

PRINCIPAL INVESTIGATOR (LAST, FIRST, MIDDLE): Shortell, Stephen M.

The Comparative Impact of Patient Activation and Engagement on Improving Patient-Centered Outcomes of Care in Accountable Care Organizations

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Study Protocol and Analysis Plan

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PCORI RESEARCH PLAN TEMPLATE

RESEARCH STRATEGY

A. Background

The Affordable Care Act (ACA) empowered the Center for Medicare and Medicaid Services (CMS) to create Accountable Care Organizations (ACOs) charged with being accountable for both the costs and quality of care for a defined group of patients. With CMS's recent approval of 123 additional shared savings ACOs, there are now more than 600 ACOs across the United States, both federal and private^{1, 2}. These organizations provide a unique opportunity to examine fundamental changes in how health care services are delivered. The ability of ACOs to succeed under the new payment models will depend importantly on a re-structuring of the doctor-patient relationship; particularly in regard to caring for patients with chronic conditions such as diabetes and cardiovascular diseases (CVD). Responsibility for patient care is increasingly being shared among members of primary care teams (physicians, nurse practitioners, physician assistants, pharmacists, nutritionists, nurses, and others) and, most importantly, involving patients and their families. In fact, engaged patients have been referred to as "...the blockbuster drugs of the 21st century"³.

The development of ACOs provides the opportunity to compare the effectiveness of practices within ACOs who are more highly involved in Patient Activation and Engagement activities (PA&E) with those less highly involved in regard to patient-reported outcomes of care, patient experience of care, and selected clinical measures. It also provides an opportunity to engage patients (a requirement of the ACA legislation) in the research and, in particular, in reviewing the results of performance feedback data on subsequent patient outcomes of care. Further, the national network of ACOs that has developed across the country and is likely to grow provides a platform to rapidly leverage and disseminate study findings. This will be further facilitated by our related ongoing research on ACO developments (Shortell, et al. 2014)⁴, physician practices (Shortell, et al. 2014)⁵, primary care practices (Rodriguez, Anastario et al. 2008; Rodriguez, von Glahn et al. 2013; Rodriguez, Giannitrapani et al. 2013)⁶⁻⁸ and patient activation and engagement (Shortell et al. 2014)⁹. Preliminary evidence from our patient-informed national web-based survey of PA&E activities in ACOs, presented in Table 1, suggests the potential for much greater involvement than currently exists. These findings underscore the importance and salience of the current proposal.

The central question that this proposal addresses is **whether patients with diabetes or CVD who receive care from primary care practices with high involvement in patient activation and engagement (PA&E) initiatives report better patient-reported outcomes (PROs), better experiences of care, and selected clinical measures (blood pressure, HbA1c, and LDL-C) compared to patients who receive care from primary care practices with low involvement in PA&E activities**. In addition, we will examine: (1) whether the impact of PA&E initiatives on outcomes is stronger for patients who score higher on the patient activation measure (PAM) than those who score lower¹⁰; and (2) whether the effect is stronger for patients who improve their PAM scores over time compared to patients who do not. We will also assess the characteristics of primary care teams in practices associated with both high and low involvement in PA&E activities in regard to the degree of coordination, perceived team effectiveness, leadership, and team culture that they exhibit. Finally, we will explore the impact of providing structured feedback to practices on the PRO, patient experience, clinical indicators, and teamwork assessment results to both practice teams and patient advisory groups on any improvement activities undertaken by the primary care teams. In the sections that follow,

Table 1. Preliminary Results of the Patient Activation and Engagement Survey (n=75 ACOs)

	Mean (SD)
Percentage of PCPs that have received training in PA&E methods and techniques	47.8 (30.7)
Percentage of PCPs that work with patients/families to develop a treatment plan that sets goals for their care	62.0 (29.6)
Percentage of ACO's high-risk chronic illness patients that participate in peer support groups or group visits	19.0 (18.9)
Percentage of PCPs that offer patients/families evidence-based decision aids (e.g., paper or online tools to help make informed choices among their options for treatment)	47.7 (30.5)
Percentage of ACO's that formally assess the health literacy level of patients/families	26.7%

we define each of these concepts, their specific measures, and the role they play in our overall logic model and research design. The definition of *patient activation* used throughout the proposal is the patient's understanding of their role in the care process and having the knowledge, skills, and confidence to take on that role. *Patient engagement* denotes a broader concept, which includes patient activation, the interventions designed to increase it, and the patient behaviors that result from it.

CRITERION 1 – IMPACT OF THE CONDITION

We will study patients with diabetes (ICD-9CM 250.XX) and/or CVD (ICD-9CM 393-459). Uncontrolled diabetes can result in high-cost complications including retinopathy¹¹, incident myocardial infarction (MI), stroke, congestive heart failure (CHF), and nontraumatic lower extremity amputation (LEA)¹², contributing to high health care expenditures in the United States¹³. These and related chronic conditions represent an estimated 75 percent of all U.S. health care expenditures¹⁴.

It is estimated that 26% of adults over age 18 have multiple chronic conditions (MCC) and this percent has increased since 2001. The prevalence of MCC significantly increases with age¹⁵. For adults over 65, as many as 85 percent suffer from one or more chronic diseases¹⁶. At least 18.8 million Americans have diagnosed diabetes. An additional 7 million people are estimated to be undiagnosed¹⁷. Diabetes is the sixth leading cause of death and is rising as a cause of mortality as well as in prevalence, with an annual total cost of \$245 billion for diagnosed cases¹⁸. Heart disease (which includes CAD and CHF among other conditions) affects about 26.5 million in the US while hypertension affects over 76 million Americans¹⁹. The cumulative death toll from CVD was nearly 600,000 deaths per year in 2010²⁰, with 715,000 heart attacks per year in the U.S.²¹ at an annual cost of \$108.9 billion for health care services, medications, and lost productivity²². Altogether, CVD accounts for 29 percent of all deaths in the U.S. No other group of chronic conditions imposes this level of impact on our population; however many people are still undiagnosed or untreated. Among those diagnosed and treated, levels of adherence to medication and lifestyle changes remain low and physicians often do not know how to better activate patients in clinical settings.

