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Research Objectives, Background, and Conceptual Framework

RESEARCH OBJECTIVES

The broad objective of this study is to explore the effects of an AmeriCorps member-delivered coaching intervention designed to reduce hospital readmissions. As discussed below, similar transition coaching interventions led by registered nurses (RN) have been found effective at reducing hospital readmission rates and medical costs. Unfortunately, increasing demands on medical resources (including nurses' time) and hospital cost pressures have undermined the adoption of such interventions. Our intervention tests a "task-shifting" strategy for addressing this dilemma. If the role of "coach" can be effectively played by Americorps volunteers, it could allow for much wider diffusion of services that reduce medical costs and improve clinical outcomes.

Findings of positive effects could motivate further initiatives and research on the role that volunteer organizations could play to productively augment traditional medical providers.

The specific objectives of this project are as follows:

Quantitative objective (1): We will estimate the efficacy and cost implications of the AmeriCorps member-delivered coaching intervention in comparison to usual care. The outcomes to be investigated include cost of implementation, patient satisfaction, clinical outcomes (including readmission rates), and medical care cost avoidance.

Quantitative objective (2): We will estimate the efficacy and cost implications of the AmeriCorps member-delivered coaching intervention in comparison to a similar intervention delivered by a registered nurse. Along with the outcomes identified above, we will additionally estimate differences in patient engagement, by means of home visit completion rates and interventional phone call completion rates.

Qualitative objective: Through qualitative interviews and thematic content analysis of intervention phone call recordings, we will explore possible mechanisms behind program effectiveness and identify opportunities to improve training of AmeriCorps coaches.

Stratified random assignment of patients across the three arms of the trial will ensure that credible

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causal inferences can be drawn about program effects.

Congruent with the goals of this grant, our project will "increase the nation's understanding and knowledge about the importance and potential of volunteering," specifically as it pertains to the utilization of volunteers to deliver behavioral health interventions that are severely under-resourced. Our project relates directly to one of the CNCS strategic focus areas ("Healthy Futures") by "providing support for health needs within communities." Further, our project maps to one of the CNCS funding priorities ("Economic benefits of national service, volunteering, and civic engagement") by "testing hypotheses that can provide causal evidence of economic benefits" associated with this novel intervention.

BACKGROUND

In the United States, the problem of inadequate self-management of chronic conditions is pervasive. One-half of patients do not take their chronic disease medications as prescribed, and only 1 in 10 patients follow recommended guidelines for lifestyle changes, such as smoking cessation or weight loss. (Haynes 2002). Hospital readmissions are largely preventable but remain high due in large part to inability of individuals with chronic illness to manage problems in the transition period from hospital to home. National 30-day hospital readmissions among Medicare beneficiaries range from 15% to 25% (Coleman 2004), costing an estimated \$15-17 billion to Medicare annually (Jencks 2009; Medpac 2014). At University Hospitals Case Medical Center (UHCMC), our general medicine patients experienced a readmission rate of 17.9% in 2014.

Minority and low-income communities bear a disproportionate burden of chronic disease and its complications (CDC 2011), and they are less likely to engage in effective self-management of their conditions (Thackeray 2004; Bailey 2014).

Contributors to this gap in self-management include a lack of patient understanding of, and agreement with, the care plan, and low confidence and motivation to make healthy choices (Willard-Grace 2015). Health coaching addresses this gap by equipping people with the knowledge, skills, and confidence to manage their chronic conditions (Ghorob 2013).

Transition coaching interventions have been shown to reduce hospital readmissions in several studies

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(Coleman 2006; Voss 2011). One of the investigators (SG) conducted a quasi-experimental prospective cohort study at six Rhode Island hospitals evaluating a coaching intervention called the Care Transitions Intervention (CTI). The CTI reduced readmissions by 39% (odds-ratio of 0.61 with 95% CI of 0.42-0.88; Voss 2011). In a cost analysis led by this investigator, the cost avoided per patient receiving the CTI was \$3752 compared to internal controls (Gardner 2014).

A major constraint to delivering interventions to support self-management (like the CTI) is a serious shortage of health workers. Primary care clinicians are in increasingly short supply (Pettersen 2012) and overwhelmed by the expanding preventive and chronic care needs of their growing patient populations (Ostybye 2005; Yarnall 2003). Despite some recent increase in the supply (Auerbach, 2011, 2015), analysts also anticipate a growing shortage of RNs due to increased demand for medical services (Juraschek 2012).

