FFS beneficiaries at Hospital X. Again simple linear regression was calculated to predict ComPass^{2c} subjects' 30-day readmission rate based on time. A non-significant regression equation was found ($F(1,3) = .915$, $p = .409$) with an R^2 .234. ComPass^{2c} subjects' 30-day readmission rate is equal to 19.860 + -.560 (time) percentage when time is measured in quarters. ComPass^{2c} subjects' 30-day readmission rates decreased -0.6% for each quarter of time. At the subject level, 125 out of total of 832 Compass^{2c} subjects were readmitted to the hospital following the index discharge from Hospital X with a 30-day readmission rate of 15%.

Other post-discharge outcomes.

The impact of the ComPass^{2c} program on other outcomes including seven and 14-day physician outpatient visits, 30-day observation visits, 30-day Emergency Department (ED) visits, and 30-day mortality are observed at the hospital (aggregate) level in Medicare FFS subjects following discharge from Hospital X. Baseline rates are from January 1, 2010 through December 31, 2010. Quarterly provisional rates are provided but due to lag time in Medicare claims reporting only final quarterly rates are used for analysis reflecting a total of eight quarters from May 1, 2012 through April 30, 2014.

Seven and 14-day post-discharge physician follow-up visits.

Seven day post-discharge physician follow-up visit rates increased over the eight quarters from baseline of 17.9% to 39.2% in quarter eight (see Appendix G). Simple linear regression was calculated to predict 7-day physician follow-up visit rates based on time. A significant regression equation was found ($F(1,7) = 69.886$, $p = .000$) with an R^2 of .909. Seven day physician follow-up visit rate is equal to 16.227 + 2.810 (time) percentage when time is measured in quarters. The 7-day physician follow-up visit rate increased 2.8% for each quarter of time.

Fourteen day post-discharge physician follow-up visit rates also increased over the eight quarters from the baseline of 30.5% to 61.4% in the eight quarter (see Appendix H). Simple linear regression was calculated to predict 14-day physician follow-up visit rates based on time. A significant regression equation was found ($F(1,7) = 155.986$, $p = .000$), with an R^2 of .957. Fourteen day physician follow-up is equal to 28.960 + 3.993 (time) percentage when time is measured in quarters. The 14-day physician follow-up visit rate increased 4% for each quarter of time.

Thirty-day post-discharge observation visit rates.

The 30-day observation visit rate was variable by quarter however the overall quarterly rates trended upward. The baseline rate was 1.6%, peaked to 3.0% in quarter seven, and declined to 1.8% in the last available quarter (see Appendix I). Simple linear regression was used to predict 30-day observation visit rates based on time. A non-significant regression equation was found ($F(1,7) = 2.798$, $p = .138$) with and R^2 of .289. Thirty-day observation visit rate is equal to 1.271 + .135 (time) percentage when time is measured in quarters. The 30-day observation visit rate increased 0.1% for each quarter of time.

Thirty-day post-discharge emergency department visit rates.

Emergency Department visit rates trended downward over the course of the ComPass^{2c} program. The baseline ED visit rate was 15.1%, peaked to 18.8% in quarter six, and then dropped to 10.8 % and 10.9% in quarters seven and eight (see Appendix J). Simple linear regression was calculated to predict 30-day ED visit rate based on time. A non-significant regression equation was found ($F(1,7) = 1.845$, $p = .217$), with an R^2 of .209. The 30-day ED visit rate is equal to 16.871 + -.440 (time) percentage when time is measured in quarters. The 30-day ED visit rate decreased by -0.4% for each quarter of time.

Thirty-day post-discharge mortality rates.

Thirty day mortality rates varied over the course of the ComPass^{2c} program. The 30-day mortality rate was below the baseline of 5.2% from quarters one through seven and peaked to 6.3% in quarter seven then returned close to the baseline rate in quarter eight at 5.0% (see Appendix K). Simple linear regression was calculated to predict 30-day mortality rate based on time. A non-significant regression equation was found ($F(1,7) = .441$, $p = .528$), with an R^2 of .059. The 30-day mortality rate is equal to 3.749 + .110 (time) percentage when time is measured in quarters. The 30-day mortality rate increased 0.1% for each quarter of time.

Research question number 2: What is the reach of the ComPass^{2c} program in Medicare FFS beneficiaries discharged from an academic hospital in New England?

A total of 4,520 Medicare FFS beneficiaries were hospitalized at Hospital X between May 1, 2012 and November 30, 2014. The following numbers of subjects were excluded based on ComPass^{2c} exclusion criteria: 34 left against medical advice, 126 died prior to discharge, 32 transferred to another acute care hospital, 89 were discharged to hospice or hospice home care, one discharged to long-term care facility, two discharged to veterans hospital, 41 transferred back to prison facility, 27 psychiatric transfers, 538 oncology admissions, 278 psychiatric

admissions, and 817 surgical admissions. This left 2,643 subjects potentially meeting eligibility criteria for the ComPass^{2c} program (Table 2). A little over a half of eligible Medicare FFS subjects at Hospital X were female with mean age of 77 years (SD = 14). The ComPass^{2c} program reached 832 Medicare FFS beneficiaries which is approximately one-third (32%) of eligible Medicare FFS subjects hospitalized at Hospital X.

Comparisons were made between those eligible for the ComPass^{2c} program and those who enrolled (Table 2). Enrolled subjects were slightly older than those eligible to enroll (79 versus 77 years). The ComPass^{2c} program enrolled 36% of eligible subjects aged 90 years or older and 68% of eligible subjects with a history of two or more hospital admissions in the prior six months. All subjects were de-identified prior to receipt of the study data. This made it impossible to separate enrolled subjects from those who were eligible but not enrolled, as would be necessary to conduct statistical comparisons based on independent samples. Consequently, only informal descriptive comparisons of characteristics (age, gender, prior hospitalizations) of the enrolled and eligible groups were possible and no formal statistical testing was performed to identify potentially significant differences.

Thirty-day readmission risk factor characteristics of ComPass^{2c} subjects analyzed are presented in Table 2. Seventy percent of Compass^{2c} subjects answered the SRH questionnaire; of those who answered 56% reported the health as “very good-to-good” and 44% as “fair-to-poor”. About one third of the ComPass^{2c} subjects answered the 3-item BHLS (n = 238). Almost half (47%) of subjects had inadequate health literacy defined as a BHLS score of less than or equal to nine. Thirty-nine percent of subjects were prescribed problem medications. Twenty-eight percent of subjects had a history of two or more hospital admissions in the preceding six months.

Research question number 3: What is the consistency of implementation of key ComPass[2c] program elements in Medicare FFS beneficiaries discharged from an academic hospital in New England?

Phone calls and home visits were the essential implementation elements of the ComPass[2c] program and presented in Table 3. It is important to note that phone call documentation by ComPass[2c] staff could represent either a call was placed to the subject but did not necessarily mean contact was made with the subject. This style of documentation occurred consistently throughout the program. Change in PAM® scores determines the impact of the ComPass[2c] program elements.

Table 2

Implementation of ComPass[2c] Elements by Intervention Level

		Intervention Level			
	Overall (n = 832)	Low risk (n = 247	Moderate risk (n = 454)	High risk (n = 118)	No Model (n = 13)
Phone calls (%)	741(89)	231(94)	391(86)	108(92)	11(85)
Mean (SD)	3	2(1.66)	3(2.38)	4(2.99)	5(5.68)
Median	2	2	2	3	3
Mode	2	2	2	3	2[a]
Range	0-15	0-13	0-13	0-15	0-15
Home visit	202[b]	1(0.4)	150(33)	47(40)	4(31)
Mean (SD)	0	-	0.35(0.53)	0.99(1.81)	1(2.60)
Median	0	-	0	0	0
Mode	0	-	0	0	0
Range	0-8	0-1	0-2	0-8	0-6
30-day readmission (%)	125(15)	12(5)	91(20)	18(15.3)	4(31)

Note. [a]Multiple modes identified with the smallest value shown. [b]One subject assigned to Low risk intervention received a home visit and four subjects with no model assigned received a home visit.

Post-discharge telephone calls.

All subjects enrolled in the program were to receive telephone contact. Overall, 741 (89%) ComPass[2c] subjects received at least one phone call. In the low risk intervention, subjects

were to receive post-discharge phone calls on days 1-3. Ninety-four percent of subjects in the low risk group received at least one phone call with a mean of two calls. Subjects assigned to moderate risk intervention were to receive weekly phone calls for thirty days. Eighty-six percent of these subjects had at least one phone call with a mean of three calls. Ninety-two percent of subjects assigned to the high risk intervention had at least one telephone call with a mean of four calls.

Post-discharge home visits.

Home visits were planned for both the moderate and high risk level of intervention. A total of 572 subjects were enrolled in the moderate and high level intervention combined; overall 197 (34%) of those subjects received at least one home visit. One home visit was planned for moderate risk subjects with 33% receiving at least one home visit. Subjects in the high risk group were to receive weekly home visits for the first month post-discharge. In the high risk group, 40% of subjects received at least one home visit, 11% received three or more home visit, and 9% received four or more home visits. From February 1, 2013 through March 20, 2014, it was documented by ComPass^{2c} staff that 49 (11%) subjects assigned to moderate risk level and five (4%) assigned to the high risk level are known to have refused their home visit.

Patient activation.

The 13-item Patient Activation Measure® (PAM®) was used to assess change in subjects' knowledge, skills, and confidence for self-management of their health and provides insight into the implementation of the ComPass^{2c} intervention. The PAM® was administered pre-and-post the ComPass^{2c} intervention. Coaches and nurses read from a script prepared by the CCTP stating participation in the survey was voluntary. A total of 160 subjects (19%) completed the

first administration of the PAM®, 74 subjects (9%) completed the second administration, and 46 subjects (6%) completed both administrations of the PAM®.

PAM® scores were calculated and each subject was placed into one of the four levels of activation (see Appendix D). The subjects who completed the first administration of the PAM® had a mean score of 41.1 (SD = 5.23) with 74% of subjects at level three or above. Next, the subjects who completed the second administration of the PAM® had a mean score of 41.0 (SD = 4.76) but fewer subjects (65%) were level three or above. The mean change in PAM® scores was 0.15 (SD 4.79), with no significant change in PAM® level ($\chi^2(6) = 3.819$, $p = .701$) from first to second administration.

Additional Statistical Analysis.

After conducting the planned analysis of the ComPass^{2c} program evaluation several observations emerged. First, as the 30-day readmission rates declined, an upward trend was noted in the 30-day observation stay rates over the course of the ComPass^{2c} program. Next, 30-day ED visit rates dropped over four points in the last two quarters of available data compared to quarters zero through six. Third, a smaller than expected number of subjects assigned to the ComPass^{2c} intervention levels that included a home visit actually received a home visit. Finally, fewer than expected subjects completed the PAM® questionnaire. These observations lead to the following questions:

Is there are correlation between quarterly 30-day all-cause readmission rates and quarterly 30-day observation stay rates in Medicare FFS beneficiaries discharged from an academic hospital in New England?

Further analysis was performed using Pearson's r and Spearman's rho to determine if there was a correlation between quarterly 30-day readmission rates and 30-day observation stay

rates. The results revealed a negative but non-significant correlation between quarterly 30-day readmission rates and 30-day observation visit rates. ($r = -.54$, $p = .13$; $r_s = -.63$, $p = .06$).

Is there a difference in mean 30-day ED visit rates between quarters zero through six and quarters seven through eight**?**

Independent samples t-test were performed to determine if there was a difference in 30-day ED visit rates between quarters zero through six and quarters seven through eight. There was a significant difference in the mean 30-day ED visit rates for quarters zero through six (M = 16.3%, SD = 0.07) and quarters seven through eight (M = 10.9%, SD = 1.22, $t(7) = 1.89$, $p = .001$).

Of the subjects assigned to the moderate and high risk interventions, are subjects who had a home visit different from subjects who did not have a home visit?

A comparison of moderate and high risk intervention subjects who did and did not have a home visit was performed using Chi-square test of independence (see Table 3). The 54 subjects who were known to have refused a home visit but assigned to either moderate or high level interventions are not included in this analysis. Subjects with a home visit were slightly younger, 79 versus 81 years. Females were more likely to not receive a home visit. There was no difference in BHLS scores between groups, 46% of subjects with a home visit had inadequate health literacy versus 40% without a home visit. Subjects who did not receive a home visit were more likely to not have completed the SRH survey. Finally, the 30-day readmission rate was not different between subject who had a home visit and those without a home (23% versus 17%).

Table 3

Characteristics of ComPass2c Subjects with and without a Home Visit[\]

Characteristics	Home visit[a] (n = 197)	No home visit (n = 321)	χ^2	df	p

Age years, mean (SD)	79 (13)	81 (14)	6.323	3	.09
< 65 (%)	22 (11)	31 (10)			
65-74	42 (21)	50 (16)			
75-89	98 (50)	156 (49)			
≥90	35 (18)	84 (26)			
Gender, female (%)	108 (55)	208 (65)	5.11	1	.02
BHLS score					
≤ 9 inadequate	32(46)	40(40)	0.47	1	.49
Self-rated health (%)			32.33	4	.00
Excellent	0	0			
Very good	9 (5)	6 (2)			
Good	55 (28)	73 (23)			
Fair	85 (43)	87 (27)			
Poor	5 (3)	10 (3)			
No answer	43 (22)	145 (45)			
30-day readmission (%)	45 (23)	56(17)	2.266	1	.13

Note. df = degree of freedom. BHLS = Brief Health Literacy Screen.
[a]Moderate and high risk intervention level subjects only.

Are subjects who completed the PAM® questionnaire different from those subjects who did not?

Subjects who completed the PAM® were compared with subjects who did not complete the PAM® using Chi-square test of independence with results presented in Table 4. There was no difference by age group, gender, SRH, BHLS scores ≤ 9, or 30-day readmission between subjects who did and did not completed the first administration of the PAM®.

Table 4

Comparison of ComPass[2c] Subjects Who Did and Did Not Complete the PAM® at Time One

	PAM® (n = 160)	No PAM® (n = 672)	χ^2	df	p	95% CI	
Characteristics						LL	UL
Age years (%)			1.710	3	.635		
<65	16(10)	74(11)					
65-74	27(17)	138(21)					
75-89	82 (51)	334(50)					
≥90	35(22)	126(19)					
Gender, female (%)	100(63)	405(60)	0.27	1	.603		
Self-rated Health (%)[a]			4.448	5	.495	.482	.508
Excellent	1(0.6)	0					

Very good	5(3)	24(4)			
Good	58(36)	238(35)			
Fair	45(28)	194(29)			
Poor	4(3)	14(2)			
No response	47(29)	202(30)			
BHLS (%)					
≤ 9	16(36)	95(49)	2.74	1	.098
30-day readmission rate (%)	22(13.8)	103(15.3)	0.252	1	.616

Note. PAM® = Patient Activation Measure. df = degrees of freedom. CI = confidence interval. LL = lower limits. UL = upper limits. BHLS = Brief Health Literacy Screen.
[a]Due to cell counts less than 5 the Exact test was used to for significance.

Next, as seen in Table 5, there was no difference between subjects who did and did not complete the second administration of the PAM® by age group, gender, SRH, BHLS score ≤ 9, or 30-day readmission.

Table 5

Comparison of ComPass[2c] Subjects Who Did and Did Not Complete the PAM® at Time Two

Characteristics	PAM® (n = 74)	No PAM® (n = 758)	χ^2	df	p	95% CI LL	95% CI UL
Age years (%)			1.072	3	.784		
<65	9(12)	81(11)					
65-74	12(16)	153(20)					
75-89	40(54)	376(50)					
≥90	13(18)	148(20)					
Gender, female (%)	51(69)	454(60)	2.302	1	.129		
Self-rated Health (%)[a]			7.046	5	.213	.203	.224
Excellent	0	1(0.1)					
Very good	1(1)	28(4)					
Good	24(32)	272(36)					
Fair	18(24)	221(29)					
Poor	4(5)	14(2)					
No response	27(37)	222(29)					
BHLS (%)							
≤ 9	9(33)	102(48)	2.17	1	.141		
30-day readmission rate (%)	9(12)	116(15)	.548	1	.470		

Note. PAM® = Patient Activation Measure. df = degrees of freedom. CI = confidence interval. LL = lower limits. UL = upper limits. BHLS = Brief Health Literacy Screen.
[a]Due to cell counts less than 5 the Exact test was used to for significance.