Diabetes represents one of the largest documented health disparities between Latinos and non-Latino whites²³ and Latinos often receive suboptimal treatment. For example, Latinos are less likely than whites to receive appropriate HbA1c and lipid screening^{24, 25} and are less likely to achieve treatment goals, including glycemic, cholesterol, and blood pressure control²⁶⁻²⁹. Since Latinos, African-Americans, and certain Asian sub-groups are more likely to have diabetes compared to whites, many studies have focused on developing and testing interventions to improve outcomes of diabetes care through patient activation and engagement among these vulnerable patient populations³⁰⁻³³. ACOs can play an important role in implementing PA&E initiatives that span clinical and community settings, including community health worker or health coach models for diabetes care management. The care of patients with diabetes and CVD presents many challenges for health care delivery systems³⁴. Knowledge is emerging on how to better care for patients with these conditions, but little is known about how patients can be better activated and engaged in their own care and what health care providers and care teams can do to promote such engagement and with what results. This proposal directly addresses these issues.

B. Significance

CRITERION 2 – ATTEMPTS TO IMPROVE HEALTH CARE AND OUTCOMES

It is increasingly obvious that to improve patient outcomes and experience of care will require enhanced PA&E³⁵. There is a small but growing literature suggesting that more activated patients experience better health outcomes³⁶⁻⁴⁰. But much less is known about how to accomplish this^{41, 42}. For example, national data on trends between 2008 and 2012 indicate essentially no change in the percentage of patients with blood pressure under 140/90, the percentage of heart care patients with LDL-C < 100, the percentage of diabetes care patients with LDL-C < 100, and the percentage of patients with diabetes who have blood pressure under 130/80 and HbA1c under 9 percent⁴³. We recognize that for patients with diabetes over age 85 that strict adherence to these numbers is controversial and therefore we will exclude patients over 85 from this study.^{44, 45} In addition, almost no systematic data are available on patient-reported outcomes of care in terms of physical and social functioning and related dimensions. Patients often struggle to live their lives while adhering to multiple medications, experiencing side effects, and trying to change behaviors such as smoking, diet, and physical activity. The results from this research will provide important knowledge and guidance for others, particularly in regard

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to what health care organizations and teams might do to strengthen their PA&E efforts and the impact on measures of most interest to patients.

SPECIFIC AIMS

Based on the above discussion, the specific aims of the study are outlined below:

- 1) To answer the question: Do patients with diabetes and CVD receiving care from practices with higher versus lower PA&E activities have better patient-reported outcomes (PRO) of care, patient experience, and clinical outcomes?
- 2) To answer the question: Is the relationship of PA&E activities and improved PROs stronger for more highly activated patients than for less activated patients at baseline?
- 3) To assess the stability of the PA&E-outcome relationship over two measurement periods at the individual- and practice-level.
- 4) To assess changes over time in patient-reported outcomes of care, patient experience, and clinical measures, as a function of changes over time in PA&E activities and patient activation.
- 5) To explore key capabilities of practice teams that might account for their greater involvement in PA&E activities and the resulting impact on outcomes of care.
- 6) To assess the extent to which patient and practice team feedback was used and can help explain patient outcome changes over time.

CRITERION 4 – PATIENT CENTEREDNESS

We will include patients and caregivers at the front end of the study, as well as gather ongoing input from them throughout the study. The vehicle for this will be patient advisory groups in each of the ACOs under study. We will either build on existing advisory groups at a site (where one exists) or ask sites to form new advisory groups to aid in finalizing study instruments, interpreting survey results, and providing feedback to practices on their PA&E activities. While we will encourage a participatory approach that includes patient input, because we are interested in pragmatic approaches, we will allow patient advisory structures to be tailored by each site. In order to understand those differences, we will monitor how frequently the advisory groups meet, what they prioritize and discuss, and the actions they take; and we will use meeting minutes and one-on-one interviews with patient advisory group members during site visits to assess their awareness and nature of involvement in PA&E initiatives. This will include learning about their experiences of their advisory roles, convenience and usefulness of patient advisory group meetings, perceived importance of involvement in the research project, including practice feedback on the research surveys and related issues. A central role of patient advisory groups is to review the study measures and proposed study design in the first few months of the project and then to meet 2-3 times annually to provide ongoing project input, to review round one measurement results, and to suggest how those results might inform the ACO practices' ongoing PA&E improvement efforts.

The primary purpose of the proposal is to directly address patient-centeredness of care by comparing practices with high involvement in PA&E activities versus those with low or no involvement in regard to PRO and relevant clinical measures.