"Task shifting" is one way health systems and the public health community can address a shortage of traditional care providers head-on. Task shifting involves the delegation of tasks to workers who are less specialized and less costly. In doing so, task shifting presents potential opportunities to improve healthcare access and reduce medical costs by making more efficient use of available human resources (WHO 2008). In a variety of settings, task shifting has been found to yield cost savings without compromising the quality of care (Abegunode 2007; Callaghan 2010; Mdege 2012; Buttorff 2012).

Over the past two years, three investigators (NC,SG, KS) have developed a curriculum to train volunteers as transition coaches. This curriculum was developed and is intended as a free resource for other organizations. This curriculum which blends online modules with small group practice, was evaluated in a pilot study in 2015. In this pilot, 32 volunteers were trained in motivational interviewing (MI). None had previous training in MI. All 32 volunteers graduated from the training, and all achieved criterion-performance for MI based on expert guidelines of fidelity to MI as measured by an evidence-based coding instrument of audio recorded conversations. The average number of sessions to attain criterion performance was 3.5, with a range of 3-7 sessions. 59% of students achieved proficiency, a skill level that would qualify them to deliver MI in a clinical trial. Mean performance across five components of performance showed a significant increase from baseline to follow-up on the coded evaluation of student conversations. This increase was a large effect size for all

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but one parameter of performance. The component that did not show a large effect size had a small though significant effect size.

In June 2015, ServeOhio, in partnership with CNCS, awarded UHCMC an AmeriCorps grant for a program led by 3 investigators (NC, SG, KS) to train AmeriCorps service members in this novel curriculum as coaches to help reduce hospital readmissions at UHCMC.

The grant from CNCS will finance the program management, data collection, and data analysis activities to compare the effects of the AmeriCorps-delivered coaching intervention against usual care. The grant will further finance the time of RNs trained to deliver the CTI, allowing us to compare the effects of AmeriCorps-delivered coaching to RN-delivered coaching. Further, the grant will finance qualitative analyses to uncover mechanisms behind any differences we detect. The importance of this work lies in its potential to demonstrate the value of layperson volunteers as capacity-extenders in a resource-constrained medical economy, extending access to evidence-based services that reduce costs and improve clinical outcomes.

CONCEPTUAL FRAMEWORK

Quantitative studies have documented that quality and patient safety are compromised during the vulnerable period when patients transition between different settings because of high rates of medication errors, incomplete and inaccurate information transfer, and lack of appropriate followup care (Forster 2003; Beers 1992; Dudas 2001; van Walraven 2002, 2004; Moore 2003; Cornish 2005; Coleman 2005). During care transitions, patients frequently receive medications from different prescribers, who rarely have access to patients' comprehensive medication lists (Coleman 2003; Partnership 2002). These types of problems conspire to increase rates of readmission to high-intensity care settings when patients' care needs are not met, leading to greater health care costs.

The Care Transitions Intervention (CTI) is a patient-centered coaching intervention to empower individuals to better manage their health. Coached patients received (1) tools to promote cross-site communication, (2) encouragement to take a more active role in their care and to assert their preferences, and (3) continuity across setting and guidance from a "transition coach." The primary roles of the transition coach is to encourage the patient and caregiver to assert more active roles during care transitions. Rather than functioning as another care provider, the transition coaches

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facilitate the patient's and the caregiver's roles in self-care.

While the CTI utilizes RNs in the role of transition coach, AmeriCorps members might be particularly well-suited to serve in this role for the following reasons:

Less unlearning to do.

The primary roles of coaches is to encourage the patient and caregiver to assert a more active role. Rather than functioning as another care provider, coaches facilitate the patient's and the caregiver's roles in self-care. A key attribute of coaches is the ability to shift from doing things for the patient to encouraging him or her to do as much as possible independently. For healthcare providers, the shift might be more difficult than for a coach who hasn't been in a provider role.

Closer cultural concordance.

To be effective, self-management support must be culturally appropriate. The AmeriCorps workforce is more culturally and linguistically concordant with patient populations than registered nurses. 38% of AmeriCorps service members are from typically underrepresented racial or ethnic groups. (Americorps 2006). This is 13 percentage points greater than the general American population, and 21 percentage points greater than the registered nurse population, with 16.8% minority. (HRSA 2010)

Less costly.

The cost of an RN coach salary and benefits is \$70,980 annually; the cost of an AmeriCorps service member coach is \$15,140. The cost to train one RN in the CTI is an additional \$3000. The curriculum we've developed to train volunteer coaches is free.