Finally, no differences were found by age group, gender, SRH, BHLS scores ≤ 9, or 30-day readmission between subjects who did or did not complete the PAM® at both administration times (Table 6).

Table 6

Comparison of ComPass^{2c} Subjects Complete the PAM® at time One and Two

Characteristics	PAM® (n = 46)	No PAM® (n = 786)	χ^2	df	p	95% CI LL	95% CI UL
Age years (%)[a]			1.114	3	.774	.763	.785
<65	7(15)	83(11)					
65-74	8(17)	157(20)					
75-89	23(50)	393(50)					
≥90	8(170	153(20)					
Gender, female (%)	28(61)	477(61)	.001	1	.980		
Self-rated Health (%)[a]			1.521	5	.870	.861	.879
Excellent	0	1(0.1)					
Very good	1(2)	28(4)					
Good	17(37)	279(36)					
Fair	12(26)	227(29)					
Poor	2(4)	16(2)					
No response	14(30)	235(30)					
BHLS (%)							
≤ 9	5(36)	106(47)	.713	1	.398		
30-day readmission rate (%)	4(9)	121(15)	1.527	1	.216		

Note. PAM® = Patient Activation Measure. df = degrees of freedom. CI = confidence interval. LL = lower limits. UL = upper limits. BHLS = Brief Health Literacy Screen.
[a]Due to cell counts less than 5 the Exact test was used to for significance.

Summary

The data support the conclusion that the ComPass^{2c} program may have been effective in reducing 30-day all-cause readmission rates in Medicare FFS beneficiaries discharged from an academic hospital in New England. There was a relative risk reduction of 23% for Medicare FFS beneficiaries enrolled in the ComPass^{2c} program compare to baseline 30-day all-cause

readmission rates. The 30-day readmission rate for ComPass^{2c} subjects of 15% over the course of the program is well below the baseline rate of 21% for Hospital X. Unfortunately, the limited amount of data for 30-day readmission rates of ComPass^{2c} subjects from quarters four through eight does not fully explain the decline that consistently occurred for Medicare beneficiaries discharged from Hospital X across quarters one through eight.

The impact of the ComPass^{2c} program on seven and 14-day physician outpatient visits, 30-day Emergency Department (ED) visits, 30-day observation visits, and 30-day mortality at Hospital was favorable. Seven and 14-day physician outpatient follow up visits increased during the course of the program. Acute care utilization as seen with ED and observation visits within 30-days remained stable. Lastly, 30-day mortality was stable during the course of the ComPass^{2c} program.

The ComPass^{2c} program was able to reach approximately one-third of eligible Medicare FFS beneficiaries discharged from an academic hospital in New England. The majority of enrolled subjects were 70 years of age or older, 39% of subjects were prescribed high risk medications and a third had a prior history of hospitalization. Forty-four percent of subjects reported their health as fair to poor. Finally, almost half of enrolled subjects had inadequate health literacy.

The consistency of implementation of key ComPass^{2c} program elements varied. Phone calls were consistently implemented at all levels of intervention with almost 90% of subject receiving a phone call from the transition coaches or nurses. Home visits were implemented less often however with 33% of moderate risk level subjects and 40% of high risk level subjects receiving a home visit by a transitions coach or nurse. In part, subjects were known to refuse this element of the ComPass^{2c} program.

The PAM® questionnaire was used to assess subjects' change in knowledge, skills and confidence for self-management related to the ComPass^{2c} intervention. The response rate was low with only six percent of subjects completing the PAM® at both pre and post-intervention measurement times. No change in patient activation was found following the ComPass^{2c} program. ComPass^{2c} subjects were already at a high level of activation prior to the intervention.

Additional analyses based on several observations were conducted. No relationship was found between the decline in 30-day all-cause readmission rates and an upward trend in observation visits rates in Medicare FFS beneficiaries discharged from Hospital X. Besides female gender, subjects who did not receive a home visit were similar to subjects who did not receive a home visit. ComPass^{2c} subjects who completed the PAM® were similar to subjects who did not complete the PAM® by age, gender, SRH, BHLS score ≤ 9, and 30-day readmission rates.

In conclusion, the findings of the ComPass^{2c} programs support the presumption that the ComPass^{2c} program may have been effective in reducing 30-day all-cause readmission rates in Medicare FFS beneficiaries discharged from an academic hospital in New England. The program was able to reach a third of Medicare beneficiaries who had risk factors associated with 30-day readmission including older age, a prior history of hospitalization in the past six months, and inadequate health literacy. Key ComPass^{2c} program elements, specifically home visits, were not consistently implemented and no a change in patient activation was found following the completion of the program.

Chapter 5

Discussion

This chapter presents a discussion of the program evaluation conducted for the Community Passport 2 Care (ComPass^{2c}) at an academic hospital in New England. The findings of the ComPass^{2c} program's effectiveness in reducing 30-day all-cause readmission rates, reach into the population, and implementation of key program elements at Hospital X are compared to other scholarly work. Next, the usefulness of the RE-AIM framework in the evaluation of the ComPass^{2c} program is presented. Third, the limitations of the ComPass^{2c} program evaluation as they pertain to effectiveness, reach and implementation follow. Fourth, the impact of the ComPass^{2c} program evaluation to Hospital X is offered. Equally important, the implications of the ComPass^{2c} program evaluation for the Doctor of Nursing Practice (DNP) specific to research, practice, policy, and education will round out the discussion. The chapter will end with a summary of the discussion points and a conclusion of the ComPass^{2c} program evaluation.

Discussion of ComPass^{2c} Program Evaluation Findings

Effectiveness

Thirty-day all-cause readmission rates.

A 20% reduction in 30-day all-cause readmission rates in Medicare fee-for-service (FFS) beneficiaries was the primary goal of the Centers for Medicare and Medicaid Service (CMS) Community-based Care Transitions Program (CCTP). The data from CCTP funded ComPass^{2c} program suggests the program was successful in reducing the 30-day all-cause readmission rates at an academic hospital in New England. Over the course of the ComPass^{2c} program the reduction of 30-day all-cause readmission rates was significant from 21% to 16.2% ($p = .027$), an

absolute risk reduction of 4.8% and a 23% relative risk reduction. Based on the quarterly rate of 16.2%, this meets the 20% reduction set by CMS, however quarterly rates will vary over time.

Findings from the Greater New Haven Coalition for Safe Transitions and Readmission Reductions (Co-STARR) are compared to ComPass[2c] program results. Co-STARR was a CCTP funded program that partnered Yale New Haven Hospital and St. Rafael's Hospital with the Area Agency on Aging of South Central Connecticut (Jenq, Doyle, Belton, Herrin, & Horawitz, 2016). The adjusted readmission rates for the target population in the Co-STARR program decreased from 21.5% to 19.5%, with an absolute risk reduction of 2% and relative risk reduction of 9.3%. The reduction in readmission rates did not reach the 20% readmission reduction goal however.

In the Annual CCTP Report, there was no significant overall impact of the CCTP on 30-day unadjusted readmission rates by the end of the first year and only four sites met the readmission reduction target ("CCTP Evaluation," 2014). Critics of the Annual CCTP report complained of the preliminary nature of the report (Langston, 2015). Three cohorts of CCTP sites were included in the evaluation; the first cohort had been providing services to Medicare FFS beneficiaries for nine to eleven months, the second cohort between five and eight months, the third cohort between three and five months. The evaluation period for cohorts two and three was too short for program development and partnership to occur between community-based organizations and hospitals. In fact, the authors of the report repeatedly stated the preliminary nature of the results. The consequence of not meeting CMS targets at the completion of the two year contract led to 29 programs to voluntarily withdraw or for CMS to end funding of those programs (Markwood, 2015). Currently only 18 programs remain active (https://innovation.cms.gov/initiatives/CCTP/).. There is yet to be a follow up CCTP re-evaluation made public.

Since 2010, 30-day readmissions have declined nationally. Two recent studies evaluated the change in readmission rates since the passage of the ACA. Zuckerman, Sheingold, Orav, Ruhter, & Epstein (2016) examined monthly hospital-level readmission rates from October 2007 through May 2015 in elderly Medicare FFS beneficiaries. They found readmission rates declined from 21.5% to 17.8% in targeted conditions (AMI, HF, and PN) and from 15.3% to 13.1% in non-targeted conditions. The most rapid rate of decline for both targeted and non-targeted conditions occurred from April 2010 to October 2012. Lu, Huang, & Johnson (2016) evaluated readmissions during fiscal years 2013-2015 for AMI, HF, and PN in acute care hospitals subject to Inpatient Prospective Payment System and the HRRP. Excessive readmissions were significantly reduced with the greatest effect in small, public, and rural hospitals. CMS has credited the decline in readmission rates for Medicare beneficiaries to programs like the HRRP and the CCTP program (Conway & Gronniger, 2016).

Seven and 14-day post-discharge physician follow-up visit rates.

Another goal of the CCTP was to facilitate early post-discharge outpatient follow-up visits. Seven and 14-day post-discharge physician follow-up visit rates increased significantly during the course of the ComPass^{2c} program for all Medicare FFS beneficiaries at Hospital X. CMS expected successful programs to reduce 30-day readmissions and increase the percentage of patients who see a physician within one to two weeks after hospital discharge. Based on this outcome, the ComPass^{2c} program was successful.

Research has found an association between early outpatient follow-up and reduced risk for 30-day readmission. In populations of HF subjects discharged from acute care hospitals; those who attended 7-day follow-up appointments with community providers had a reduced risk for 30-day readmission (Hernandez et al., 2010; Baker, Oliver-McNeil, Deng, & Hummel,

2015). Likewise, in Medicare FFS subjects with Chronic Obstructive Pulmonary Disease (COPD), follow-up within 30-days reduced the risk of 30-day rehospitalization (Sharma, Kuo, Freeman, Zhang, & Goodwin, 2010).

Based on the evidence of a positive relationship between early post-discharge follow-up and a reduction in 30-day readmissions, the heart failure quality improvement initiative at Hospital X included mandatory follow-up within seven days with either a cardiologist or the HF nurse practitioner from Hospital X. Ryan et al (2013) saw an increase in 7-day outpatient follow-up visit rates from 19.6% to 46.9% ($p < .01$) accompanied by a 30% reduction in HF 30-day readmissions between 2008 and 2011 following the initiative. Due to the success of this initiative, it became standard practice at Hospital X for all hospitalized patients to have an outpatient follow-up visit with their primary care provider or specialist within 7-10 days of discharge after 2011. There is likely a synergistic effect between the ComPass^{2c} program and Hospital X's practice for early ambulatory follow up post-discharge.

The Dartmouth Atlas of Health Care tracks post-hospitalization outcomes in Medicare FFS beneficiaries. Trends in 14-day ambulatory visit rates post medical discharge for Medicare FFS beneficiaries began to rise after 2008, peaked in 2012, but began to decline by 2014 (http://www.dartmouthatlas.org/). Ambulatory visits within 14-days of discharge at the national, state, and county levels were 61.7%, 64.5% and 63.3% in 2008 respectively. In 2012 those rates increased to 64.7%, 68.1%, and 66.9%. By 2014 there was a declined in 14-day ambulatory rates to 63.1%, 64.6%, and 62.3%. Hospital X's 14-day post-discharge follow-up rate of 61% at the end of the ComPass^{2c} program is slightly below the national, state and local rates.

Thirty-day post-discharge observation visit rates.

When a patient returns to the hospital within 30-days of discharge, instead of admitting the patient to the hospital, providers can admit to observation status in an effort to keep readmission rates low. An increase in hospital observation visit stays within 30-days of hospital discharge is an unintended consequence of initiatives to reduce 30-day readmissions. CMS expected successful CCTP interventions to reduce 30-day readmission rates without increasing 30-day post-discharge observation visit rates. Thirty-day observation visits for Medicare FFS beneficiaries discharged from Hospital X varied from quarter to quarter during the ComPass^{2c} program although not to statistical significance. In the Annual CCTP Report, observation visit rates were found to be 18% higher in CCTP-hospitals compared to controls overall; however, CCTP programs that had been operating longer had similar observation visit rates as controls ("CCTP Evaluation," 2014).

National trends in monthly hospital-level observation visits within 30-days following discharge for Medicare FFS beneficiaries were examined from October 2007 to May 2015 (Zuckerman et al., 2016). For targeted (AMI, HF, PNA) and non-targeted conditions, an increase was seen in observation visit rates, ranging from 2.6% to 4.7% and 2.5% to 4.2%, respectively. However, no significant correlation was observed between the change in readmission rates and change in observation visit rates within hospitals (Pearson $r = -.03$, $p = .07$). Additional analysis for a correlation between 30-day readmissions and observation visit rates was conducted for the ComPass^{2c} program. Similar to Zuckerman et al. (2016), a negative but non-significance correlation ($p = .06$) was found. Full ComPass^{2c} program data may have helped to determine if a significant correlation in 30-day readmission rates and observation visits was occurring.

Thirty-day post-discharge emergency department visit rates.

Excessive emergency department (ED) visits within 30-days post hospital discharge is an important negative indicator of the quality of care and care coordination. Overall, during the course of the eight quarters of ComPass^{2c} data, ED visit rates at Hospital X remained stable. When examined more closely, the last two quarters of ComPass^{2c} program data showed a significant decline in 30-day ED visit rates. A trend of stable to declining ED visit rates at Hospital X signal the absence of a negative unintended consequence of the ComPass^{2c} program. While the ComPass^{2c} program was not designed to reduce ED visits, the elements of the transitional care interventions (medication reconciliation, early symptom recognition with an action plan, and early provider follow-up visits) shifted care from urgent acute care like the ED to outpatient providers. Indeed, CMS expected successful programs to be able to reduce 30-day readmission rates without an increase in 30-day post-discharge ED visits.

Other readmission programs had similar or improved ED visit rates when compared to the ComPass^{2c} program. In the Annual CCTP report, ED visit rates were compared pre (2010) and post-demonstration (2012) between CCTP hospitals and hospitals internal and external to CCTP market areas. There was no difference in 30-day ED visit rates pre and post between CCTP hospitals and comparison hospitals with all three groups having a similar decline of 0.2% points. In another transitions care program that targeted low-income elders, no difference was seen in 30-day ED visit rates between the intervention group and the control group (Ohuabunwa et al., 2013). Results were different in a national transitional care program conducted in Singapore where subjects enrolled in the ACTION program were less likely to have a visit the ED within 30-days of hospital discharge (19% versus 32%, $p < .001$).

In contrast, ED visits within 30-day of a medical discharge for Medicare beneficiaries have increased nationally. According to the Dartmouth Atlas of Health Care, national 30-day

post discharge ED visits increased from 18.5% in 2010 to 20.9% in 2014. Moreover, in the county to which Hospital X is located, 30-day post-discharge ED visits increased from 18.8% to 20.9% over the same time period (http://www.dartmouthatlas.org/). In the face of trends demonstrating increasing 30-day ED visits rates at the national and local levels, stable to declining rates as seen at Hospital X signals ComPass^{2c} program success.

Thirty-day post-discharge mortality rates.

Mortality is another important outcome to monitor as an increase in mortality may indicate an intervention is harmful. CMS expected successful CCTPs to reduce 30-day hospital readmissions without causing adverse outcomes such as mortality. The 30-day mortality rate in Medicare FFS subjects at Hospital X were lower in quarters one through seven compared to 2010 baseline rates. Only the last quarter available for analysis revealed a higher mortality rate compared to baseline. The Annual CCTP Program Evaluation did not report on mortality therefore no comparisons can be made. A comparison to a national transitional care program in Singapore reported a higher 30-day post-discharge mortality rates between the intervention and comparison groups (7.0% versus 3.1%) but did not perform statistical testing. Stable 30-day post-discharge mortality rates support ComPass^{2c} program success. Add the JAMA cardiology Feb 2017 article.