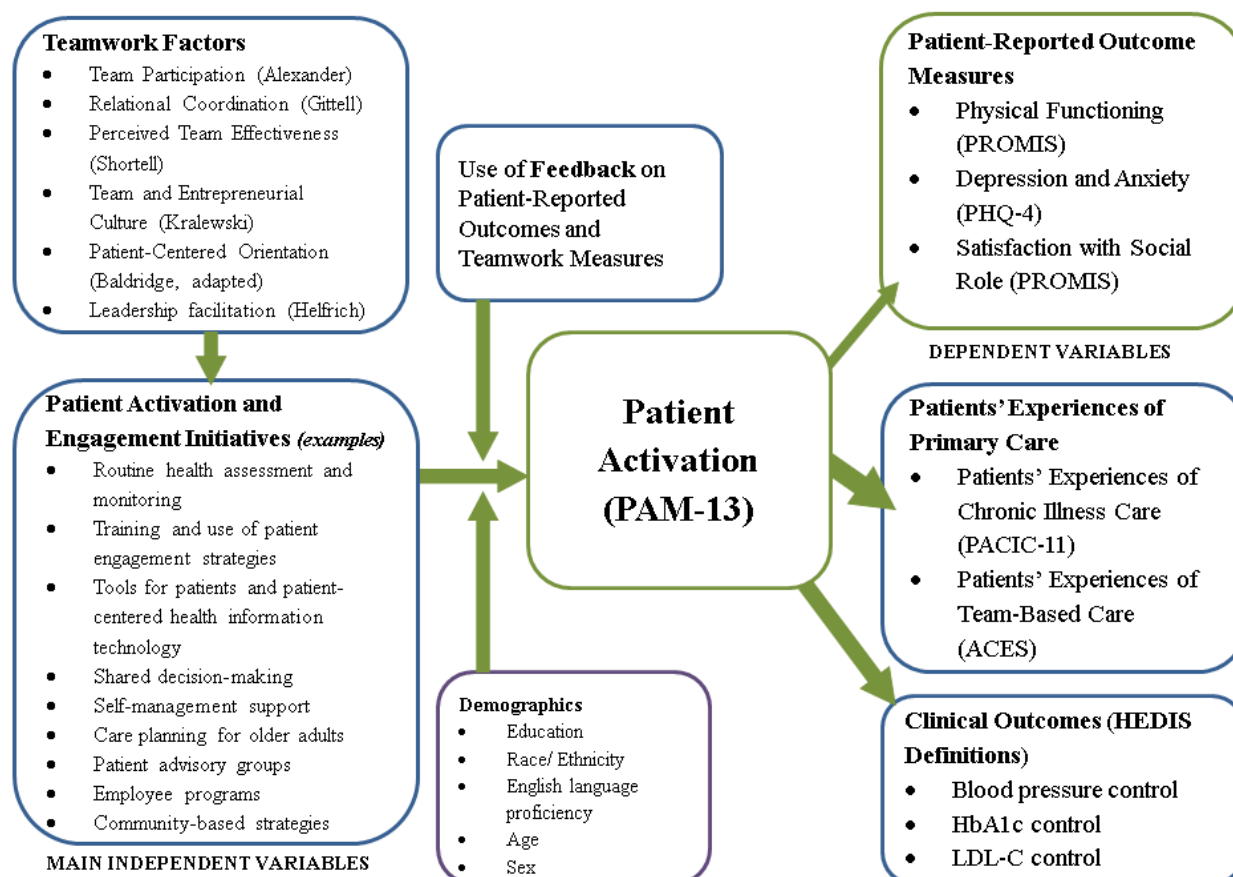
C. Study Design or Approach

RESEARCH PLAN

The logic model and conceptual framework figure on the following page (see Figure 1) provides the basis for the research design and analytic plan.

We posit that practices that have more highly developed PA&E and better teamwork will more effectively activate patients with diabetes and/or CVD. In turn, we posit that more highly activated patients will be more likely to achieve improvements on patient-reported outcomes, patient care experiences, and clinical measures over time compared to less activated patients. We also will also examine the roles that patient advisory groups and primary care team use of performance feedback data play in influencing improvements in patient activation and outcomes of care over time.

Figure 1. Logic Model



We will engage patients and primary care practice teams within two accountable care organizations (ACOs). In each ACO, we will randomly select eight practices: four who score high on PA&E activities and four who score low. We will survey practice team members twice: once at baseline and one a year later. We will also conduct two site visits: one near the beginning of the study and one during the 13-18 month period of the study.

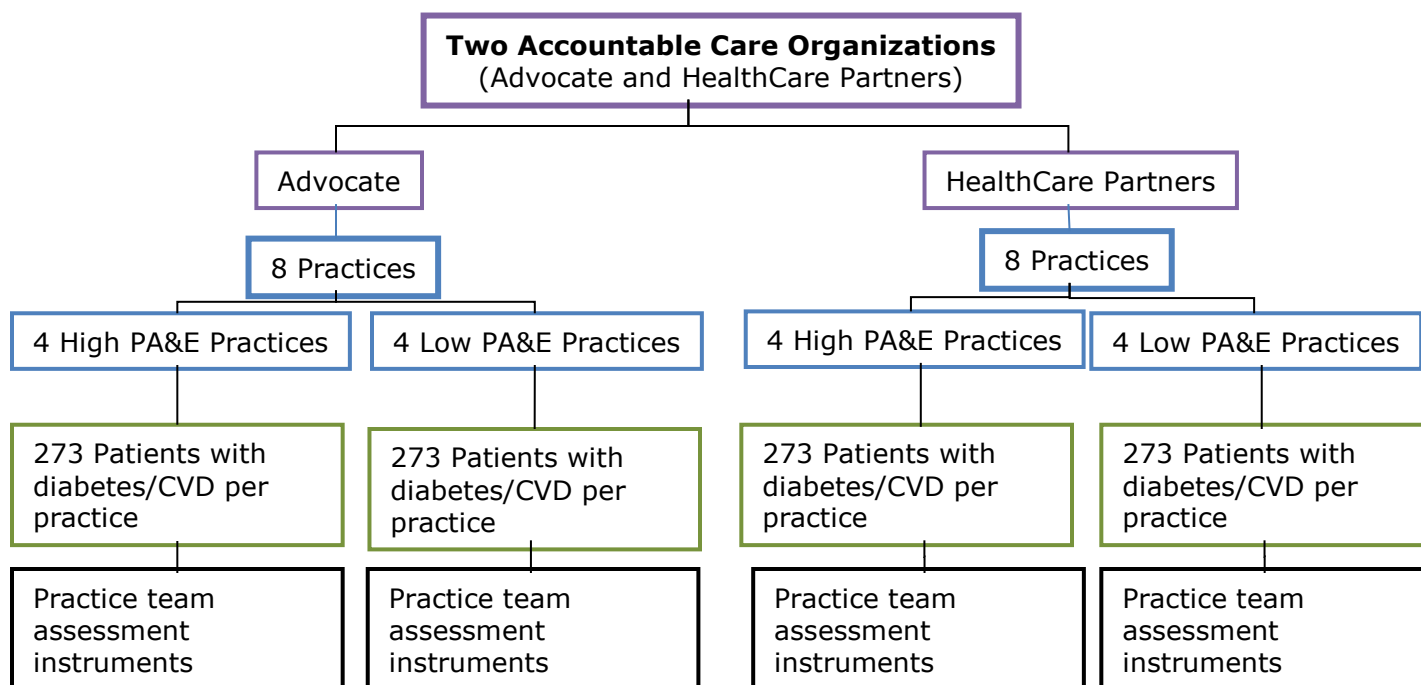
We will randomly select four high and four low PA&E sites within each ACO using a broad definition of PA&E activities including: (1) patient care outreach in regard to disease prevention and health promotion; (2) changes in the clinician-patient relationship, particularly in the areas of communication, motivational interviewing, and patient involvement in treatment care plans; (3) shared decision-making; (4) patient self-management of their condition(s); (5) end of life/advanced serious illness care patient engagement and family involvement; and (6) patient involvement in the overall design of care and in organization-wide efforts to improve the quality of care. See methods section for a description and Appendix I for an example of the instrument to be used for determining the “more highly involved” and “less highly involved” practices.