Research Design and Work Plan

RESEARCH DESIGN

The study population will consist of patients admitted to general internal medicine service of UHCMC over a two year period, from January 2016 through December 2017. Exclusion criteria are kept to a minimum, in order to make this as much of a "real world" and pragmatic trial as possible. Patients who reside outside of Cuyahoga will be excluded (for feasibility of home visits). Based on data for 2014, we anticipate a total of 12,304 discharges during this period.

From this population, patients will be randomly assigned to one of three groups: (1) patients

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approached by the RN coach (Coaching Intervention by RN, or CI-RN); (2) patients approached by the AmeriCorps coach (CI-AC); and (3) patients not approached due to resource limitations (usual care, or NoTreat). We will employ an intention-to-treat approach, where patients approached by a coach will remain in that coach group regardless of whether or not a home visit or follow-up calls are successfully completed.

Patients will be randomized across the three arms. We will do so based on a stratified random assignment procedure, to ensure balance along the dimensions of patient severity and age. A computer program will be used to ensure proper random assignment procedures, including allocation concealment.

The number of patients in the CI-AC and CI-RN groups will be limited by the coaching resources available for each intervention. Based on prior research, we envision one FTE of annual coaching employment can accommodate a caseload of 25 patients per month. In the CI-AC, 1100 patients will be coached: 8 AmeriCorps members at 0.25 FTE each, for 22 months with total caseload of 50 patients per month. In the CI-RN group, 550 patients will be coached: 4 RNs at 0.25 FTE each, for 22 months with a total caseload of 25 patients per month. In the sample of non-approached patients, there will be approximately 9000 patients.

Data sources and data collection methods

Data pertaining to patient satisfaction, medical costs, utilization and clinical outcomes will be obtained from the hospital system. Patient satisfaction measures will draw upon Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey data. Data pertaining to patient characteristics, including medical history and reason for hospitalization, will be obtained from the hospital's electronic medical records. Patient zip codes will be used in conjunction with data available from the Census Bureau to obtain socio-economic characteristics of the patient's neighborhood. Data will also be collected in the form of qualitative interviews and intervention phone call recordings. These are discussed in more detail below (see Qualitative methods).

Quantitative methods (1)

Patient outcomes will be compared across the CI-AC and NoTreat groups. Standard statistical tests will be employed to evaluate covariate balance across the two groups. Effects will be estimated by way

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of univariate comparisons and multivariate regression, using logistic models for binary outcomes (e.g. readmission at 30/60/90 days). Cost outcomes will be log-transformed to address anticipated skew in the distribution of costs. The generalized Gamma method developed by Manning, Basu and Mallahy (2005) will be applied to model costs if log-transformed costs are observed to be highly skewed or kurtotic. Auxiliary analyses will be performed to test for variation in treatment efficacy across different coaches (i.e. coach-specific effects).

Obtained estimates will reflect "intention-to-treat" (ITT) effects; that is, the CI-AC group will consist of all patients approached to participate in the CI-AC intervention regardless of their decision to participate. Estimates of the effect of "treatment on the treated" (TOT) can be obtained by dividing the ITT estimate by the participation rate in the CI-AC group.

In light of the expected sample sizes and the baseline 30-day readmission rate (17.9%) at UHCMC, a relative reduction of 12% (2.1 percentage points) can be established as statistically significant at the 5% level. This is a much smaller effect than prior research on the CTI has found (e.g. 30% in Coleman et al. 2006).

Quantitative methods (2)

Patient outcomes will be compared across the CI-AC and CI-RN groups. Standard statistical tests will be employed to evaluate covariate balance across the two groups. Other methodological details are identical to those discussed above. Our analysis will formally test the "non-inferiority" of the CI-AC intervention relative to the CI-RN intervention (Walker and Nowacki 2010; Schumi and Wittes 2011). As such, one-sided statistical tests will be employed under the null hypothesis that the CI-AC intervention is as efficacious (or more so) than the CI-RN intervention. Auxiliary analyses will test for differential effects at the level of individual coaches.

Along with patient satisfaction, clinical outcomes and medical costs, we will also estimate differences in completion rates for patient home visits and intervention phone calls. These intermediate outcomes could potentially explain differential effects observed across different patient groups (CI-AC versus CI-RN) or across different coaches.

Qualitative methods

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Qualitative interviews will be conducted with 14 subjects in the CI-AC group and 6 subjects in the CI-RN group. Subjects will be limited to those who were discharged to the community. Half of the subjects selected for interviews will be patients who had a readmission within 30 days of discharge. This approach is necessary to be able to understand the experiences of persons readmitted and not-readmitted in each of the two intervention arms. While purposefully stratifying the sample by subject characteristics at baseline is not possible because of the prospective, readmission-based design, we will attempt to match our selection of the not rehospitalized patients to the characteristics of the rehospitalized patients where possible by illness severity, race/ethnicity, gender and socioeconomic status using a quota sampling grid. There will be a total of 20 in-depth qualitative interviews.