Reach

The ComPass^{2c} program enrolled 32% of eligible Medicare FFS beneficiaries at Hospital X from May 1, 2012 to November 30, 2014. The participation rate is low compared to other transitional care programs. The Co-STARR program reported 12,482 eligible subjects, 9229 enrolled subjects, and a substantially higher participation rate of 74% (Jenq et al., 2016). It is worth noting that the Co-STARR program's transitional care interventions differed from that of

ComPass^{2c} program. The Co-STARR program included transitional care consultants (TCCs), who enrolled subjects during hospitalization and conducted weekly post-discharge follow-up telephone calls. These telephone calls focused on subject's understanding of discharge instructions, medication management, and follow-up appointments with community providers, support services, and monitoring clinical signs and symptoms. Unlike the ComPass^{2c} program coaches and nurse, the TCCs did not make routine home visits as part of the transitional care intervention. Home visits took up time of ComPass^{2c} coaches and nurses, thereby limiting their ability to enroll more subjects at Hospital X.

The ComPass^{2c} participation rate was similar to two transitional care effectiveness trials. An advanced practice nurse-led transitional care program for heart failure that included home visits conducted at an academic hospital over eight months had 140 eligible subjects, enrolled 56 and a 40% participation rate (Stauffer et al., 2011), similar to the ComPass^{2c} program. Another care transitions program that did not include home visits and was directed at low-income elders at an academic hospital over eight months screened 433 subjects, approached 230 eligible subjects, and enrolled 72 for a 32% participation rate (Ohuabunwa et al., 2013).

The low participation rate may speak to the acceptability of the program intervention to subjects and their families. Other community-based organization participating in the CCTP identified categories of Medicare beneficiaries that were difficult to enroll including those subjects with active caregivers ("CCTP Evaluation," 2014). According to the CCTP evaluation, active care givers were less likely to enroll their loved one because they felt they were already providing the care the program planned to do. Moreover, some caregivers misinterpreted the intent of the program and thought the health care team did not feel the caregiver was providing good care.

Representativeness.

There are similarities between enrolled subjects and the eligible-to-enroll population of Medicare FFS beneficiaries hospitalized at Hospital X. Enrolled subjects were similar in age compared to subjects eligible to participate in the ComPass^{2c} program. This similarity is not a surprise as those >64 years of age was the target of the ComPass^{2c} intervention. More females enrolled in the program (61%) compared to the number of females in the eligible-to-enroll population (54%). This may indicated that the ComPass^{2c} program was more acceptable to women than men. A comparison between those eligible-to-enroll in the ComPass^{2c} program at Hospital X and the intervention target population for the Co-STARR program reveals similarities to the ComPass^{2c} program in both age and gender (Jenq et al., 2016).

Several differences were seen between enrolled subjects and those eligible-to-enroll in the ComPass^{2c} program. More enrolled subjects had a history of a prior hospitalization (28%) in the preceding six months compared to the population of those eligible-to-enroll (8%). One explanation is that prior hospitalization is a strong risk factor for readmission (Donze, Lipsitz, Bates, & Schnipper, 2013; Fleming, Gavin, Piatkowski, Chang, & Mukamal, 2014; Hasan et al., 2009). ComPass^{2c} staff targeted subjects with known risk factors for readmission. A second explanation is that prior hospitalization was based on administrative data of an admission to Hospital X in the preceding six months for the eligible-to-enroll population. In the enrolled group, prior hospitalization was based on self-report and could have included a hospitalization at another facility. More subjects in the target population during the intervention period of the Co-STARR program (53.8%) had a history of hospitalizations in the preceding six months compared to the eligible-to-enroll subjects at Hospital X.

Implementation

Post-discharge telephone calls and home visits.

Implementation of the ComPass^{2c} program was measured by completed post-discharge telephone calls and home visits. Implementation of phone calls was high; 89% of subjects received at least one post-discharge phone call overall. By level of intervention, 86% of moderate risk subjects, 92% of high risk subjects, and 94% of low risk subjects received at least one post-discharge phone call. The ComPass^{2c} program had a similar but slightly higher percentage of post-discharge phone calls compared to another CCTP. In the first 9-month process evaluation of the Sun Health CCTP, 79% (19 out of 24) of subjects received at least one post-discharge follow up phone call (Logue & Drago, 2013).

Implementation of home visit was low, with 34% of ComPas^{2c} subjects assigned to models that included home visits actually receiving one. When stratified by intervention level, more high risk subjects (40%) received home visits compared to moderate risk subjects (33%). Other initiatives to reduce 30-day readmissions using similar transitional care models had the same result. In an effectiveness trial conducted at an academic hospital in Rhode Island utilizing the CTI®, implementation of home visits was similarly low, with 25% of subjects completing a home visit (Voss et al., 2011). Likewise, a quality improvement initiative at one hospital in Rochester, New York also using CTI® reported 44% of subjects completed the home visit (Smirnow et al., 2014).

Subject refusal of a home visit was recognized during the ComPass^{2c} program. For fourteen months of the of the program (2/1/13-3/20/14), there was documentation by staff of their recommendation to subjects to enroll in either the moderate or high level interventions but subjects' refusal of the home visit. Eleven percent of subjects enrolled in moderate level and 4% of subjects enrolled in the high level intervention are known to have declined the home visit

during this time period. This type of documentation did not continue throughout the ComPass^{2c} program. Refusal of the home visit may indicate that subjects or family caregivers do not find home visits acceptable.

Further analysis of ComPass^{2c} subjects with and without the planned home visit revealed interesting findings. It was theorized that ComPass^{2c} subjects who did not complete the home visit would be more likely to experience a readmission within thirty days; however, no difference was found between these groups. A comparison of these results to a quality improvement project to reduce 30-day readmissions utilizing CTI® had different findings (Smirnow et al., 2014). In this project, readmission rates were compared among subject who completed the CTI® intervention defined as one home visit and three other encounters, to subject who were partial completers defined as at least one home visit, and subjects who were non-completers defined as no home visit and included subject who declined or were lost to follow-up prior to the home visit. Thirty-day readmission rates were significantly lower ($p < .05$) in the group who completed the entire CTI® (10.1%) compared to partial completers (16.5%) and non-completers (22.6%).

Patient activation.

The Patient Activation Measure® (PAM®) was used to assess change in subjects' knowledge, skills, and confidence for self-management of their health and provides insight into the implementation of the ComPass^{2c} intervention. The ComPass^{2c} program interventions were designed to encourage subject engagement in their own healthcare rather than "doing" for the subject. Unfortunately no change in activation was found at the completion of the ComPass^{2c} program. Subjects who completed the pre-intervention PAM® survey were already at a high level of activation leaving little room for change in activation. Further analysis of subjects who

completed the first, second or both administrations of the PAM® survey was conducted to determine if those who completed the survey were different from those who did not complete the survey. No differences were found in the two groups by age, gender, self-reported health, BHLS score, or 30-day readmission.

The low response rate of the PAM® survey is worth further discussion. Completion of the PAM® declined from first to second administration with only 6% of subjects completing both PAM® administrations. One possible explanation for the low response rate is that subjects simply refused to complete the survey. Another explanation is the priority of ComPass^{2c} staff to deliver the intervention rather than the PAM® survey. The coaches and nurses were tasked with skills transfer related to discharge instructions, medication management, and red-flag symptoms, the personal health record, and post-discharge medical care follow up rather than on assessments and surveys (Coleman, Rosenbek, & Roman, 2013). The PAM® survey may have competed with the intervention itself.

Appraisal of the RE-AIM Framework

The RE-AIM framework guided the ComPass^{2c} program evaluation. The RE-AIM framework includes methods for evaluating the impact of evidence-based health behavioral interventions such as those within the ComPass^{2c} program in "real world" settings (http://re-aim.org/). The effectiveness, reach, and implementation of the ComPass^{2c} program are compared to the original efficacy and effectiveness research of CTI® and TCM® to determine how each element may differ and add new insight to how these transitional care interventions perform in the clinical setting.

Effectiveness

Efficacy research occurs within a controlled setting, with highly trained research personnel, resources, and support staff. The effectiveness domain within the RE-AIM framework considers these factors when evaluating how robust an evidence-based intervention is in clinical practice. The 23% relative risk reduction in 30-day readmission rates in the ComPass^{2c} program was not as pronounced as in the original research. The CTI® studies had a relative risk reduction between 30-60%. The TCM® studies relative risk reductions ranged from 25-45%.

The level of education and training of CTI® and TCM® research staff was different than that of ComPass^{2c} staff and may have impacted the effectiveness of the ComPass^{2c} program. In two of the three research studies testing CTI® (Coleman et al., 2004; Coleman et al., 2006) and all four of the studies testing TCM® (Naylor et al., 1999; Naylor et al., 2004) Naylor et al., 2013; Naylor et al., 2014) masters prepared advanced practice nurses (APN) were utilized to deliver the transitional care intervention. Additionally, the research APNs had more extensive training in the interventions compared to ComPass^{2c} staff. The TCM® APNs had 2-months of training and orientation to the intervention (Naylor et al., 2004). The APNs in the CTI® had certification in chronic disease self-management (Coleman et al., 2004). In comparison ComPass^{2c} coaches were bachelor's prepared social workers and transition nurses were registered nurses with less training in these interventions.

Another factor to consider, which may have impacted the ComPass^{2c} program effectiveness, is the role responsibilities of the transition coaches and nurses. The coaches and nurses in the CTI® and TCM® studies focused solely on delivery of the intervention. Separate research staff was responsible for tasks including screening subjects for eligibility, reviewing charts, approaching subjects to participate in the research, and performing initial assessments. In

contrast, the ComPass^{2c} coaches and nurses had competing roles and were responsible for screening, reviewing charts, approaching subjects, performing initial assessments, and delivering the intervention. Despite less expertise and the number of roles ComPass^{2c} coaches and nurses were responsible for; the program was successful in reducing 30-day readmission rates in Medicare FFS beneficiaries.

Reach

The reach of an intervention is defined by the number and proportion of subjects willing to participate (http://re-aim.org/). A total of 832 subjects were willing to participate in the ComPass^{2c} program out of 2,643 potentially eligible Medicare FFS beneficiaries hospitalized at Hospital X. The estimated participation rate for the ComPass^{2c} program was 32%.

The ComPass^{2c} program participation rate is compared to the original trials testing the TCM® and CTI® interventions. Similar participation rates were seen between the ComPass^{2c} program and TCM® trials. In the TCM® studies where subjects were approached during hospitalization, the participation rate was 28% for elders older than 65 years and hospitalized for medical and surgical reason (Naylor et al., 1999), 37% for elders older than 65 years with heart failure (Naylor et al., 2004), and 40% for cognitively impaired elders older than 65 years (Naylor et al., 2014). In the CTI® studies, participation rates were higher; 76% for elders older than 65 years and hospitalized for medical and surgical reasons (Coleman et al., 2006) and 52% for Medicare FFS beneficiaries (Parry et al., 2009). No participation rate was reported for one of the CTI® studies (Coleman et al., 2004).

The number of potentially eligible subjects is important is the calculation of the participation rate. The number of potentially eligible ComPass^{2c} subjects is only an estimate. There are several factors that could alter this count and change the participation rate. For

example, an unknown number of subjects were discharged before they could be approached, hospitalized on weekends or holidays when ComPass^{2c} staff was not available, or would have been excluded based on further review. These factors would have reduced the count of eligible subjects. A lower number of subjects eligible for the ComPass^{2c} program (denominator) would increase the participation rate.

The differences in the populations of subjects targeted in the TCM® and CTI® research studies and in ComPass^{2c} program may help to explain the disparity in participation rates. While the TCM®, CTI®, and ComPass^{2c} targeted subjects over the age of 65 years, the ComPass^{2c} program and the TCM® studies looked to enroll frail elders such as those with multiple, active chronic health conditions including cognitive dysfunction, history of depression, moderate-to-severe functional impairment, multiple hospitalizations in the prior six months, hospitalization within the past 30 days, fair to poor self-rating of health, or history of non-adherence to medical therapies. The CTI® studies targeted subjects based on medical diagnosis and those making multiple transitions including to subacute care facilities and not necessarily with other factors that increase their risk for readmission. Furthermore, the ComPass^{2c} program targeted subjects who were not English speaking whereas neither TCM® nor CTI® included this group. Subjects with these characteristics may not be as willing to participate. Ultimately, by evaluating the ComPass^{2c} program through the lens of the RE-AIM framework, similar participation rates were found between the program and the original research trials.

Implementation

Implementation refers to the intervention being delivered as it was designed (http://re-aim.org/). Implementation interacts with efficacy to produce effectiveness in the clinical setting (Glasgow et al., 1999). The number and percentage of completed planned post-discharge phone

calls and home visits in ComPass^{2c} subjects are compared to the original TCM® and CTI® research trials.

Implementation of post-discharge phone calls was high across the entire ComPass^{2c} program but varied with the intervention level. ComPass^{2c} subjects in the moderate level intervention were intended to receive at least two post-discharge phone calls within 30-days of discharge. A total of 70% of subjects in the moderate level intervention received two or more calls. Implementation of post-discharge phone calls was the similar to the CTI® clinical trials where between 72% (Coleman et al., 2004) and 94% (Parry et al., 2009) of subjects received phone calls. ComPass^{2c} subjects in the high risk intervention did not have a planned number of post-discharge phone calls in the first 30-day following hospital discharge but were to receive monthly phone calls after day 30 and up to day 90. Sixty-five percent of ComPass^{2c} subjects in the high risk intervention received three or more post-discharge phone calls. None of the TCM® studies (Naylor et al., 1999; Naylor et al., 2004; Naylor et al., 2013; Naylor et al., 2014) offered information on completion of post-discharge phone calls. Overall, through the use of the RE-AIM framework the ComPass^{2c} program was found to be successful in implementing post-discharge phone calls in the clinical setting consistent with the original research trials.

The implementation of the home visit by ComPass^{2c} staff was low. It was intended that ComPass^{2c} subjects in the moderate risk intervention would receive one home visit and subjects in the high risk intervention would receive four home visits in the first 30-days. Thirty-three percent of subjects in the moderate level and 9% of subjects in the high risk level interventions received the intended number of home visits. This is in sharp contrast to the original CTI® and TCM® research where 86% - 100% of subjects received a home visit (Coleman et al., 2004; Coleman et al., 2006; Naylor et al., 1999; Parry et al., 2009). By using the RE-AIM framework,

implementation of home visits in clinical practice was found to be more difficult than in the research setting.

Limitations of Program Evaluation

Effectiveness

The first limitation of the ComPass^{2c} program evaluation of effectiveness was the lack of a comparison group. The comparison group could have been subjects who were eligible Medicare FFS beneficiaries but did not enrolled in the ComPass^{2c} program, similar to the comparison group used in the Co-STARR Program (Jenq et al., 2016). A comparison group could have been from another non-partnering hospital either in or outside of Hospital X's service area, as was used in the Annual CCTP program evaluation ("CCTP Evaluation," 2014). This researcher did not have access to data from other area hospitals. The comparison group would have allowed for analysis of trends in effectiveness outcomes during the same time period as the ComPass^{2c} program.

The use of aggregate-level billing data was a limitation that influenced effectiveness outcomes in the ComPass^{2c} program evaluation. Billing data may be delayed during a specific time period and create an incomplete picture. Only paid billing claims were counted; this may bias the counts, for example, of either readmitted subjects (numerator) or the total count of hospitalized subjects (denominator). Delays in the billing process could occur due to missing or incorrect information, such as Medicare account numbers or dates of birth. Also, aggregate-level data does not provide demographic information or the actual number of cases that were counted in determining rates. These factors could have affected the rates for all effectiveness outcome measures.

A lack of data for the entire ComPass^{2c} program limited the program evaluation for 30-day ED visit and 30-day mortality rates. CMS provided finalized data to the CBO from May 1, 2012 through April 30, 2014. The program ended November 30, 2014; seven months of program data were not available for analysis. For example, in the first seven months of the ComPass^{2c} program 30-day ED visit rates were stable compared to baseline but the last six months, the 30-day ED visit rates dropped significantly. The remaining seven months of program data would have provided a better understanding of the effect the ComPass^{2c} program had on effectiveness outcomes, especially 30-day ED and mortality rates, at Hospital X.

Thirty-day readmissions.