We will randomly select 273 patients with diabetes and/or CVD from each of the 16 practices. Given the 16 practice sites, we will have data from 4,368 patients. We will follow them as cohorts over a two-year period. See Figure 2 below for selection design. Patients will complete the 13-item PAM measure, patient-reported outcomes (PROMIS), and experience of care measures between 7-12 months and again between 19-24 months. We will obtain measures of blood pressure, HbA1c and LDL-C at 12 months and 24 months from the EHR. We expect a 50% response rate to the first survey round and 65% response rate to the second survey round, with 3% undeliverable and 20% attrition over the two-measurement period, leaving 1102 patients, or 69 patients per practice, available for analysis. The calculations provided

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below for the PROMIS self-reported measures and for blood pressure provide evidence of sufficient statistical power to detect meaningful differences between practices on these key variables of interest.

Figure 2. Selection and engagement of ACO practices, patients, and teams



Study Sites

Advocate Health Care (Advocate) and Advocate Physician Partners (APP) operate both a commercial and a Medicare ACO. In 2011, Advocate joined with its largest commercial insurance partner to create AdvocateCare, providing care to 370,000 covered lives. In 2012, Advocate was chosen to participate in the Medicare Shared Savings Program (MSSP), becoming one of the largest Medicare ACOs in the country, serving an estimated 106,000 Medicare beneficiaries.

HealthCare Partners ACO (HCP) was formed in 2010 as one of the early Dartmouth-Brookings demonstration ACOs⁴⁶. They hold both CMS and private payer risk-based contracts collectively accountable for 50,000 lives. They serve high proportions of Medicaid patients in low-income communities who tend to face many social and financial barriers to self-management in care for diabetes and CVD. Approximately 55% of HCP's Southern California patients are Latino. Table 2 compares key characteristics of the partnering ACOs. Both Advocate and HCP are highly committed to this study as indicated by their letters of support and related materials in this proposal.

Table 2. Summary of key characteristics of the two participating ACOs

	Advocate ACO	HealthCare Partners ACO
ACO Established	MSSP: July, 2012 AdvocateCare (Commercial): 2011	MSSP: January, 2014 Cigna (Commercial): April, 2013 Anthem (Commercial): July 2013
Location	Illinois	Senior ACO (MSSP): CA, FL, NV Commercial ACO: Greater Los Angeles, CA, NV (Cigna)
Patient population	MSSP: 106,000 Commercial: 370,000	Senior (MSSP): 56,689 Commercial: 65,739
ACO Contract Lives	MSSP: 106,000 Commercial: 370,000	Senior (MSSP): 56,689 Commercial: 65,739

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Patient Race/Ethnicity	<ul style="list-style-type: none"> 57% Non-Latino White 22% African American 8% Latino 5% Other/multi-racial 3% Asian/Filipino 1% American Indian/Alaska Native 1% Middle East 1% Eastern Indian 2% Unknown/Declined 	<ul style="list-style-type: none"> 55% Latino 25% Non-Latino White 15% Asian/Pacific Islander 10% African-American 	CLINIC/PRACTICE SELECTION <p>Advocate ACO and HealthCare Partners ACO have 150 and 69 primary care practice sites, respectively. Using the list of PA&E activity domains previously described (see Appendix I for a draft of the checklist instrument), we will randomly select four practices from each ACO that score in the top quartile of the PA&E activities and four practices from each ACO that score in the bottom quartile. This will maximize the difference between those practices with high involvement and those with little or no involvement.</p>
Payer Mix	<ul style="list-style-type: none"> Commercial: 70% Medicare Advantage: 5% Advocate Employee: 5% Medicare ACO: 20% 	<ul style="list-style-type: none"> HCP commercial: 68% HCP Medicaid: 13% HCP Senior: 19% 	
ACO Risk Arrangement	<ul style="list-style-type: none"> Shared savings (no risk) 	<ul style="list-style-type: none"> Shared savings (no risk) 	
Why Selected?	<ul style="list-style-type: none"> Named among the nation's Top 5 largest health systems based on quality by Truven Analytics, Largest health system in Illinois and one of the largest health care providers in the Midwest. Operates more than 250 sites of care, including more than 150 primary care sites and 12 hospitals that encompass 11 acute care hospitals, the state's largest integrated children's network, five Level I trauma centers (the state's highest designation in trauma care), two Level II trauma centers, one of the area's largest home health care companies, and one of the region's largest medical groups. Advocate Health Care trains more primary care physicians and residents at its four teaching hospitals than any other health system in the state 	<ul style="list-style-type: none"> Large, well-developed, well-established integrated delivery system with group and IPA models representative of American health care (69 primary care sites). 30+ yrs of integrated care and health delivery experience and refinement: directly/indirectly aligns with IHA's Triple Aims. Diverse patient populations with wide arrays of cultural/socioeconomic backgrounds and varying ranges of health status. Innovative use of patient-centric health /wellness programs coupled with technology. Robust data warehouse. Broad dissemination of best practices nationally. 	HEALTH CARE TEAM SELECTION <p>We define the membership of primary care teams based on administrative designations of team membership. Based on our preliminary data, we expect a varying number of care teams up to a total of approximately 160 teams from the 16 practice sites. Within each of the practices, we will randomly select</p>

patients from teams with sufficient patients with diabetes and/or CVD diagnoses to equal the 273 patients with diabetes and/or CVD diagnoses. While the statistical analysis will be at the practice level, we will provide team-level scores to the practices for their use.