Qualitative interviewers will be trained by Dr. Perzynski, and follow a semi-structured interview guide designed to elicit responses from participants that reflect upon their care and self management with a particular focus on understanding how the two types of care providers in the coaching intervention differed in their delivery of the intervention or in the effectiveness of patient self management learning and motivation. These interviews will be audio recorded and transcribed verbatim. For the 20 interview subjects, all telephone intervention sessions will also be audio recorded and transcribed verbatim.

Data from the qualitative interview transcripts and telephone intervention transcripts will be managed and analyzed using NVivo qualitative data analysis software. Dr. Perzynski will lead a team consisting of all study investigators in coding and analyzing the qualitative data. He will hold a training session which includes the coding and analysis protocol and collaborative coding of a practice transcript. We will use a thematic constant comparative approach in which sets of themes are identified in open coding and each occurrence of a theme is compared to all others in the text of the transcripts (Glaser 1965; Boieije 2002). Our approach is similar to the taxonomic approach described by Bradley (Bradley, Curry et al. 2007) in which theories are systematically developed by synthesizing inductive themes with deductive reasoning. First, all interview transcripts will be open coded. For example, if participants discuss problems getting to post-discharge doctor appointments, that text would be coded as "transportation barrier." Themes from the initial coding pass will be condensed and revised, and a coding dictionary will be developed. Another pass through the transcripts will search for each instance of each code in the coding dictionary. The consistency of the investigators in identifying themes will be calculated using an inter-rater reliability statistic such as Cohen's kappa. Incidence of

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coded themes will be compared across participant characteristics measured in the trial at baseline including illness severity, age, socioeconomic status, gender and race. A comparative conceptual map of readmission will be developed that illustrates the synthesis of our qualitative analysis.

WORK PLAN

Our work plan consists of three broad phases:

Project setup (Oct 1, 2015 -- Dec 31, 2015) -- coaches will be trained and procedures put into place to manage the assignment of patients to coaches.

Intervention period (Jan 1, 2016 -- Dec 31, 2017) -- intervention is delivered over this period.

Evaluation and dissemination (Jan 1, 2018 -- Sept 30, 2018) -- final nine months are reserved for analysis of quantitative and qualitative data, production of manuscripts, presentation of findings at scientific meetings, and other dissemination activities discussed below.

The study will have an ongoing monthly oversight, planning and evaluation meeting with the PI and investigators, along with the program manager. The program manager will be responsible for the day-to-day project management.

Dissemination Plan

From the breadth of this multi-disciplinary and mixed methods study, at least three manuscripts are expected, focusing on the following: (1) effects of the AC-CI intervention relative to usual case; (2) effects of the AC-CI intervention relative to RN-CI; and (3) qualitative assessment of patient experiences to identify mechanisms behind program effectiveness and opportunities for improvement. We will seek to have these manuscripts published in high profile medical, health services and/or health economics journals to reach a multi-disciplinary national and international audience of academics, practitioners and healthcare leaders. Results will also be presented at a number of professional conferences, such as AcademyHealth and the American Society of Health Economists (ASHE) conference.

With positive results from our study, we will aim for broad adoption of our coach training and collaboration with AmeriCorps model across the country. Specifically, beginning in the third year of

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the grant, and with grant funding from CNCS, we will be able to pursue several avenues of communication to academic medical centers to share our model and support program adoption. With AmeriCorps programs in 50 states, and personal behaviors accounting for 80% of healthcare costs (Gerteis 2014), there is potential for transformation of the U.S. healthcare system from partnership with AmeriCorps to deliver health behavior coaching.

To facilitate adoption of our program model, we'll:

1. Create an online toolkit. The toolkit will be freely available, materials sufficient to guide an academic medical center or other healthcare organization, in application to AmeriCorps, program creation, organization and management, and the training of service members as coaches.
2. Host a massive open online course (MOOC) through Case Western Reserve University where AmeriCorps members can receive the coach training at no cost. We have already begun exploring with the AmeriCorps program with the Camden Coalition of Healthcare Providers in Camden, NJ, training their coaches with our curriculum using Skype.
3. Partner with the American Association of Medical Colleges (AAMC) to convene medical educators to explore avenues for partnership with medical schools. We were recently awarded the AAMC Clinical Innovation award, and are presently discussing ways to collaborate.