There are several limitations of the ComPass^{2c} program that may have impacted 30-day readmissions rates. First, the denominator for calculating readmissions is based on hospital admissions. Hospital admissions have been declining for more than a decade (http://www.dartmouthatlas.org/). The national rate of hospital discharges per 1,000 Medicare beneficiaries was 345.4 in 2004 and declined by 26% to 254.1 in 2014. By state level data, the trend was similar with a decline of 18.7% over the same time frame. During the course of the ComPass^{2c} program from 2012-2014, the admission rate at the state level changed 11.4%, from 276 per 1,000 Medicare beneficiaries to 244.4. Fewer hospital admissions mean a smaller denominator for 30-day readmission improvement.

A second limitation of the ComPass^{2c} program that affected 30-day readmission rates is the performance measure (*Community-based care transitions*, 2014). CMS held CCTP sites responsible for a 20% reduction in readmissions for the total high-risk Medicare FFS population hospitalized at CCTP partner hospitals regardless of how many beneficiaries actually received program services. For example, in the first year of the ComPass^{2c} program, cardiac, vascular,

and respiratory diagnoses were target conditions for enrollment; however, the performance measure included Medicare beneficiaries without these targeted conditions in the calculation of the 30-day readmission rate. CCTP sites were held accountable for some Medicare beneficiaries not eligible to enroll in the program.

A third limitation to the ComPass[2c] program evaluation was unadjusted 30-day readmission rates. CMS had requested the following disclaimer to accompany public any reporting of CCTP readmission data, "The readmission data present here are calculated using raw, unadjusted Medicare claims for the specified period of time. They do not indicate impact or take trends or other initiatives into consideration. These metrics are provided by CMS for performance monitoring purposes only and while they inform evaluative results, they do not constitute the entirety of the program evaluation" ("Use of program data," 2015, para. 2). Unadjusted readmission rates do not stratify by risk and do not take into account issues such as severity of illness that may bias the results across hospitals and demographic groups (Jencks et al., 2009).

Lastly, other initiatives may have had an influence on 30-day readmission rates. The Hospital Readmission Reduction Program (HRRP) was also created by the Affordable Care Act to address excessive 30-day readmissions. Effective October 1, 2012, the HRRP began imposing financial penalties to hospitals with excessive 30-day readmission rates for the target conditions of acute myocardial infarction (AMI), heart failure (HF), and pneumonia (PNA). The financial penalties threatened by HRRP may have been a catalyst for hospitals to create initiatives to reduce 30-day readmissions (Zuckerman, Sheingold, Orav, Ruhter, & Epstein, 2016). In fact Hospital X established a heart failure (HF) program focused on reducing excess 30-day readmissions during 2009-2010 in response to the HRRP. The HF program at Hospital X was

successful in reducing 30-day readmissions in patients with heart failure from 27.5% to 19.1 in the years leading up to the ComPass^{2c} program (Ryan, Kang, Dolacky, Ingrassia, & Ganeshan, 2013). A lower baseline rate of readmissions for the targeted condition of HF at the start of the ComPass^{2c} program made it more difficult to achieve additional reductions.

Seven and 14-day post-discharge physician follow-up visits.

An important limitation to early post-discharge follow-up rates was the type of provider Medicare acknowledged. Medicare only tracked physician follow up visits and did not include non-physician providers such as nurse practitioners and physician assistants. Indeed, Hospital X's heart failure initiative was successful impart due to the inclusion of an advance practice registered nurse (APRN) as a post-discharge provider. According to the Medical Staff Office, Hospital X employs 146 advance practice nurses and physician assistants who are qualified to provide early post-discharge follow-up care. Seven and 14-day follow-up visits rates would have been even higher at Hospital X's if non-physician providers were included.

Reach

The first limitation to the reach of the ComPass^{2c} program was the inclusion criteria targeting specific conditions. At the start of the program, CMS limited enrollment to beneficiaries with the primary diagnosis of heart failure, myocardial infarction, stroke, transient ischemic attack, pneumonia, chronic obstructive pulmonary disease, and asthma only. Often the admitting diagnosis was differed from the discharging diagnosis with the cause of the admission not clear until discharge. This made it difficult for coaches and nurses to determine if a subject was eligible for enrollment.

A second limitation to the reach was the work schedule of ComPass^{2c} coaches and nurses. The coaches and nurses were available Monday-Friday from 8 am – 5pm and not on holidays.

Subjects who were eligible but hospitalized and discharged over weekends would have been missed by the coaches and nurses. Furthermore, coaches and nurses split their time between hospital enrollment activities and delivery of post-discharge activities including home visits. The post-discharge activities reduced the amount of time dedicated to enrollment reducing reach.

A third limitation to the reach of the program was the lack of a robust electronic health record (EHR). Coaches and nurses needed real-time information for rapid identification and risk assessment of eligible subjects. The ComPass^{2c} program coaches and nurses received a list of subjects hospitalized by target conditions at the start of each day Monday through Friday from Hospital X via email. Coaches and nurses had access to Hospital X's EHR, however the EHR did not allow for queries to check eligibility. Therefore, ComPass^{2c} staff had to manually review each potential subject electronic and paper record. A key to the ComPass^{2c} program success is effective and efficient identification of Medicare beneficiaries who are at risk for readmission and stand to benefit from the program. This information gathering took valuable time away from enrollment activities. In this case, Hospital X's EHR may have negatively impacted ComPass^{2c} participation rate.

Representativeness.

A full description of ComPass^{2c} subjects risk for readmission was limited for several reasons. First, during the course of the program, the Project BOOST® risk assessment tool was modified and definitions of risk factors were changed. Because of these changes, psychological problems, physical limitations, poor health literacy, patient support, and polypharmacy were not analyzed. In addition, in the final eight months of the ComPass^{2c} program, the Project BOOST risk assessment tool and Brief Health Literacy Screen was not used in favor of Hospital X's risk

assessment instrument. The information on subject's risk using Hospital X's tool was not included in the data provided by the CBO.

Next, CMS required all data to be de-identified, which limited the evaluation of the representativeness of ComPass^{2c} subjects. ComPass^{2c} subjects could not be characterized, for example, by their race/ethnicity, and dually eligible for Medicare and Medicaid. Race/ethnicity (Joynt, Orav, & Jha, 2011; Rodriguez, Joynt, Lopez, Saldana, & Jha, 2011; Vivo et al., 2014) and dual eligibility status (Barnett, Hsu, & McWilliams, 2015; Vest, Gamm, Oxford, Gonzalez, & Slawson, 2010) have been found to be associated with higher 30-day readmission rates.

Lastly, de-identified data does not allow for identifying subjects who were eligible but did not enroll. Compounding this, no data were collected on subjects who were approached but declined to participate. Comparisons between those who enrolled and those who did not or who declined participation would have contributed to a better understanding of which subjects to target and how to make the ComPass^{2c} program more acceptable to subjects. Even still, the ComPass^{2c} program was not a research study but a demonstration project; it focused on identifying, screening, and enrolling potential at risk Medicare beneficiaries, as well as delivering an evidence-based intervention in everyday clinical practice.

Implementation

The evaluation of the implementation of post-discharge phone calls was another limitation. Documentation of a phone call could have meant one or two things; (1) a call was placed without an encounter with subject or caregiver, or (2) a call was placed and an encounter with the subject or caregiver occurred. An encounter would have included the delivery of the ComPass^{2c} intervention. This style of documentation occurred consistently throughout the

program. Therefore, the rate of the implementation of post-discharge phone calls may be an over estimate of the actual number of encounters.

The low response rate to the PAM® further limits evaluation of the implementation of the ComPass^{2c} program. The PAM® measured patient activation. After the receipt of the ComPass^{2c} program intervention, it was hoped that an improvement in patient activation would occur. With only 6% of subjects completing both the pre and post PAM®, the measurement of change in ComPass^{2c} patient activation may not truly represent the sample. Despite this, those who did complete the PAM® were not different from those subjects who did not complete the PAM®.

Implications of the ComPass^{2c} Program Evaluation

Hospital X

Funding for the ComPass^{2c} program ended in 2014 after 32 months. Nationally, the CCTP is also winding down with only 18 sites left operating (https://innovation.cms.gov/initiatives/CCTP/). Unfortunately, a program evaluation of the CCTP beyond the first year was not performed and there is limited published data of other CCTP programs to guide organizations wishing to address excessive readmissions. This brings added value to the ComPass^{2c} program evaluation, especially to Hospital X.

The ComPass^{2c} program evaluation suggests that the program was successful in reducing 30-day readmissions at Hospital X; however, the innovation of the CCTP was not the interventions used to improve care transitions. Instead, the innovation of the CCTP was the broader strategy of partnering community-based organizations (CBOs) and acute care hospitals to improve safety and quality of care (Langston, 2015). Hospital X and the CBO individually have their own strengths but lacked strong connections to each other despite providing services

to the same populations. The CCTP facilitated the development of a relationship between these organizations and the integration of seamless care across the health care continuum.

For continued success, Hospital X may find value in partnering with the CBO. This is especially important if Hospital X plans on joining an Accountable Care Organization (ACO). An ACO is a "voluntary partnership between health care providers in a care delivery system who agree to accept joint responsibility for the medical care and management as well as the cost and quality outcomes of a designated population of patients" ("What is an ACO?," n.d., para. 4). ACO's are required to meet certain health care quality and utilization metrics, such as 30-day readmissions, in order to earn financial savings (RTI International [RTI], 2017). A partnership between Hospital X and the CBO could help the Hospital X meet these metrics.

In order to maintain the improvement in the reduction of 30-day readmission rate at Hospital X, investment in a robust EHR is essential. Hospital X plans to go live with a new comprehensive EHR in 2018. Inclusion of an evidence-based risk assessment instrument that uses real-time information to identify patient-specific risk for 30-day readmission integrated into the EHR would utilize staff appropriately. The ComPass^{2c} program is resource intensive and not all patients will benefit from these transitional care interventions. Some patients may be of low risk for readmission while other are at very high risk, with needs beyond the scope of interventions found within the ComPass^{2c} program. Targeting the right intervention to the right patient is crucial. As an example, the Post-Acute Care Transition Program (PACT) utilized the LACE instrument (**L**ength of stay, **A**cuity of visit, modified **C**harlson comorbidity index, and number of **E**mergency room visits in the prior six months of index admission) within a community hospital that was part of an integrated health system (Smith, Pan, & Novelli, 2016). LACE scores were calculated by bedside nurses on the day of discharge; scores of 11-15 were

referred to (PACT) through the EHR. Since the publication of the PACT study, the LACE tool has been integrated into the hospital's EHR (J. Smith, personal communication, March 9, 2017, see Appendix L). The use of the LACE instrument with referral through the EHR eliminated case-finding activities that are resource intensive.

Hospital X's EHR must address the communication of health information between the hospital, patients and caregivers, community providers, skilled nursing facilities, and other community support services involved in a patient's care. The PACT program mentioned above had access to discharge summaries at the time of home visits, used standardized documentation in the EMR from home visits, had the ability to update medication lists and communicate in real-time to relevant providers via the EHR. A comprehensive EHR however, may not be enough maintain a reduced 30-day readmission rate. As noted in the PACT study, combining a comprehensive EHR with programs like the ComPass^{2c} programs are synergistic in negotiating care transitions and meeting Hospital X's safety and quality goals.

The Doctor of Nursing Practice

The Doctoral of Nursing Practice (DNP) competencies described in the Essentials of Doctoral Education for Advanced Nursing Practice help to guide the discussion of the implications of the ComPass^{2c} program evaluation for the DNP (American Association of Colleges of Nursing [AACN], 2006). The DNP interested in improving outcomes during transitions in care will want to; (1) utilize theoretical underpinnings from both nursing and other disciplines; (2) demonstrate organizational and systems leadership for quality improvement; (3) critically appraise and apply best evidence; (4) leverage information systems, (5) participate and/or lead interdisciplinary teams; (6) focus on clinical prevention and population health; and (7) advance nursing practice. The role of advocacy in health care policy related to the DNP is

discussed in the policy section below. These recommendations for the DNP will be compared to the DNP essentials and the associated competencies.

The DNP focused on improving outcomes following care transitions will need to integrate nursing theory and theory from other disciplines to inform his/her practice. For example, from nursing science, the Transitions Theory describes types of transitions, how nursing interventions impact the facilitators and inhibitors of healthy transitions, as well as the patterns of response to both the transition and the nursing interventions applied (Schumacher & Meleis, 1994; Meleis & Transgenstein, 1994). It will be important for the DNP to also explore theory and frameworks outside of nursing such as the RE-AIM framework, from the evaluation sciences. The use of the RE-AIM framework was of value to the ComPass^{2c} program evaluation because the framework appraised not only 30-day readmissions but other factors important for the success of clinical programs. Through this appraisal, RE-AIM domains not meeting goal can be ascertain with changes made to improve the program and its outcomes. The DNP could also use the RE-AIM framework as part of program planning.

Organizational and systems leadership for quality improvement competencies include the DNP to ensure accountability for quality and safety of health care for populations. The DNP will need to identify individuals or target population with excessive 30-day hospital readmissions within his/her organization and compared against the national or regional rates to determine if gap in quality exists. Target populations may be based on factors such as a diagnosis, surgical procedure, age, race/ethnicity, payer type, or a combination of these such as with the ComPass^{2c} program. Accountability for quality and safety for populations would continue with the DNP facilitating organizational changes in practice to address the gaps in quality. Based on the

ComPass[2c] program evaluation, the DNP should facilitate change within Hospital X to enable early provider follow-up upon transition from the hospital.

Predicated on the target population, the selection of evidence-based strategies to reduce excessive 30-day readmissions require knowledge and understanding of prior research conducted. In the ComPass[2c] program, transitional care delivery models were chosen based on evidence of successful for elders with multiple comorbidities. Furthermore, the analysis of data from the ComPass[2c] program evaluation provides practice-based evidence of the success of these interventions at Hospital X. The critical appraisal of evidence from both research and the practice setting are competencies within the Clinical Scholarship and Analytical Methods for Evidence-Based Practice DNP essentials.

Use of a real-time clinically based data to determine risk for 30-day readmission integrated within the EHR will assist in recognizing those targeted individuals. The DNP will need to be knowledgeable about the evidence of risk factors associated with 30-day readmission and risk assessment instruments that are valuable in spotting these individuals. Just as important, the DNP will need to communicate this critical element during the build of the health care information system that will go-live at Hospital X in the coming year. Expertise in the evidence of risk factors for readmission, risk assessment tools, and use of the EHR are competencies found in the Information Systems/Technology and Patient Care Technology for the Improvement and Transformation of Health Care DNP essentials.

Interprofessional collaboration for improving outcomes is critically important to the success of initiatives to reduce 30-day hospital readmissions. Individuals transitioning from acute care hospitalization will interact with health care professionals from a variety of disciples and across many settings of care. The ComPass[2c] program initially included partnerships

between the CBO and acute care hospitals but grew to include home healthcare agencies, skilled nursing facilities, subacute rehabilitation hospitals, as well as other community providers. The DNP will need to know who the stakeholders are and form partnerships among them. The Interprofessional Collaboration for Improving Patient and Population Health Outcomes prepares the DNP to play a central role in establishing interprofessional teams, team membership, and team leadership.

The ComPass^{2c} program and the program evaluation is an example of population health risk reduction. The Clinical Prevention and Population Health Essential address the development, implementation, and evaluation of interventions to improve population health. Again, real-time clinical data is required for state-of-the-program evaluation and the EHR can provide this level of population data. In the ComPass^{2c} program, evaluation data was based on 6-9 month old administrative data that did not allow for timely evaluation. Guided by the RE-AIM framework and assisted by the EHR, the DNP can determine if the program is attaining its outcomes at Hospital X. Outcomes can be compared to publically available population data such as the Dartmouth Atlas of Healthcare or potentially through state Hospital Associations.

The doctoral prepared nurse is educated to practice at the highest level of nursing practice. A doctoral prepared nurse (DNP) serves as a mentor, role model, and lends support to other nurses. The ComPass^{2c} program and evaluation demonstrates the impact nursing has on healthcare. First, the evidence-based transitional care delivery models were nurse –led interventions. Next, these transitional care delivery models were transferred into clinical practice. Third, the ComPass^{2c} program was nurse developed and implemented across multiple settings to include acute care, subacute care, home care, and community. Lastly, the program evaluation was a DNP scholarly project. Nurses at all levels and across all settings have the

capacity to significantly impact the quality and safety of healthcare. The ComPass^{2c} program and its evaluation is an exemplar to other nurses especially within Hospital X of their capabilities.