PATIENT SELECTION

To project the sample size requirements given 16 practices (8 high PA&E and 8 low PA&E), we estimated the design effect (DE) to account for the clustering of patients within practice sites. While PROMIS data from participating ACO patients are presently unavailable, recent studies of change over time on the PROMIS physical functioning measure informed our sample size estimates for the PROMIS measure⁴⁷. Having been selected using item-response theory (IRT) methods and extensive testing, the PROMIS physical functioning measure is a precise measure that is sensitive to small changes in physical functioning over time. Given the published estimates and a range of design effect estimates (intraclass correlation (ICC)=0.01-0.04) to account for the clustering of patients within practices, a clinically meaningful change (e.g.,

a 3-5 point change out of 100) on the PROMIS physical functioning measure can be detected with 50-65 patients per practice. Based on prior experience, we expect a minimum 50% response rate for completing the first patient survey and a 65% response rate for the second survey. We expect a 3% rate for undeliverable addresses and a 20% drop-out rate between the two survey periods based on our previous research. Patient-level blood pressure data from adult diabetic patients at HCP ACO practices were used to calculate the design effect ($ICC=0.01-0.02$). Previous research suggests that population-level improvements in blood pressure on the order of 3-5 mm Hg are clinically meaningful⁴⁸⁻⁵⁰. Based on a two-sided difference of means with a power of 0.90, we estimate that an average of 140 patients per practice are needed to detect a 3 mm Hg difference in change in systolic blood pressure over time between the high ($n=8$) vs. low ($n=8$) PA&E practices. Based on these calculations, we will randomly select 273 patients per practice ($n=4,368$) with diabetes or CVD diagnoses from each of the practice sites and teams in the two ACOs for inclusion in the study. Given the assumptions of response rates and attrition noted above, this will yield a final total of 1102 patients with two time points for analysis of the PROMIS (69 patients per site). In addition we expect to receive retrospective clinical outcomes data from the EHR for most of the sampled patients ($n=4,368$). Thus, even with slightly lower than expected survey response rates, our study will be sufficiently powered to detect clinically meaningful differences between high and low PA&E practices on both patient-reported (PROMIS) and clinical, e.g., blood pressure, outcome measures.

MEASURES

Measurement of Site PA&E Activities

We will categorize the more than 150 Advocate ACO primary care practice sites and the 69 HCP ACO practice sites as high vs. low PA&E involvement based on a brief 40-item practice assessment of the six domains of PA&E activities (see Appendix I). This list was developed in consultation with a National Advisory Committee to our study of ACO involvement in PA&E and the preliminary results of the survey (see page 2) supported by the Gordon and Betty Moore Foundation. This checklist instrument, including measures of the degree of implementation, will be completed by the person most knowledgeable about each practice's PA&E activities. Based on past experience this will be the Chief Medical Officer or Quality Improvement leader. Each of the ACOs practices will be categorized into quartiles based on their overall PA&E score. We will then sample practices for involvement from the top and bottom quartiles to finalize four highly involved PA&E practices and four low involved PA&E practices within each of the two ACOs for engagement in the research study.

Patient Activation (PAM)

We will use the 13-item PAM Measure (Hibbard et al, 2005 – see Appendix II)¹⁰ This short form has similar psychometric properties to the longer 22-item form with Rasch overall person reliability of 0.81 and .79 for patients with diabetes and .82 for patients with CVD. Patient activation has been associated with positive health behaviors such as aerobic exercise and receiving preventive cancer screenings, as well as more favorable emotional health.⁵¹⁻⁵³ The summed response scores are then categorized into a 4-part ordinal variable, representing activation levels. The levels of activation are similar to the Transtheoretical Model, where individuals progress through stages before changing their behavior, such as quitting smoking.⁵⁴ Individuals are thought to move through these stages of activation sequentially, although stages may change with time and stressful circumstances can lower patient activation.^{51, 55} An individual in the lowest level of activation is a passive participant in health care decisions. An individual in the second level of activation has the knowledge and confidence to take a more active role in their health care, but has not yet acted on it. In the third level of activation, the patient plays an active role in making health care decisions with their providers. The highest level of activation describes a patient who has the knowledge and confidence to take action about their own health care, even during times of stress⁵⁵. We will assess the extent to which practices with high PA&E activities and high team functioning more effectively transition patients to higher levels of activation over time.

Patient-Reported Outcome Measure – PROMIS Physical Functioning and Social Functioning

The PROMIS Physical Functioning (Short Form 12a) and Social Functioning (Short Form 8a) will be used to measure patient reported outcomes of care (See Appendix II). We will also include the depression and anxiety measures (PHQ-4). The PROMIS instruments were developed through extensive psychometric testing, have been extensively studied and validated, with reliability coefficients in the range of 0.85-0.95 for the physical functioning measure⁴⁷ and 0.85-0.94 for

the social functioning measure⁵⁶. Previous research indicates that the estimated minimally important difference for the PROMIS physical functioning is about 0.20 (small effect size) of the baseline standard deviation⁵⁷.