Organizational Capability

We have assembled a team with strong and complementary expertise, and established working relationships. They will meet on a regular basis to oversee all aspects of the project management, ongoing intervention refinement, data collection, analysis, interpretation, and dissemination.

Mark Votruba, PhD: brings strong leadership, health services research, and economic evaluation experience to this project. As Principal Investigator, he will lead the team and supervise all aspects of the work from intervention implementation to data collection, analysis and dissemination.

Kurt Stange, MD, PhD: is a family physician/epidemiologist with more than two decades experience with quality improvement research and development. He is an internationally recognized expert in implementation science and in mixed qualitative and quantitative research methods. He will advise on all aspects of the project, particularly on the evaluation design and conduct, and analysis and

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dissemination of the findings.

Adam Perzynski, PhD: is an experienced social scientist with a strong background in mixed methods, qualitative and health services research. He will supervise training in qualitative data collection, and will lead the management and analysis of the qualitative data.

Nick Cohen, MD: has experience training volunteers in motivational interviewing and health coaching, having trained over 130 volunteers in this approach. He also has substantial on-the-ground experience with quality improvement projects. He has established collaborations to share the volunteer training curriculum for coaches with the Association of American Medical Colleges as recipient of an Clinical Innovation Challenge award, and with the AmeriCorps program at Camden Coalition of Health Care Providers. He will contribute significant time and effort to the dissemination of findings for this project. He will work under Dr. Votruba's supervision to manage the field work for the project, and will be involved in the analysis and interpretation of findings.

Stefan Gravenstein, MD, MPH: is an experienced health services researcher and quality improvement expert, having conducted clinical trials with over 1000 prospectively enrolled participants. He has extensive experience with large databases to prospectively follow large populations (over 50,000). He is experienced in training coaches for care transitions and monitoring coaching fidelity as described in this proposal. He has published over 140 peer reviewed papers and chapters, 12 related to care transitions.

Cost-Effectiveness and Budget Adequacy

The total request for the first year is \$299,614.90; \$299,339.98 for year two; and \$299,083.60 for year three.

Personnel costs consist of salary support for the investigator team, a research assistant, and (for two years) the salary of 1.0 FTE registered nurse. AmeriCorps members stipends and other costs of operating that program are part of the match.

Consultant costs include training in the CTI for the four RNs, professional transcription of audio recorded interviews, and development of an online toolkit for free public access to disseminate our training model.

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Travel costs include domestic travel for the RNs to attend CTI training, mileage reimbursement for coaches, and travel for the research team to present research at national meetings, as well as to provide direct in-person support by an investigator (NC) to other organizations implementing the program.

Other costs include stipends for patients who are interviewed, and photocopying of patient education materials.

Prior studies of the CTI estimated medical costs savings of \$3752 per participating patient (Gardner 2014). Assuming the CI-AC and CI-RN interventions yield comparable cost avoidance effects, this would imply potential savings totaling over \$6 million (1650 patients x \$3752), far exceeding the requested budget.

Executive Summary

A multi-disciplinary team of Case Western Reserve University researchers propose to evaluate the efficacy of a volunteer-led coaching intervention designed to reduce hospital readmissions. Nurse-led transition coaching have proven effective at reducing hospital readmissions and medical costs. However, diffusion of such interventions has been undermined by the scarcity of registered nurses and hospital cost pressures. Our intervention tests a task-shifting strategy for addressing this dilemma. If the role of "coach" can be effectively played by well-trained volunteers, it could allow for much wider diffusion of services that reduce medical costs and improve clinical outcomes. Building on our existing efforts to train AmeriCorps volunteers as transition coaches, we will examine the effects of a randomized volunteer-led coaching intervention on readmission rates, medical costs, and patient satisfaction. Approximately 1100 patients will receive the volunteer-led coaching intervention over the two-year intervention period of the project. Effects will be estimated relative to usual care ($N > 9000$), as well as relative to a similar nurse-led coaching intervention ($N \approx 550$) to test for potential inferiority of the volunteer-led intervention. Through qualitative interviews and thematic content analysis of intervention phone call recordings, we will explore possible mechanisms behind program effectiveness and identify opportunities to improve the training of volunteer coaches. Dissemination activities include creating an online toolkit to promote model adoption and hosting a MOOC to provide free coaching training to AmeriCorps volunteers. Findings of positive effects could motivate further initiatives and research on the role volunteer organizations could play to productively

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augment traditional medical providers in delivering cost-effective interventions.