Finally, although dissemination is not a separate DNP Essential it is inherent in all of the Essentials and deserves discussion. The dissemination of program findings is valuable to stakeholders, leadership, and other organization who may be considering similar initiatives. The DNP will need to present serial evaluation findings to stakeholders as opportunity for change and refinement to the program. Similarly, in order to maintain support, especially for funding, the DNP will need to present program evaluation data to leadership at Hospital X. Other organizations can benefit from the lessons learned from implementing initiatives to reduce 30-day readmission. The DNP should present program findings at regional, national, and international forums and for journal publication. On a separate note it is also important for there to be a body of literature documenting the contributions of the DNP to healthcare.

Policy

Evidence-based transitional care practices have intersected with health care policy. Transitional care management services have been recognized as reimbursable services for Medicare FFS beneficiaries with moderate to high complexity medical and/or psychosocial problems (Department of Health and Human Services, Centers for Medicare and Medicaid Services [CMS], 2016). For example, CMS reimburses providers for patient contact within two business days after hospitalization and upon return to the community, coordination of services, and a face-to-face visit with a provider within seven to 14-days.

Health plans have developed transitional care management programs. The state Medicaid program implemented the Transitional Care Program that includes comprehensive discharge and

transitions planning for its beneficiaries who were recently hospitalized ("Husky Transitional Care Program," 2014). Nurse Inpatient Discharge Care Managers are on-site at hospitals in order to collaborate closely with their members and hospital staff. Following hospital discharge the program's Transitional Care Nurses provide telephonic services to assist members with appointment scheduling, transportation, medication reconciliation, and health education.

Programs that provide care management services to vulnerable elders have incorporated transitional care into their programs. Many CBOs that participated in the CCTP are committed to continue care transitions services to the elderly and at-risk populations they serve (Markwood, 2015). The state home care program for elders has included care transitions as a service provided through this program and the CBO behind the ComPass^{2c} program, is one of three agencies in the state who administers this program.

A gap in policy exists for the reimbursement by CMS for others to provide home-based transitional care services. Evidence has supported the importance of the home visit to the self-management component within transitional care (Hansen, Young, Hinami, Leung, & Williams, 2011; Leppin et al., 2014). Organizations such as home health care agencies, durable medical equipment providers, and hospital-based or community-based transitions programs are unable to obtain reimbursement for these services within the home. Advocacy for CMS policy change to include reimbursement of home-based transitional care services is needed.

Finally, the CCTP was a product of the Affordable Care Act (ACA) whose aims are to improve the quality, safety, and reduce cost of health care in the Medicare system. The future of the ACA is unclear at the time of this writing due to political uncertainties. Advocacy for ACA policies that have been successful and areas that need improvement is necessary. Furthermore, the ComPass^{2c} program connected vulnerable individuals with other community services like

those providing meals to elders. Programs such as these rely on state and federal funding for a portion of their operating cost; funding which is also uncertain. The DNP has the preparation for, and must add their voices to, the debate vital programs for our most vulnerable citizens and on the future of health care in the United States.

Education

Thirty-day hospital readmissions have captivated healthcare along with evidence for strategies to reduce them. Still, the ComPass^{2c} program evaluation found no change in patient engagement following these strategies. Active engagement by patients and their caregivers in self-care is essential in improving quality and safety in care transitions. The coaching strategy applied within the ComPass^{2c} program utilized disease self-management guided by motivational interviewing techniques meant to engage subjects to take a more active role in their care. Self-management is described as a process that "focuses on developing skills, such as problem solving, decision making, appropriate use of healthcare resources, formation of patient-provider partnership, action planning, and self-tailoring" (Lorig & Holman, 2003). Self-management has been shown to improve outcomes such as quality of life and reduce hospitalizations in diabetes (Ferguson, Swan, & Smaldone, 2015), heart failure (Jonkman et al., 2016), and COPD (Jonkman et al., 2016). Coaching self-management behaviors however requires a paradigm shift for nurses when they are less task oriented "doers" but instead assume the role of coaches (Coleman et al., 2013). The coach transfers skills and tools to empower the patient and caregiver for self-management.

Motivational interviewing (MI) methods can be complementary to self-management behaviors and improve patient engagement needed for safe care transitions. MI is an approach to help move individuals from ambivalence about making a behavior change to action through

personal motivation and commitment (Miller & Moyers, 2006). The level of patient engagement in self-management behaviors is important to improvements in health related outcomes including health care utilization for patients with chronic disease (Hibbard, Greene, & Tusler, 2009). MI techniques combined with self-management education have shown promising results for improving behavior change in diet and weight loss for diabetics (Ekong & Kavookjian, 2016), heart failure self-care (Creber et al., 2016) and increased use of emergency action plans in COPD (Benzo et al., 2013).

Nursing, at all education levels and across all settings of care, plays a central role in fostering patient and caregiver engagement in self-management. Nonetheless, nurses lack the education and skills in patient engagement strategies such as MI. In fact, MI is not routinely included in baccalaureate or graduate nursing education. The Nursing Alliance for Quality Care (NAQC) (2013) endorsed the need for nurses to be educated in techniques to improve patient engagement. They recommended the inclusion of patient engagement as competencies within the Nursing: Scopes and Standards of Practice, Accreditation standards, Baccalaureate, Masters and DNP Essentials, and NCLEX examination blueprints (Sofaer & Schumann, 2013). Furthermore, the NAQC recommends the development of curricula supporting these competencies.

Several studies have examined MI education for nurses. A quality improvement project utilizing web-based continuing education on brief MI techniques adapted for short encounters with hospitalized patients was offered to nurses on four units in a community hospital (Welch, 2014). This QI project found MI continuing education was feasible for the inpatient setting and that 90% of nurses were accepting of this new approach to improve the safety and quality of care for patients with chronic medical conditions. In a qualitative study of undergraduate nursing students' use of MI in an outpatient setting, the students described MI as transforming their

nursing practice (Howard & Williams, 2016). These students identified timing of their education in MI, opportunity for application of MI with actual patients, and immediate debriefing with instructor following patient encounters as most important in developing proficiency in MI. A study of graduate nurse practitioner (NP) students found statistically fewer close-ended questions, more open-ended questions, less advice-giving without permission, increased reflections, and increased summary following a brief MI module (Nesbitt, Murray, & Mensink, 2014). All NP students agreed the MI education was useful and suggested more presentations, demonstrations, and follow up sessions be included in future modules. All students reported use of MI in their clinical practicums. These studies suggest MI education is feasible in the clinical and academic setting, nurses value the content, and they intend to apply it in their practice.

As noted above, the ComPass^{2c} program incorporated motivational interviewing within self-management coaching. However, evidence suggests that motivational interviewing skills decline over time. A meta-analysis examined the lasting effect of motivational interview training immediately post training, 3-months, 6-months, and >6-months (Schwalbe, Oh, & Zweben, 2014). The initial effect size post training was 0.76 with a small change in effect size at three (d = - 0.17) and 6-months (d = - 0.04). Significant heterogeneity was seen in these findings leading the authors to perform additional analysis between groups that had received post MI workshop training and groups without post workshop training. There was no significant change in MI skills at 3 (d = 0.04) and 6-months (d = 0.03) in the groups that had post MI workshop training whereas groups who had no post workshop training showed a decline in MI skills at 3 (d = -0.35) and 6-months (d = -0.30). Frequency of post MI training (5-8 sessions), spreading the training over 6 months, and the number of hours of post MI training (5-12 hours) were found to

increase the effect size. These results suggest the importance of post MI training to sustain MI skills over time.

The acquisition and retention of MI skills has been proposed as a process that evolves over time. Experts in the field of MI have created a theoretical framework consisting of eight stages of MI development (Miller & Moyers, 2006). The length of time for the development of adherence and competence in MI techniques is not clear but has been suggested to take weeks to months (De Roten, Zimmermann, Ortega, & Despland, 2013). The use of the MI framework and evidence that clinicians' MI skills need to be support over time will be important in educational programs designed for nursing students at all levels and practicing nurses.

Future Research

A substantial portion of individuals at risk for hospital readmission and poor outcomes are a challenge to enroll and engage in transitional care interventions. Many ComPass^{2c} subjects were difficult to engage and activate as evidenced by low rates of completed home visits and lack of change in activation scores. In the Annual CCTP Evaluation (2014), CBO sites reported subjects with behavioral health problems including depression, other mental health illness, and active substance abuse as a challenge to enroll and engage, citing low levels of compliance and activation. Subjects with active caregivers were also difficult to enroll in CCTP often due to caregivers feeling they were already doing everything their loved one required. A qualitative study of subjects enrolled in CTI® found that some were unconvinced and disinterested in assuming a more active role in managing their health (Parry, Kramer, & Coleman, 2006). Moreover, in a recent survey of U.S. hospitals, mental health and substance abuse was identified as the greatest patient-related barrier to reducing hospital readmissions (Figueroa et al., 2017).

Safety-net hospitals (SNH) may have a higher proportion of patients with very high risk of readmission including mental health and substance abuse. A SNH is defined by the Institute of Medicine as a hospital that "organizes and delivers a significant level of health care and other health-related services to uninsured, Medicaid, and other vulnerable patients" (Lewin & Altman, 2000, p. 21). SNH are more likely to be large sized teaching hospitals in low income urban areas (Sutton, Washington, Fingar, & Elixhauser, 2016) and provide health care to higher proportions of ethnic minority groups, non-English speaking individuals, and those living at or below federal poverty levels (Gaskin & Hadley, 1999). SNH are also more likely to have excessive 30-day hospital readmission rates than other types of hospitals (Figueroa, Wang, & Jha, 2016; (Joynt & Jha, 2013). Despite this, SNH are less likely to use strategies to reduce 30-day readmissions (Figueroa, Joynt, Zhou, Orav, & Jha, 2017).

Groups that may have been excluded from transitional care programs in the past, including those with mental illness, substance abuse, non-compliance, non-English speaking, and those who receive their care at SNH may benefit from more intensive transitional care interventions. A social-work led intervention to reduce 30-day readmissions and a current CCTP site is attempting to do just this (Basso Lipani, Holster, & Bussey, 2015). Future research and programs should attempt to enroll and engage those non-traditional subjects and subjects in the SNH setting.

Summary

The ComPass^{2c} program aimed to improve the quality and safety of care transitions for beneficiaries in the Medicare FFS system. At Hospital X, the ComPass^{2c} program reduced the relative risk of 30-day all-cause readmission by 23%. The ComPass^{2c} program had other successes including an increase in post-hospital discharge physician follow-up rates without

change in 30-day observation visit rates, ED visit rates, and mortality rates. The ComPass^{2c} program reached one-third of the target population and those enrolled were representative of the general population of Medicare FFS beneficiaries hospitalized at Hospital X. Implementation of post-discharge phone calls was high but low for home visits; with other programs reporting comparable findings. In addition, there was not change in patient activation following the intervention. The low number of completed home visits and lack of patient activation brings into question the acceptability of the ComPass^{2c} program to subjects and their caregivers.

The appraisal of the RE-AIM framework in the evaluation of the ComPass^{2c} program compares the original transitional care research to the application of these interventions in the "real world" setting. The ComPass^{2c} program was effective in reducing 30-day readmissions and reaching at-risk-populations in the clinical setting; however, implementation of home visits were substantially lower compared to the research setting. Future efforts should focus on improving the implementation of home visits.

Several limitations affect the evaluation of the ComPass^{2c} program. Overall, the lack of a comparison group, the absence of the last seven months of program results, and the use of billing data affect the evaluation of the effectiveness outcomes of the ComPass^{2c} program. Declining trends in hospital admissions, an inappropriate performance measure, other 30-day readmission initiatives, and competing priorities may have interfered with the ability of these CCTPs from meeting the 20% reduction in 30-day readmissions. Targeting only a few conditions, the work hours of coaches, responsibilities of coaches, and an antiquated EHR may have limited the reach of the program. De-identified subject data, changes in the risk assessment tool, and not knowing which subjects were approached and declined participation challenged

representativeness. Finally, the documentation of calls placed versus calls with encounters and the low response rate of the PAM® hamper the evaluation of program implementation.

Regardless of these limitations, the impact of the ComPass^{2c} program is the partnerships that developed between Hospital X, the CBO, skilled nursing facilities, home healthcare, payers, and other community resource organizations toward to mutual goal of improving care transitions. Hospital X would benefit from a continued partnership with the CBO. The ComPass^{2c} program evaluation at Hospital X highlights the need for a robust EHR. The EHR can improve communication with patients and caregivers, providers, other facilities and agencies towards safer transitions. A robust EHR can help identify at-risk subjects and allow for targeting interventions to those who will benefit most. Population outcomes can be tracked with an EHR in real-time with timely refinements to programs. The ComPass^{2c} program evaluation provides added value to Hospital X's quality and safety goals as it looks to the future.

The results of the ComPass^{2c} program have implications for practice, policy, education specific to the DNP¸ and future research. In subsequent quality improvement (QI) initiatives to reduce 30-day readmissions, the DNP will need to consider which groups are at risk, appraise the evidence for effective interventions, leverage the EHR to advance QI initiatives, identify and collaborate with stakeholders, evaluated program process and outcomes, and disseminate results. The DNP will need to be familiar with existing policy that is supportive of care transitions and advocate for policy changes at the local, regional, and national levels. Education about MI strategies to enhance patient activation and engagement needs to be provided to both practicing nurses and nursing students at all levels. Finally, to further impact reductions in 30-day readmissions, future research should test transitional care interventions in subjects at risk for

readmission who have historically been excluded, who are difficult to enrolled and activate, and who are admitted to the safety net hospital setting.

Conclusion

Reducing hospital readmissions has become a national priority to improve quality of care and lower health care spending. Section 3026 of the ACA of 2010 created the CCTP to reduce 30-day all-cause readmissions in the Medicare FFS population. In New England, the CCTP program called ComPass^{2c} was developed utilizing two evidence-based transitional care models, the Care Transition Intervention® (CTI®) and the Transitional Care Model® (TCM®).

The purpose of the ComPass^{2c} program evaluation guided by the RE-AIM framework was to determine the effectiveness in reducing 30-day readmissions in Medicare FFS beneficiaries discharged from one academic hospital in New England. The other outcomes included determining the reach of the ComPass^{2c} program and the consistency of implementation of program elements including post-discharge phone calls and home visits at an academic hospital in New England.

The retrospective analysis of the ComPass^{2c} program found a significant reduction in the unadjusted 30-day all-cause readmission rate. The ComPass^{2c} program reached 32% of eligible Medicare FFS beneficiaries and those enrolled were representative of the population admitted to Hospital X. Implementation was high for phone calls but low for home visits. There was no change in patient activation scores at the completion of the program.

Nurses are on the front lines of healthcare across all settings. Transitional care interventions have the capacity to bridge the gaps between acute hospitalization and return to the community. Nurses deliver the transitional care interventions that impact the quality and safety of care. The DNP is in a unique leadership position to determine the need for systems change at

all levels of care, implement and evaluate evidence-based interventions in clinical practice, facilitate interprofessional collaboration, and disseminate practice-based evidence. Future research should test transitional care interventions in subjects at risk for readmission who have historically been excluded, difficult to enroll and activate, and in safety net hospitals.

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Appendix A

RE-AIM Framework Image

Figure B1. The five domains of the RE-AIM framework: Reach, Effectiveness, Adoption, Implementation, and Maintenance. Reprinted from Cummings Online Resources, RE-AIM: Introduction, In Cummings Graduate Institute for Behavioral Health Studies Library website, by L. Christianson, 2017, retrieved March 4, 2017 from http://azhin.org/cummings/re-aim. ©2017 by Lori Christianson. Reprinted with permission.

Re: RE-AIM framework image

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Lori Christianson <lchristianson@cummingsinstitute.com>

Sat 3/4/2017 6:41 AM
To:

...
To help protect your privacy, some content in this message has been blocked. To re-enable the blocked features, click here.
You replied on 3/4/2017 7:19 AM.

1 attachment

RE-AIM.jpg
596 KB94 KB Download

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Diahann, hello!