Patient Reported Outcome Measure – PACIC-11

The Patient Assessment of Chronic Illness Care scale (PACIC-11) developed and validated by Glasgow et al⁵⁸ (Medical Care, 2005; see Appendix II) will be used to assess the extent to which practices engaging in more PA&E activities and with higher team functioning will be able to effectively improve patients' experiences of chronic illness care over time. The PACIC-11 has high Cronbach's alpha internal consistency, reliability of 0.93, and reasonable test-retest reliability of 0.58. It also demonstrates convergent validity with the Hibbard PAM measure and several dimensions of the Ambulatory Care Experiences Survey (ACES), the precursor to the Clinician Group Consumer Assessment of Healthcare Providers and Systems (CG-CAHPS) survey (Rodriguez and Crane 2011)⁵⁹. We will supplement the PACIC-11 with selected items from the Ambulatory Care Experiences Survey (ACES) focused on patients' experiences of primary care teams (Rodriguez, Rogers et al., 2007)⁶⁰. (See Appendix II)

Clinical Measures

Based on each site's EHR, we will have de-identified data for blood pressure, lipids, and HbA1c to measure percentage of hypertensive patients with blood pressure controlled (<140/90 mm Hg), percentage of patients with diabetes with blood sugar controlled (HbA1c <8.0%), and percentage of patients with cardiovascular conditions or diabetes whose lipids are controlled (LDL-C <100 mg/dL). The patient survey sampling frame includes "established" patients of each primary care physician and team. The adult diabetic and CVD patients will need to have at least two primary care visits in the baseline year (2013) to improve the reliability of reports of patients' experiences of care and to focus on an established patient population that has a high propensity to maintain clinical relationships and receive routine primary care over time. Since attribution of patients to practices and PCPs is a contentious issue in performance measurement in improvement^{61, 62}, restricting the sample to patients with diabetes and/or CVD who have ongoing relationships will also aid in team acceptance of the feedback data.

Patient Demographics

We will collect patient demographic information as part of the patient surveys, including patient age, sex, race, ethnicity, self-rated English proficiency, preferred language, interpreter use, employment status, marital status, education, and military status. We will supplement these survey data with information about patient age and sex from ACO clinical and sociodemographic data submitted to Berkeley as part of the project.

TEAMWORK ASSESSMENT INSTRUMENTS

Primary care team members from each of the 16 practices will complete the following instruments that we refer to as "teamwork assessment instruments." These are: (1) team culture, (2) team leadership, (3) relational coordination, and (4) perceived team effectiveness. These will be completed at baseline (0-3 months) and then again at 18 months. Implementation of the teamwork assessments will be overseen by a data coordinator at each ACO paid in part by the grant.

An important component of the project is to provide primary care teams and patient advisory groups with feedback on their patient's reports of physical functioning, social functioning, and experiences of primary care. As primary care practices embark on integrating new roles and responsibilities for non-physician clinicians and staff for improving patient activation and engagement, supportive practice environments that foster organizational learning and effective teamwork are essential.^{63, 64} Providing primary care teams with performance feedback on patient-reported outcomes, patient experience, and clinical quality of care measures is one important way of fostering a shared responsibility for patient care among interdisciplinary members^{65, 66} and supporting a measured approach to team performance improvement efforts.⁶⁷ When teams do not receive feedback on their collective work, members often encounter difficulties working together to modify existing workflows and procedures^{68, 69}. Consequently, team feedback on patient experience and PRO data and teamwork assessment can aid primary care teams in their process improvement efforts. The limited amount of performance feedback available to primary care teams on their patients' experiences and patient-reported outcome measures⁷⁰ can have important downstream consequences for patient care, including less patient-centered clinician-patient communication and self-management support.

Team Composition Assessment

There is not a “gold standard” for defining the membership and boundaries of health care teams. In addition to administratively-defined teams (what managers perceive to be the boundaries and membership of primary care teams), we will elicit team membership and boundaries from frontline clinicians and staff. We will ask members to state who they consider to be members of their team. This will enable us to consider differences in team composition and membership in interpreting our teamwork survey results and related measures. We will collect data on team member age, sex, race/ethnicity, current position, years working in the practice and then on the team, and hours worked per week in the practice setting.

Team Relational Coordination

This is a seven-item measure developed by Gittel et al⁷¹ and has been used in several studies of surgical teams, primary care practices and other settings. The items covered include: 1) extent of shared goals and values among team members, 2) extent of shared information and knowledge, 3) extent of mutual respect, 4) accurate communication among members, 4) timely communication among members, 5) frequency of communication among members, and 6) extent of problem-solving communication among members. It has known reliability with internal consistency of 0.80. (See Appendix III)

Team Participation

Engaging lower status primary care team members in taking on new roles and responsibilities to support patient activation and engagement is critical to practice redesign. We will use a validated seven-item scale developed by Alexander, et al. (2005)⁷² with internal consistency reliability of 0.90 which has been found to be positively associated with better outcomes of care. (See Appendix III)

Team Effectiveness

We will use select survey items from the Organization and Management of Intensive Care Unit study (Shortell, 1991)⁷³ and from the Improving Chronic Illness Care (ICICE) study (Shortell, 2004)⁷⁴ as well as the adapted Baldrige Quality Improvement Scale (Shortell, 2004)⁷⁴. These instrument components have high reliability with Cronbach’s alpha of 0.76, 0.95, and 0.86, respectively.

Group and Entrepreneurial Culture of Practices

We will assess culture at the practice level using two domains of the Group Practice Organizational Culture instrument⁷⁵, which focus on measuring the group and entrepreneurial culture orientations of teams. We posit that teams with more group and entrepreneurial oriented cultures will be associated with greater patient activation and engagement initiatives, patients that are more activated, and patients that will experience better outcomes of care. (see Appendix III)

Leadership Facilitation

We will use a seven-item subscale of the Organizational Readiness for Change (ORCA) to measure the extent to which team members believe that leadership and management supports them in their work to improve care for patients. It has an internal consistency reliability of 0.94 and has been used in previous studies assessing leadership facilitation of team and practice redesign⁷⁶⁻⁷⁸. (See Appendix III)

Feedback and Site Visits

We will work closely with the practice leaders and patient advisory groups in designing and developing feedback reports for the primary care teams. Some approaches which will be considered include^{65, 66}: 1) whether results are presented in a blinded or unblinded fashion, 2) how the information is delivered to the team, 3) facilitation and guidance for teams as they discuss their results, and 4) a system for disseminating best practices among teams within a practice site. We posit that practices with high teamwork assessments at baseline will be much more likely to undertake process improvements after receiving feedback on PROs and teamwork compared to practices with low teamwork assessments at baseline.

The data collected as part of the stakeholder engagement process, patient assessment, and teamwork assessments will be supplemented by two site visits to each of the two ACOs at two points in time to gain an insight to the strategic goals of the ACOs in improving patient activation and engagement and fostering high functioning interdisciplinary primary care teams: (1) during the 0-6 month start-up phase of the study, and again (2) during the period of 18-24 months. The purpose of these site visits is to obtain a detailed, nuanced understanding of the barriers and facilitators to improving PA&E initiatives and activating patients; to help enrich our understanding of the quantitative analysis; and to develop guidelines for others to significantly advance their PA&E efforts. We will interview practice leaders, primary care team members, patient advisory group members, and patients to get their views on the above issues. The semi-structured interview instruments that we will use will be guided by the interview guides and survey currently being used in our preliminary study of ACO PA&E activities (Shortell, et al., 2014)⁹. For example, we will ask questions about the frequency of meetings, the topics and issues discussed, which aspects of the feedback reports they found most useful, the challenges and lessons learned, what actions were taken as a result, their satisfaction with their engagement in the study, and their suggestions for improvement.

ANALYSIS SECTION

Aim 1. To assess whether patients with diabetes and CVD diagnoses receiving care from practices with higher versus lower PA&E activities have better patient-reported outcomes of care, patient experience, and clinical outcomes.

Analyses Addressing Aim 1. At each of the two cross-sections for the patient and teamwork assessment surveys, we will clean the data, examine their distributions, and conduct psychometric analysis to assess the reliability and validity of the measures. After composite variables have been constructed and properties assessed, we will examine the cross-sectional relation of PA&E activities, teamwork assessment results, and patient survey results. Using a dichotomized variable derived from baseline responses to the PA&E Practice Site Assessment Survey (see Appendix I), we will categorize sites as “high” or “low” PA&E based on the response distributions in our data. We will then assess association of key measures in two stages. In the first equation, using linear regression models, we will examine the PAM as a function of high vs. low PA&E (site level), controlling for practice size, and for patient casemix adjustment variables previously used in research that has compared organizations on patient experience and clinical quality measures^{79, 80}. Casemix factors to be considered include age, sex, educational attainment, and comorbid health conditions. We will then examine the patient reported outcome (PRO) measures, patient experience (PE) and the clinical measures as a function of the PAM, PA&E level (at site level), practice size, and casemix using multilevel regression models to account for the clustering of patients within practices. The simplified equations are:

$$PAM = Hi / lowPA \& E + PracticeSize + Casemix + \varepsilon$$

$$PE = Hi / lowPA \& E + PAM + PracticeSize + Casemix + \varepsilon$$

$$PRO = Hi / lowPA \& E + PAM + PracticeSize + Casemix + \varepsilon$$

$$ClinMeasures = Hi / lowPA \& E + PAM + PracticeSize + Casemix + \varepsilon$$

Aim 2. To assess whether the relation of PA&E activities and better PROs and clinical outcomes is stronger for more highly activated patients than less activated patients at baseline.

Analyses Addressing Aim 2. To address the extent to which PA&E activities conducted by the practice are more influential in improving PROs and patient experience among patients with high PAM levels at baseline, we will extend the Aim 1 analyses. Specifically, we will use multilevel regression with site random effects to model changes in PROs and the clinical measures over time as a function of baseline PAM scores, practice size, patient casemix, PA&E, and then by interacting PA&E and the PAM scores. The simplified equations are:

$$PE = Hi / lowPA \& E + PracticeSize + PAM + PA \& E * PAM + Casemix + \varepsilon$$

$$PRO = Hi / lowPA \& E + PracticeSize + PAM + PA \& E * PAM + Casemix + \varepsilon$$

$$ClinMeasures = Hi / lowPA \& E + PracticeSize + PAM + PA \& E * PAM + Casemix + \varepsilon$$

We will explore differences between the two extreme PAM categories (level 1=lowest activation, 4=highest activation) in addition to examining the continuous PAM measures, as we expect the biggest differences over time differences in PRO and patient experience between patients with highest and lowest baseline PAM scores.

Aim 3. To assess the stability of the PA&E-outcome relationship over two measurement periods at the individual and practice-level;

Analyses addressing Aim 3. After both waves of data collection are completed, we will assess the consistency of the results at two levels- patient-level and practice-level. We will compare the regression coefficients for models at each wave to examine differences in associations of the independent variables with outcomes at each cross-section.

Aim 4. To assess changes over time (T1 vs. T2) in patient-reported outcomes of care, patient experience and clinical measures, as a function of changes over time in PA&E activities, patient activation, controlling for patient casemix.

Analyses Addressing Aim 4. We will integrate the patient survey results and the patient level results at the practice level. We will examine ‘over time’ effects using three approaches: 1) multilevel regression with interaction term as specified here, 2) stratified by low vs. high PA&E practices and looking at coefficient differences, 3) lagged regression (using T1 to predict T2) vs. change in T1 and T2 predicting T2), etc. The simplified equations below provide a multilevel framework for studying the impact of site PA&E activities on patient activation, patients’ experiences, and patient-reported outcomes over time:

$$\Delta PRO = \Delta PA \& E + \Delta PAM + \varepsilon$$

$$\Delta PE = \Delta PA \& E + \Delta PAM + \varepsilon$$

$$\Delta ClinMeasures = \Delta PA \& E + \Delta PAM + \varepsilon$$

Given the uncertainty in distribution and variation, we will examine the inclusion of other relevant predictors including fixed effects for casemix and practice size.