I am not the creator of the graphic and have never quite been able to track it back to its origins. Under much similar circumstances, I found it at http://hungerintohealth.com/tag/food-insecurity/.

It's a good bit of timing that you should write to me. I have a new graphic sitting in my files that I keep meaning to upload to avoid just this issue. If you like it and it would be cleaner to use mine, I give you permisson :-). I'll attach it here, and it'll be on my library page in moments so you can track it back there for a citation.

Best of luck with your research.

Lori Christianson

On Fri, Mar 3, 2017 at 2:39 PM, Wilcox,Diahann <diwilcox@uchc.edu> wrote:

Dear Ms. Christianson,

I am a doctoral student at the University of Connecticut. I am trying to figure out if the RE-AIM image you displayed on your website is copyrighted and if permission is needed to reprint. If so, who did you obtain permission from?

Thank you for your assistance.

Sincerely,

Diahann Wilcox

--

Lori Christianson
Director of Instructional Design; CORE Librarian

T: 480.285.1761
E: lchristianson@cummingsinstitute.com | W: cummingsinstitute.com

Appendix B

ICD-9 Codes Used to Identify Primary Diagnosis

Table B1

Diagnosis	ICD-9 Codes
Cardiac (MI, Hypertensive heart disease, CHF)	410.00,410.01, 410.10, 410.11, 410.20, 410.21, 410.30,410.31, 410.40, 410.41, 410.50, 410.51, 410.60, 410.61, 410.70, 410.71, 410.80, 410.81, 410.90, 410.91, 402.01, 402.11, 402.91, 404.01, 404.03, 404.11, 404.13, 404.91, 404.93, 428.0, 428.1, 428.20, 428.21, 428.22, 428.23, 428.30, 428.31, 428.32, 428.33, 428.40, 428.41, 428.42, 428.43, 428.9
Diabetes Mellitus	250.00, 250.02, 250.10, 250.12, 250.20, 250.22, 250.30, 250.32, 250.40, 250.42, 250.50, 250.52, 250.60, 250.62, 250.70, 250.72, 250.80, 250.82, 250.90, 250.92
Renal	584.-584.9, 585.-585.5, 585.9, 586.
Respiratory	480.0, 480.1, 480.2, 480.3, 480.8, 480.9, 481, 482.0, 482.1, 482.2, 482.30, 482.31, 482.32, 482.39, 482.40, 482.41, 482.49, 482.81, 482.82, 482.83, 482.84, 482.89, 482.9, 483.0, 483.1, 483.8, 485, 486, 487.0, 491.0, 491.1, 491.20, 491.21, 491.22, 491.8, 491.9, 492.0, 492.8, 493.00-493.90, 494.0, 494.1, 496
Stroke	435.0-435.9, 436, 437.0-437.9
Miscellaneous (chest pain, Acute coronary syndrome, angina, cor pulmonale, pulmonary hypertension, acute respiratory failure	786.50-786.59, 411.0-411.89, 413.0-413.9, 415.0-415-19, 416.0-416.9, 518.81, 518.82, 518.84

Note. ICD-9 = International Classification of Disease, Ninth Revisions. MI = myocardial infarction. CHF = congestive heart failure.

Appendix C

Patient Activation Measure® Statements

Table C1

	Patient Activation Measure®
1	When all is said and done, I am the person responsible for taking care of my health condition.
2	Taking an active role in my own health care is the most important factor in determining my health and ability to function.
3	I am confident that I can take actions that will help prevent or minimize some symptoms or problems associated with my health condition.
4	I know what each of my prescribed medications do.
5	I am confident I can tell when I need to go get medical care and when I can handle a health problem myself.
6	I am confident that I can tell my health care provider concerns I have even when he or she does not ask.
7	I am confident that I can follow through on medical treatments I may need to do at home.
8	I understand the nature and causes of my health condition(s).
9	I know the different medical treatment options available for my health condition.
10	I have been able to maintain the lifestyle changes for my health that I have made.
11	I know how to prevent further problems with my health condition.
12	I am confident I can figure out solutions when new situations or problems arise with my health condition.
13	I am confident that I can maintain lifestyle changes like diet and exercise even during times of stress.

Note. Patient Activation Measure®13 statements. Reprinted from the Insignia Health Website, 2016, retrieved December 19, 2016 from http://www.insigniahealth.com/products/pam-survey.

Appendix D

Patient Activation Levels

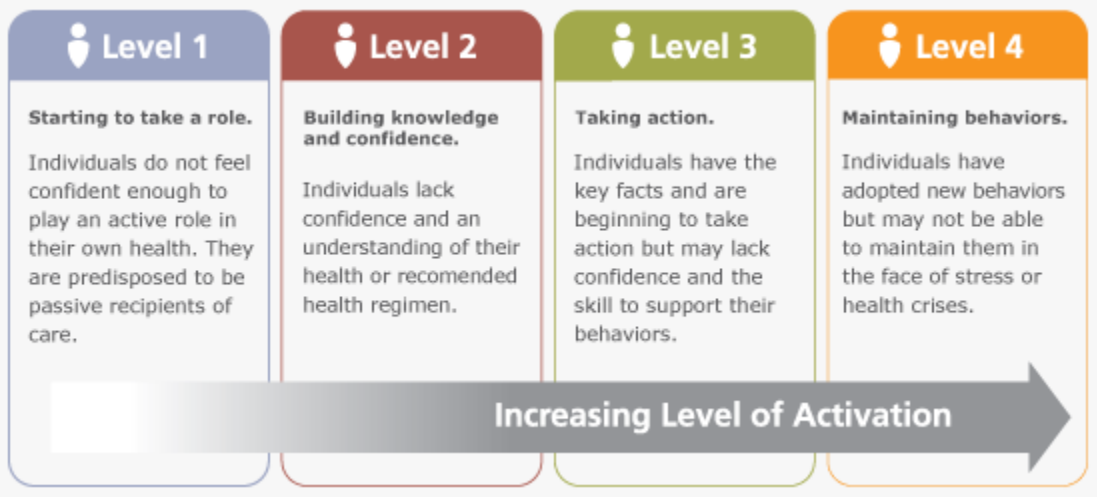

Figure D1. Levels of patient activation. ©2016 Insignia Health, LLC. All rights reserved. Patient Activation Measure® (PAM®). www.InsigniaHealth.com

RE: General Inquiry from InsigniaHealth.com

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Jim Honish <jhonish@insigniahealth.com>

Mon 12/19/2016 1:47 PM
To:

...
You replied on 12/19/2016 1:49 PM.

1 attachment

PAM Levels ~.png
2 KB2 KB2 KB2 KB573 bytes2 KB2 KB2 KB2 KB173 KB Download

Download all

Hi Diahann,
Yes – permission is granted to include the four levels of activation. Attached is an approved graphic you could use for that as well. Or you can reprint the descriptions. But if you do so, please include the text in the copyright line.

Thanks,
Jim

_____

Jim Honish
Sr. Director, Marketing
jhonish@insigniahealth.com
Sign up for our Insignia Health newsletter **here!**

From: Wilcox,Diahann [mailto:diwilcox@uchc.edu]
Sent: Monday, December 19, 2016 10:43 AM
To: Jim Honish <jhonish@insigniahealth.com>
Subject: RE: General Inquiry from InsigniaHealth.com

Hello Jim,

I would also like to include the four levels of activation as a figure in my dissertation. Could you extend permission for this as well?

Thank you very much,

Diahann

From: Jim Honish [mailto:jhonish@insigniahealth.com]
Sent: Monday, December 19, 2016 12:19 PM

To: Wilcox,Diahann
Cc: Info
Subject: RE: General Inquiry from InsigniaHealth.com

Hello Diahann,
Thank you for your inquiry regarding the Patient Activation Measure®. Yes, you have our permission to reprint the statements from the PAM-13 survey. However, you will need to cite the following text in association with the list of statements (i.e., before or after):

> ©2016 Insignia Health, LLC. All rights reserved. Patient Activation Measure® (PAM®) statements reprinted with permission. www.InsigniaHealth.com

Please ensure that there is nothing within the context of your dissertation that implies PAM is proprietary to any system (e.g., RE-AIM) or treatment.

Thanks,
Jim

_____

Jim Honish
Sr. Director, Marketing
jhonish@insigniahealth.com
Sign up for our Insignia Health newsletter **here!**

From: General Inquiry [mailto:info@insigniahealth.com]
Sent: Saturday, December 17, 2016 9:37 AM
To: Info <info@insigniahealth.com>
Subject: General Inquiry from InsigniaHealth.com

Form submission from Insignia Health

SIMPLE FORM

Inquiry Type
Other

First Name
Diahann

Last Name
Wilcox

Email
diwilcox@uchc.edu

Phone

860-280-6393

Company / Organization
University of Connecticut School of Nursing

Message
I am a graduate student and would like permission to reprint the PAM-13 questions in my dissertation entitled, "Evaluation of a Community-based Care Transitions Program to reduce 30-day Hospital Readmissions Using the RE-AIM Framework".

Appendix E

IRB Approval Letters

10/13/15 (03) 799

HUMAN SUBJECT RESEARCH – DETERMINATION FORM

This form should be completed and submitted to the UConn Health IRB when an investigator proposes a project using human materials or human data that s/he does not believe constitutes human subject research. **The form can be hand delivered to the IRB office (Munson Building on the 2nd Floor), sent by interoffice mail to HSPO, MC-3926; sent by e-mail attachment (scanned version with the signature or just attached to an e-mail)** to chasse@adp.uchc.edu **) or faxed to 860-679-1005.** This form will be reviewed by a representative of the IRB within approximately 6-10 business days. If you do not have an answer after this period of time, you **can contact Marcy Chasse at** chasse@adp.uchc.edu **or 860-679-8729 to find out the status of your submission.** The investigator must provide adequate information for the reviewer to determine whether the project constitutes human subject research. If the reviewer determines that a project is not human subject research the HSPO/IRB will have no on-going involvement with the project. If the project is deemed to meet the definition of human subject research, a complete IRB application will be required with the IRB providing guidance as to the type of review required. The IRB will also provide guidance on any HIPAA related issues.

Name of Investigator:	PI: Paula Mccauley; Co-investigator: Diahann Wilcox
Department:	PI: UCONN School of Nursing; Co-investigator: Pulmonary UCHC
Mail Code:	Co-Investigator: 2204
Phone Number:	PI: 860-486-6004; Co-Investigator: 860-679-2544
E-mail:	PI: Paula.mccauley@uconn.edu; Co-Investigator: diwilcox@uchc.edu

1. Provide the title for your project.

Evaluation of a Community-based Care Transition Program to Reduce 30-day Hospital Readmissions using the RE-AIM Framework

2. Is there external funding for this project? ☐ Yes (Attach the funding proposal and the Office of Research and Sponsored Programs routing form to this form)
   X No

3. If yes to externally funded, provide the following details:
   Log Number from the Office of Research and Sponsored Program Routing Sheet:
   N/A
   The grant award number if known (e.g. RO1CA12345)
   N/A
   The name of the funding source (e.g. National Institute of xxx, ABC Foundation etc.)
   N/A
   Grant Title (if different than project title)
   N/A

4. Provide a brief summary of the project, including its intended purpose, how it will be implemented and how it will be evaluated.

Unplanned hospital readmissions have clinically significant physiological and psychological consequences for patients and are costly to the Medicare program. Health care reform has pinpointed hospital readmissions as a key area for improving care coordination and achieving potential savings. Section 3026 of the Affordable Care Act (ACA) of 2010 created the Community-based Care Transition Program (CCTP), a national Medicare demonstration project to reduce 30-day hospital readmissions for

its beneficiaries. In Connecticut, a community-based organization called Connecticut Community Care, Incorporated (CCCI) created a CCTP called Community Passport 2 Care (ComPass^{2c}). John Dempsey Hospital (JDH) partnered with CCCI to offer the ComPass^{2c} program to Medicare FFS beneficiaries hospitalized at JDH. A knowledge gap exists regarding the effectiveness of the ComPass2c program in reducing 30-day readmission rates in Medicare FFS beneficiaries hospitalized at JDH.

The purpose of this project is to evaluate the ComPass^{2c} program guided by the RE-AIM framework, an acronym for Reach, Efficacy/Effectiveness, Adoption, Implementation, and Maintenance. The specific aims are:

1. Determine the effectiveness of the ComPass^{2c} program in reducing 30-day readmissions for Medicare FFS beneficiaries hospitalized at JDH
2. Determine the reach of the ComPass^{2c} program at JDH
3. Determine the consistency of implementation of key ComPass^{2c} program elements

A retrospective design will be used to address the aims of this program evaluation. Upon IRB determination, the investigators will submit a written request for de-identified data on subjects enrolled in the ComPass^{2c} program from the Director of Quality Improvement at CCCI. In addition, the investigator will request the CCTP Quarterly Monitoring Reports from CCCI. The quarterly monitoring reports are based on claims data and presented in aggregate form. The investigators will also submit a Data Request Form to JDH for de-identified data on subjects eligible to enroll in the ComPass^{2c} program at JDH. Subjects eligible for enrollment in the ComPass^{2c} program will be based on ComPass^{2c} inclusion and exclusion criteria.

The sample will include all Medicare FFS beneficiaries hospitalized at JDH between November 1st, 2012 and November 30th, 2014 who were either enrolled or not enrolled in the ComPass^{2c} program. Effectiveness will be answered at the aggregate level using summary statistics obtained from the CCTP Quarterly Reports. Statistical results from CCTP Quarterly Reports will be validated by using subject level data obtained from CCCI of the counts of ComPass^{2c} subjects who were and were not readmitted within 30-days following discharge from JDH.

Reach will be answered by determining the participation rate and the representativeness of those enrolled compared to those who were not enrolled based on age, gender, hierarchical condition category (HCC) risk score, principle admission diagnosis, Medicaid beneficiary status, length of stay (LOS), and history of non-elective admission in past six months.

Implementation will be answered by measuring post discharge home visits, follow up telephone contacts, and the difference between pre and post program patient activation scores. Rates of 30-day readmissions will be compared relative to the counts of completed home visits and telephone contacts. Rates of 30-day readmissions will be compared between subjects who had an improvement in PAM-13 scores and those who did not.

5. Provide detailed description of all human material and/or data elements to be used in the project.
(tabbing out of the bottom right cell will insert another row)

Human Materials	Data Set Elements/Fields	For IRB Use - Assigned Data Set #
	age, gender, HCC risk score, principle admission diagnosis, LOS, number of days enrolled in ComPass^{2c} program, Medicaid beneficiary status, Boost "8P" risk assessment, Self-report health, Brief Health Literacy	

	Screen, Patient Health Questionaire-2, assigned risk level, ComPass[2c] level of intervention delivered, 30-day all-cause readmissions, H-CAHPS (5-items), Care Transition Measure-3, Patient Activation Measure-13 score, completed home visits, and completed telephone contacts. CMS quarterly program monitoring data to include: average HCC risk score for ComPass[2c] subjects, percentage of ComPass[2c] subjects rehospitalized within 30 days of discharge from JDH, 30-day all-cause readmission rates, 30-day post discharge mortality rates, 30-day post discharge ED rates, 30-day post discharge observation stay rates, 7-day and 14-day post discharge follow up rates for all Medicare FFS beneficiaries discharged from JDH.	
	age, gender, HCC risk score, principle admission diagnosis, Medicaid beneficiary status, LOS, and history of admission to JDH in past six months	

6. Describe the source of the material / data. (e.g. existing samples in (give name of person's lab), purchased samples from (give company name), waste material gathered from (describe accordingly), downloaded data from (describe data source) etc.)

Data from the top cell will be requested from the Director of Quality Improvement at Connecticut Community Care, Inc. Data from the bottom cell will be requested from JDH using the Patient Data Request form. Both data sets will be in an electronic spreadsheet format.

7. Place an **X after** any of the following HIPAA identifiers that will be contained in the data, or indicate that none of the identifiers in this list will be contained in the information, alternatively if no protected health information is being seen or collected indicate that HIPAA is not applicable.

Names		Unique identify #s, characteristics or codes		Geographic Subdivisions	
Phone		Serial #s		Health Plan Beneficiary	
Fax		Account #s		Vehicle Identifiers	
E-mail		Social Security #s		Biometric Identifiers	
URL		License #s		Device Identifiers	
IP Address		Medical Record #s		Dates (except year)	
None of the identifiers listed above will be included with the samples/data used for the study					
The project does not involve the use of any protected health information, HIPAA is NA					X

8. Describe how the material and/or data will be labeled at the time of receipt.

N/A

If data/samples are coded, such that the provider and/or recipient could link the code back to the individual(s) from whom the data came, answer the following questions:

9. Were the data / specimens collected specifically for the currently proposed research project through an interaction or intervention with living individuals? (If yes, and the data and/or specimens contain information about an individual, the project constitutes human subject research.)

N/A

10. Explain how the code is derived; if unknown to anyone on the research team, provide a statement to that effect.

N/A

11. Describe the access, ability, possibility for anyone involved with the project to, in any way, link a code to an individual.

N/A

12. Place an X after the mechanism(s) in place to minimize the chance of the code being linked to an individual.

The key to decipher the code will be destroyed prior to initiation of the research.	N/A
The investigator(s) and the key holder have entered into a written agreement prohibiting the release of the key while individuals are living (**attach for reference**).	N/A
There are existing policies and operating procedures in place for a repository or data management center that have been approved by the IRB and that prohibit the release of the key to the investigators under any circumstances, until the individuals are deceased (**Provide IRB # of the approved registry/repository**).	N/A
There are other legal requirements preventing the release of the key to the investigators (**describe accordingly on attached document**).	N/A

Deshawn Wilson — **Signature of Investigator**

10/14/15 — **Date**

****

FOR IRB USE ONLY:

1. **Determine whether the proposed activity constitutes research according to either the Common Rule (45 CFR 46) or the FDA (21 CFR 50).**

DHHS Definition of Research:	**Yes / No**
a. Is the activity a systematic investigation (including research development, testing and evaluation)?	Y
b. Is the activity designed to develop or contribute to generalizable knowledge?	Y
FDA Definition of Clinical Investigation:	
c. Any experiment that involves a test article and one or more human subjects that requires prior submission under 505(i) or 520(g) or for which the results are intended to be submitted later to or held for inspection by the FDA as part of an application for a research or marketing permit.	N
Note: If yes to item a and to item b together and /or to item c alone, the activity is research under	

DHHS and/or FDA regulations. Proceed to question 2. If no to item a or b the activity is not research under DHHS regulations. If no to item c, the activity is not research under FDA regulation. **If the activity is not research under either regulation, skip to item 3.**

2. Determine whether the activity involves human subjects.

DHHS Definition of Human Subject	**Yes / No**
a. Are data being obtained about one or more living individuals? (if yes proceed to item b, c and d, if no proceed to item d)	Y
b. Are the data collected through an intervention (physical procedures by which data are gathered or manipulations of the subject or the subject's environment that are performed for research purposes) or interaction (communication or interpersonal contact between investigator and subject) with the individual?	N
c. Is identifiable private information being obtained? Private identifiable information includes behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place or information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public, e.g. medical record, being obtained?	N
FDA Definition of Human Subject:	
d. Does the project involve an individual (either a healthy human or a patient) who is or becomes a participant in research, either as a recipient of the test article or as a control?	N
e. Does the project involve an individual (in normal health or with a medical condition or disease) who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control?	N
Note: If no to a, the research does not involve human subjects under DHHS Regulations If yes to a, and also to b **and/or** c, the research does involve human subjects per DHHS regs If yes to a, and no to b **and** c – human subjects are not involved per DHHS regulations If no to d and e, the research does not involve human subjects under FDA regulations If yes to d and/or e, the research does involve human subjects per FDA regulations	

Note: Private information must be individually identifiable (i.e., the identity of the subject **is or may readily be ascertained** by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects under DHHS regulations.

IRB DETERMINATION – CHECK THE APPLICABLE CATEGORY(IES):

3. Human Subject Research Determination

Project is human subject research and will require an IRB submission.	
Project is not human subject research and IRB involvement is not required.	✓

4. HIPAA Determination

a. Project is Human Subject Research, if applicable; HIPAA must be addressed when IRB submission is received.	
b. Project is not human subject research, but **is research** and involves PHI, and Investigator has adequately addressed HIPAA (e.g. waiver, LDS &DUA)	

c. Project is not research but contains PHI, **Investigator must check with Compliance Office regarding HIPAA**	
d. Project contains no PHI therefore HIPAA does not pertain.	✓

Comments regarding HIPAA: If necessary provide directions for the investigator to ensure HIPAA compliance. If item 4.b is applicable, provide instruction here if necessary and only check the box and sign the form once HIPAA has been addressed.

Other Comments by Reviewer

Signature of IRB reviewer making the determination — Date: 10/29/15

NOTE: If yes to item 2, copy Office of Research and Sponsored Program on response. If 4.c is checked, copy Iris Mauriello on final determination.

UCONN
UNIVERSITY OF CONNECTICUT

DATE: November 9, 2015

TO: Diahann Wilcox, Student Researcher
Paula McCauley, DNP, APRN, ACNP-BC

FROM: Jaci L. VanHeest, Ph.D. JLVH DSS
Chair, Institutional Review Board

RE: Evaluation of A Community - Based Care Transition Program to Reduce 30-day Hospital Readmissions using the RE-AIM Framework"

A member of the University of Connecticut Institutional Review Board (IRB) has reviewed your request and has determined that this project does not meet the definition of "human subjects research" under 45.CFR. 46.102(f). Therefore, you are not required to file an application for review by the IRB.

45CFR46.102 (f) states in part:
Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains

(1) data through intervention or interaction with the individual, or
(2) identifiable private information.

The IRB notes that the UConn Health IRB also determined that the study does not require review by the UConn Health IRB.

For your information, 45CFR46 in its entirety may be viewed at:

http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm

Thank you for your interest in complying with the federal regulations for the protection of human subjects in research.

Office of the Vice President for Research
Research Compliance Services
438 WHITNEY ROAD EXTENSION, UNIT 1246
STORRS, CT 06269-1246
PHONE 860.486.8802
FAX 860.486.1044
compliance.uconn.edu

Appendix F

Quarterly 30-day readmission rates at Hospital X

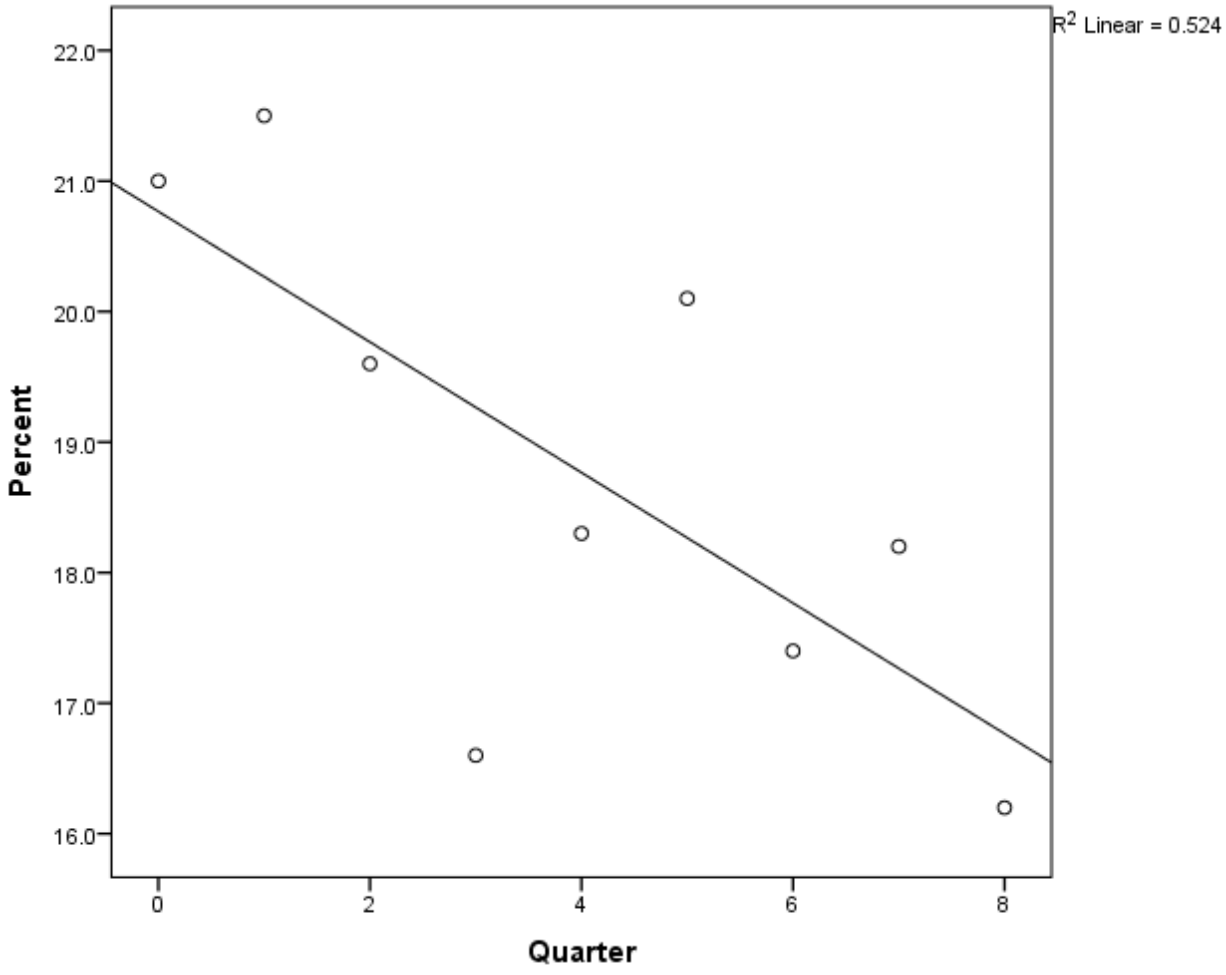

Figure F1. Scatter plot of quarterly 30-day readmission rates at Hospital X by linear regression. Quarter 0 = baseline, January 1, 2010 – December 31, 2010. Start of quarter 1 was May 1, 2012. Last available quarter (8) ended April 30, 2014.

Appendix G

Quarterly 7-day Physician Follow-up Visit Rates at Hospital X

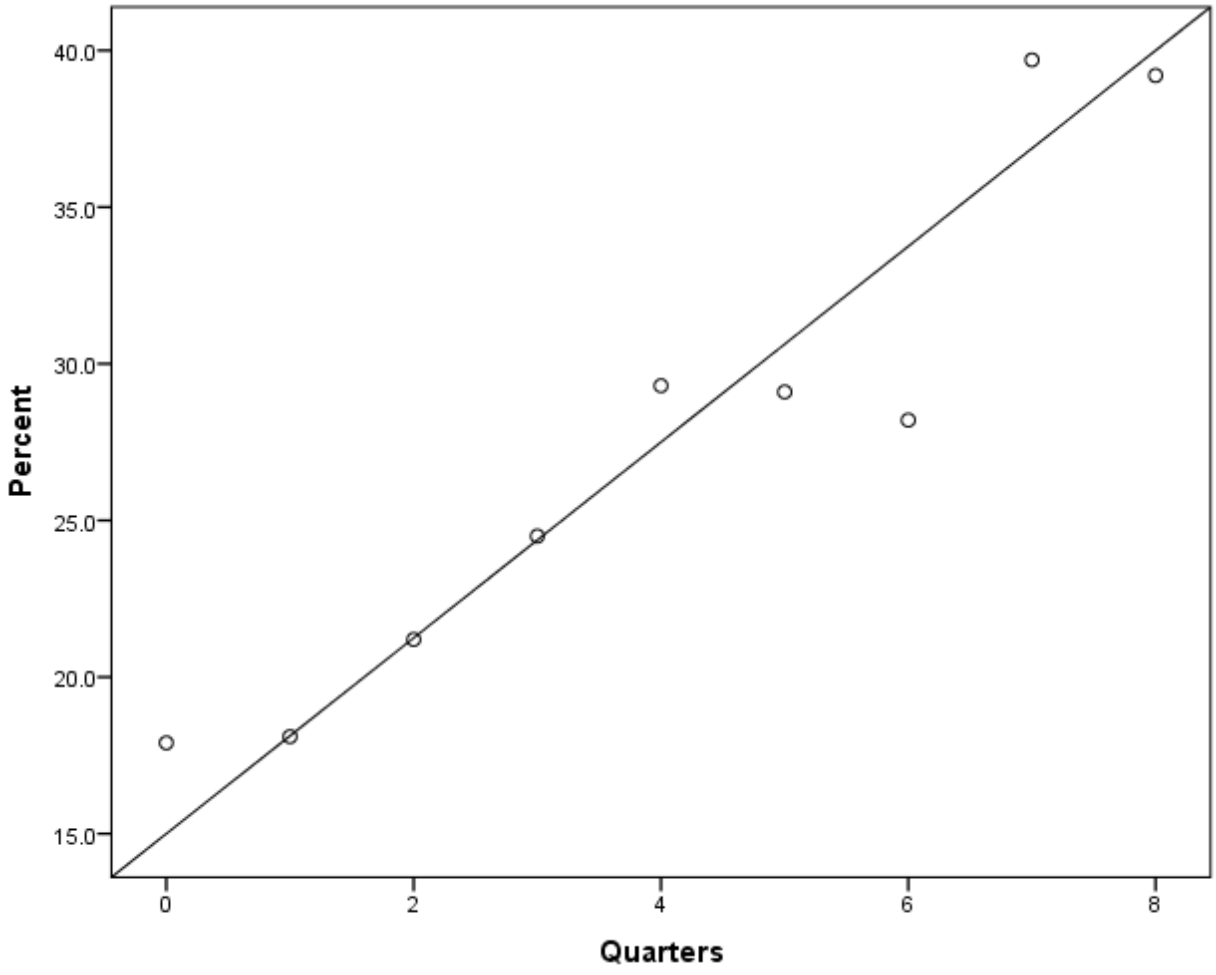

Figure G1. Scatter plot of quarterly 7-day physician follow-up visit rates at Hospital X by linear regression. Quarter 0 = baseline, January 1, 2010 – December 31, 2010. Start of quarter 1 was May 1, 2012. Last available quarter (8) ended April 30, 2014.

Appendix H

Quarterly 14-day Physician Follow-up Visit Rates at Hospital X

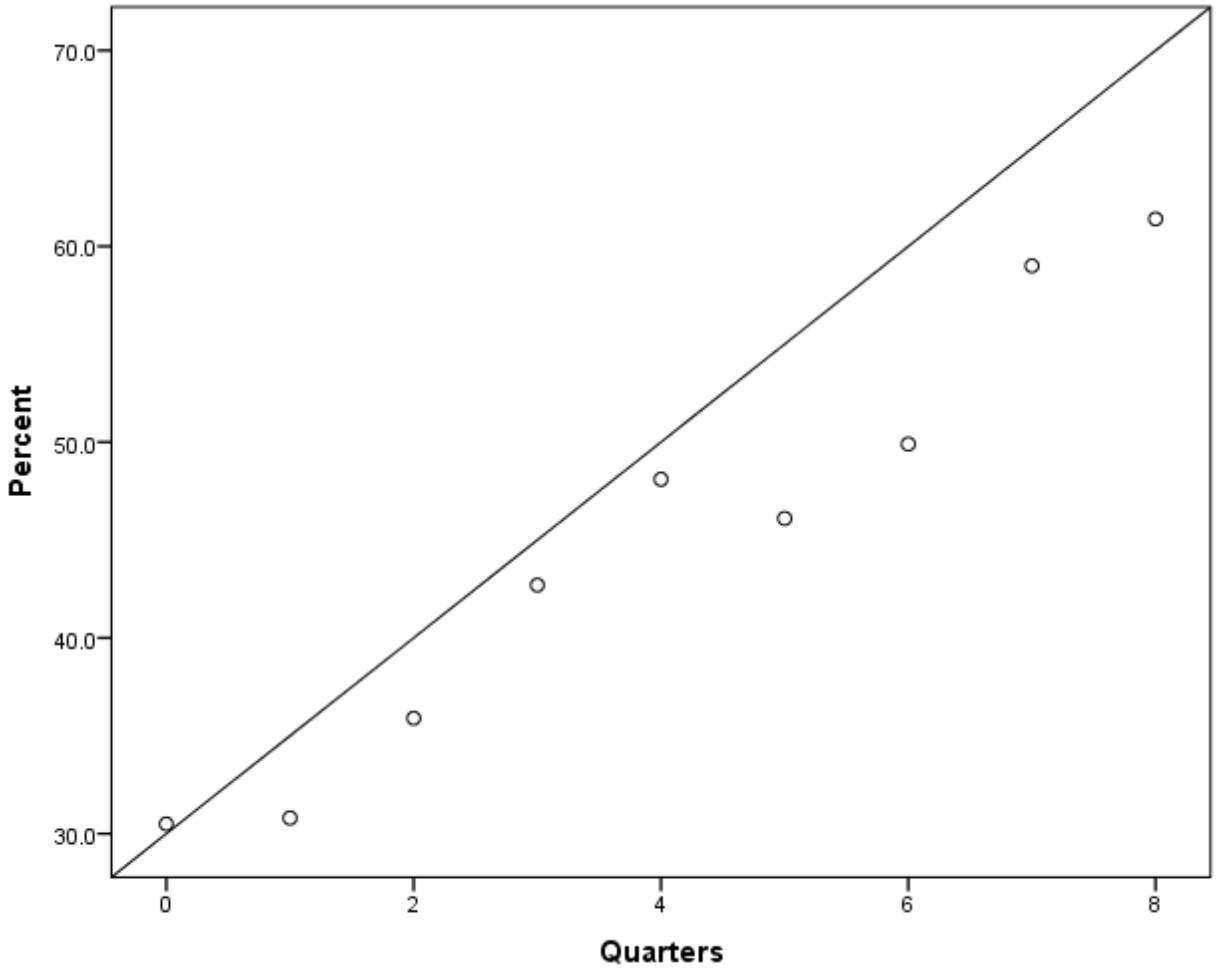

Figure H1. Scatter plot of quarterly 14-day physician follow-up visit rates at Hospital X by linear regression. Quarter 0 = baseline, January 1, 2010 – December 31, 2010. Start of quarter 1 was May 1, 2012. Last available quarter (8) ended April 30, 2014.

Appendix I

Quarterly 30-day Observation Stay Visit Rates at Hospital X

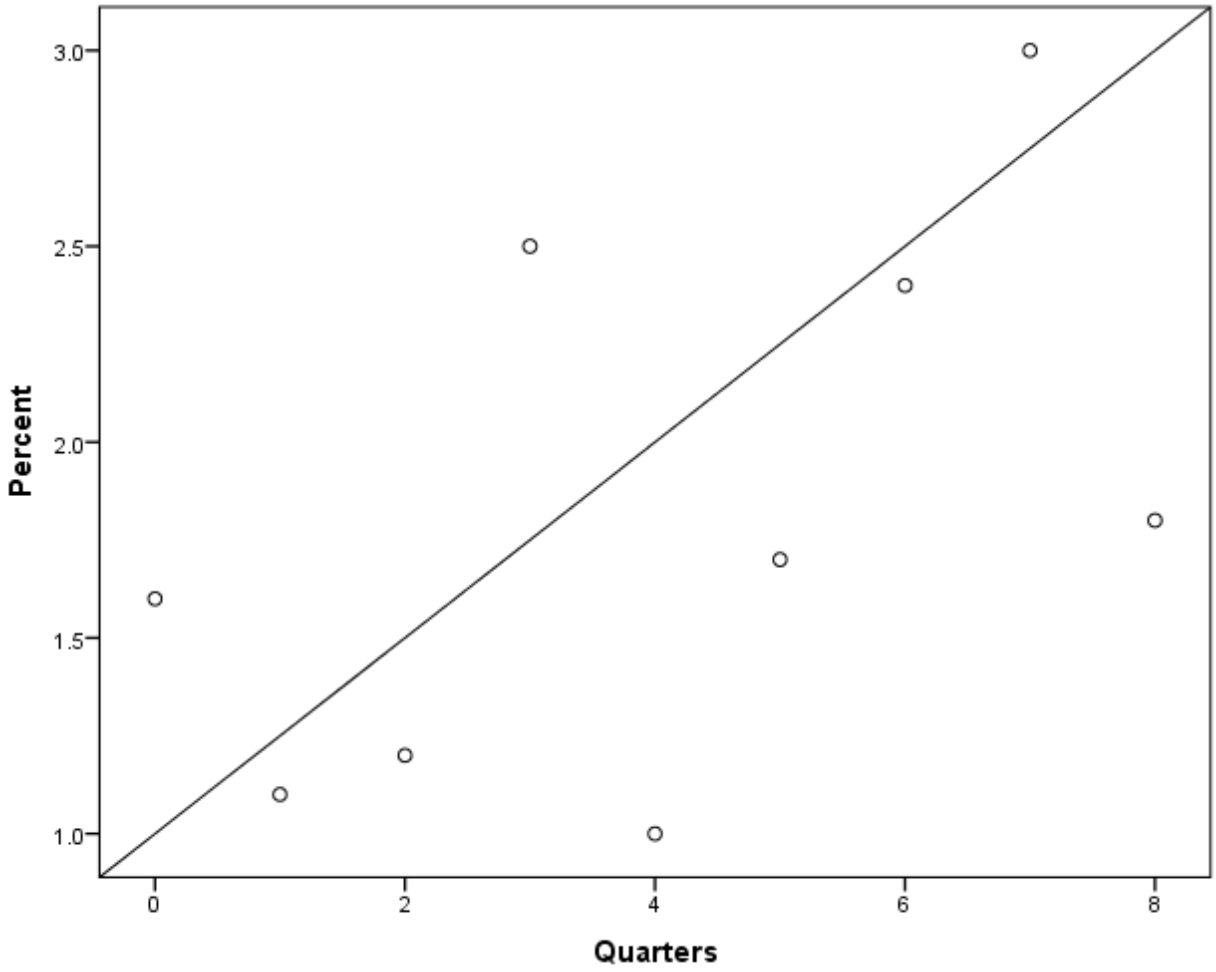

Figure I1. Scatter plot of quarterly 30-day observation stay visit rates at Hospital X by linear regression. Quarter 0 = baseline, January 1, 2010 – December 31, 2010. Start of quarter 1 was May 1, 2012. Last available quarter (8) ended April 30, 2014.

Appendix J

Quarterly 30-day Emergency Department Visit Rates at Hospital X

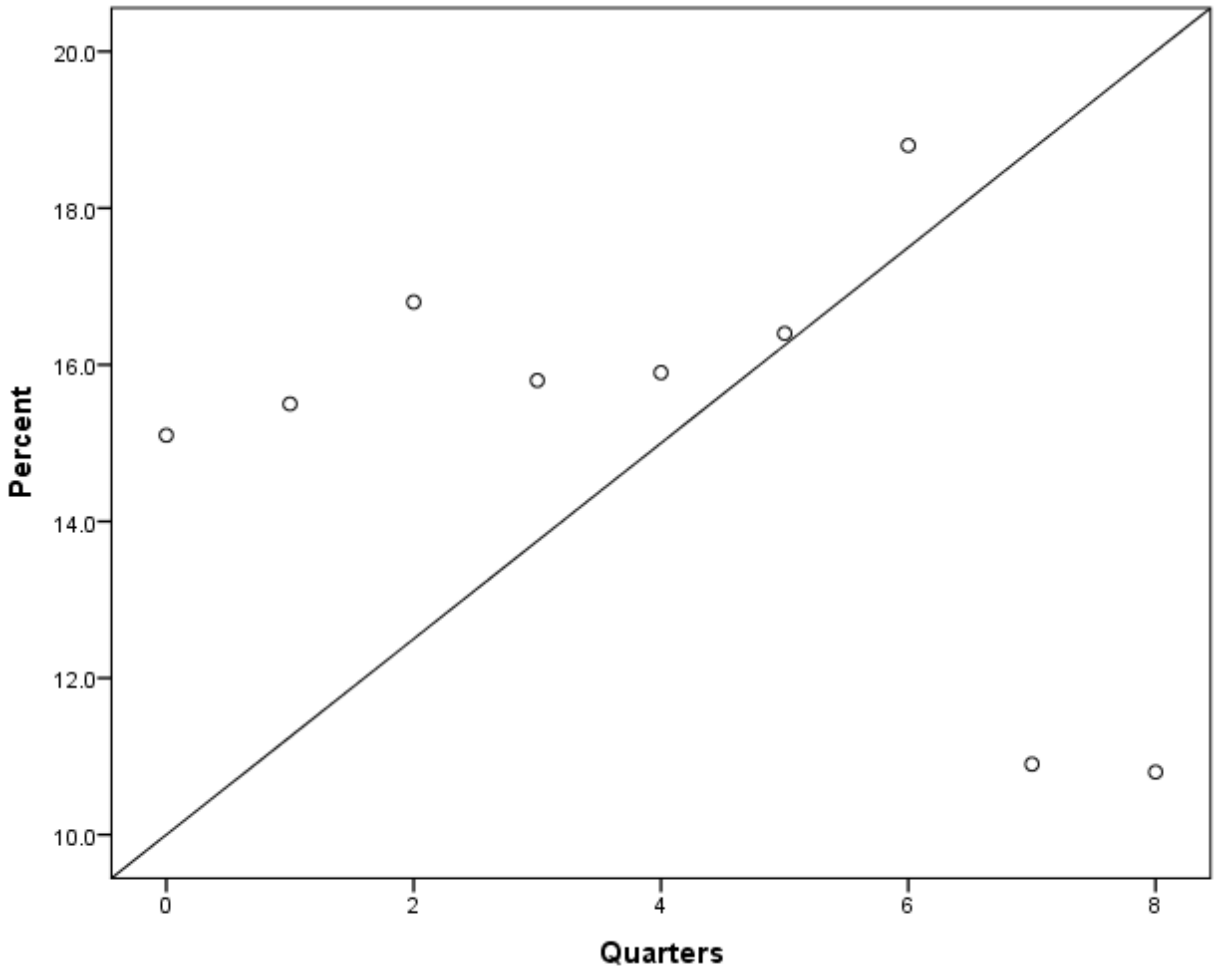

Figure J1. Scatter plot of quarterly 30-day emergency department rates at Hospital X by linear regression. Quarter 0 = baseline, January 1, 2010 – December 31, 2010. Start of quarter 1 was May 1, 2012. Last available quarter (8) ended April 30, 2014.

Appendix K

Quarterly 30-day Mortality Rates at Hospital X

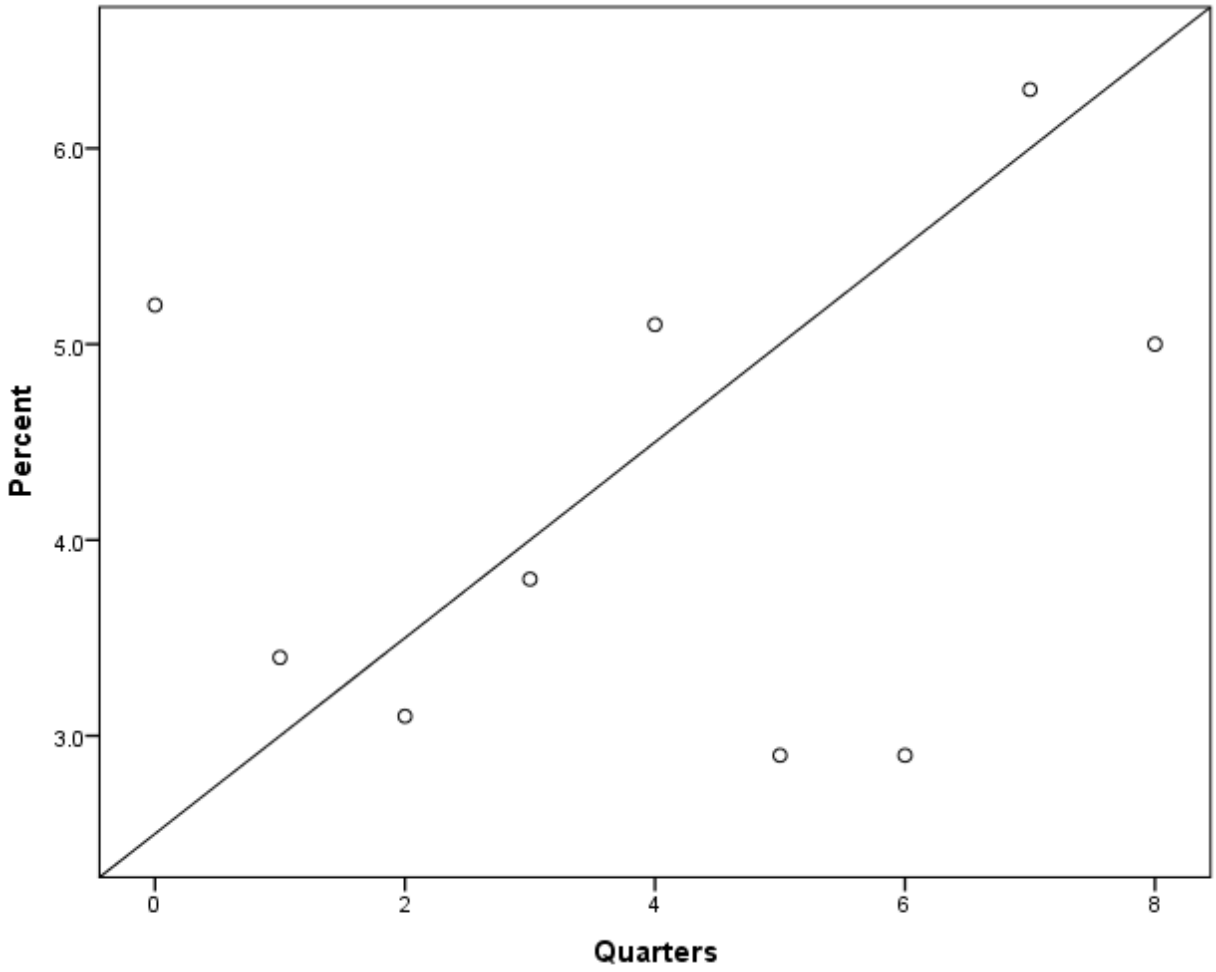

Figure K1. Scatter plot of quarterly 30-day mortality rates at Hospital X by linear regression. Quarter 0 = baseline, January 1, 2010 – December 31, 2010. Start of quarter 1 was May 1, 2012. Last available quarter (8) ended April 30, 2014.

Appendix L

Communications

Re: PACT study

DELETE REPLY REPLY ALL FORWARD
Mark as unread

Jodi.D.Smith@kp.org

Thu 3/9/2017 4:22 PM
To:

...
You replied on 3/9/2017 4:24 PM.

The hospital RNs LACEd people manually during the study and it is now integrated into the EMR. The LACE score trigger of 11-15 (we've since addended the LACE range from 9-15) to refer to PACT.

Jodi Smith, MSN, ANP, CCM, ND
Director of Hospital Operations, Specialty and Care Coordination
Kaiser Foundation Health Plan of Colorado
| (C) 303-710-0961 | ✉ Jodi.D.Smith@kp.org
https://kponline.webex.com/join/Jodi.D.Smith

Project Coord/Admin Assistant: Jenny Geselevich | ☎ 303-636-3324 | ✉ Jennifer.X.Geselevich@kp.org

"Wilcox,Diahann" ---03/09/2017 01:42:47 PM---Caution: This email came from outside Kaiser Permanente. Do not open attachments or click on links i

From: "Wilcox,Diahann" <diwilcox@uchc.edu>
To: Jodi D Smith/CO/KAIPERM@Kaiperm
Date: 03/09/2017 01:42 PM
Subject: PACT study

Good afternoon Ms. Smith,

I am a graduate student at the University of Connecticut School of Nursing. I am in the process of completing my doctoral work which is a program evaluation of the Community-based Care Transition Program that my institution participated with. In my discussion, I speak to real-time patient information, use of the EHR, and risk identification tools. Was LACE integrated into your EHR? Who calculated the LACE score? From the article, referrals were automatically sent to the PACT program based on the score of 11-15.

I look forward to your response.

Kind Regards,

Diahann Wilcox