Aim 5. To explore key capabilities of practice teams that might account for their greater involvement in PA&E activities to engage patients and the resulting impact on outcomes of care;

Analyses Addressing Aim 5. For these exploratory analyses, we will use a range of analytic techniques to assess the extent to which changes in team factors impact changes in PA&E activities, including multilevel regression modeling of the quantitative study data and comparative case study analyses of the multiple data sources. For example, we will triangulate the quantitative results with site visit data about the changes to PA&E activities, including treating PA&E as a continuous variable (0 to 40 on our index of activities) occurring at the practices that might explain increases or declines in the outcome measures and primary care teamwork.

$$PA \& E = Team + PracticeSize + Casemix + \varepsilon$$

We will explore an overall teamwork composite, but will also examine differences in effect sizes using the various team subscales assessed in the survey (e.g., relational coordination, team participation, team culture).

Aim 6. To explore the team feedback process to assess the extent to which feedback was used and could explain changes in team-related influences over time.

Analyses Addressing Aim 6. We will use comparative case analyses to compare data feedback processes and teamwork factors at the 16 practices as they relate to improvements in PROs and patient experience over time^{81, 82}.

PRINCIPAL INVESTIGATOR (LAST, FIRST, MIDDLE): Shortell, Stephen M.

CRITERION 3 – TECHNICAL MERIT (Also see Research Plan and Analysis Plan under Section C. Study Design or Approach.)

D. Project Milestones

Table 3. Project Milestones and Timeline

0-6 months	7-12 months	13-18 months	19-24 months	25-30 months	31-36 months
Wave 1 PA&E Survey Finalize enrollment of practice sites	Site feedback on wave 1 PA&E survey		Wave 2 PA&E Survey	Site feedback on wave 2 PA&E survey	
Patient identification and selection	Wave 1 Patient survey: - Patient Activation Measure (PAM) - Patient-reported outcomes (PROMIS) - Patient experience Retrospective clinical measures from EHR (BP, etc.)	Feedback results of wave 1 Patient Survey and clinical measures to practices	Wave 2 Patient survey: - Patient Activation Measure (PAM) - Patient-reported outcomes (PROMIS) - Patient experience Retrospective clinical measures from EHR (BP, etc.)	Feedback results of wave 2 Patient Survey and clinical measures to practices	
Completion of teamwork assessment instruments	Feedback to practices results of teamwork assessments	Completion of teamwork assessment instruments	Feedback to practices results of teamwork assessments	Feedback overall results to the ACO practices	
Site Visit #1			Site Visit #2		
Formation of patient Advisory Groups	Feedback of teamwork assessment to patient advisory groups	Feedback of patient survey and clinical data to patient advisory groups	Feedback of teamwork assessment to patient advisory groups	Feedback of patient survey and clinical data to patient advisory groups	
	Project deliverables on results to date	-Integration of baseline patient sources (patient survey and clinical data) and practice data sources (PA&E and teamwork results) Analysis of Wave 1 data	Project deliverables on results as of 24 months	Integration of baseline patient sources (patient survey and clinical data) and practice data sources (PA&E and teamwork results) Analysis of Wave 2 data and over time changes, report writing, and development of papers for publication etc.	

E. Patient Population

DIVERSE STUDY POPULATION

As described in Table 2 above, both HCP and Advocate ACOs serve a diverse patient population. HCP's patient population includes 55% Latino, 15% Asian/Pacific Islander, 10% African American, and 25% non-Latino white patients. Between its Medicare Shared Savings and commercial ACOs, its payer mix is 18.5% Medicare, 13% Medicaid, and 68% commercial. Advocate's large patient population includes 22% African American, 8% Latino, 3% Asian, as well as 1% each American Indian/Alaska Native, Middle East, and Eastern Indian. Its payer mix is 70% commercial, 25% Medicare, and 4% employee. Thus the proposal provides an opportunity to examine the extent to which PA&E activities may need to be customized to meet the needs of diverse populations.

F. Research Team and Environment

RESEARCH TEAM EXPERTISE

Stephen Shortell, PhD, MPH, MBA (Principal Investigator)

The PI Stephen M. Shortell, PhD, MPH, MBA, is the Blue Cross of California Distinguished Professor of Health Policy and Management and Director of the Center for Healthcare Organizational and Innovation research (CHOIR) at UC Berkeley's School of Public Health. He and his colleagues have received many awards for their research and he is an elected member of the Institute of Medicine of the National Academy of Sciences. He has extensive experience in managing large-scale studies over time and he also has extensive knowledge of accountable care organizations (which serve as the context for the proposed study). As PI he will be responsible for all aspects of the proposal and will play a lead role in measuring PA&E activities, team assessment analysis and analysis related to the six aims. He will be the primary liaison to Advocate Health System and will participate in site visits.

Hector Rodriguez, PhD, MPH (Co-Investigator)

Hector Rodriguez, PhD, MPH, is Associate Professor of Health Policy and Management and Associate Director of the Center for Healthcare Organizational and Innovation Research (CHOIR) at the University of California, Berkeley, School of Public Health. His expertise is in organizational analysis and performance measurement, particularly as it relates to ambulatory care and health care disparities. His current delivery systems research focuses on organizational interventions aimed at improving ambulatory care quality, including strategies to enhance primary care team effectiveness. He has published extensively on the measurement of patient care experiences and the impact of delivery system interventions on patients' experiences of care. As Co-investigator he will work closely with Dr. Shortell on all aspects of the study and will play a lead role in examining the team assessments and their impact on patient reported outcomes of care. He will also take the lead in examining differences by patient race, ethnicity, and language. He will be the primary liaison with HealthCare Partners and he will participate in site visits.

Susan L. Ivey, MD, MHSA (Co-Investigator)

Dr. Susan L. Ivey, MD, MHSA, is an Associate Professor in Community Health and Human Development at UC Berkeley's School of Public Health. She is a board-certified family physician who still practices medicine and who has been conducting health services research for 16 years. She is currently the Director of Research at Health Research for Action, an affiliated research center at the School of Public Health, UC Berkeley. As Co-investigator she will play a lead role in working with the patient advisory groups and tracking their involvement throughout the course of the study. She will also be involved in the development of the feedback reports, will assist in analysis of the clinical outcome measures and, as needed, will participate in the site visits.

Elliott Fisher, MD, MPH (Co-Investigator)

Dr. Fisher is the director of The Dartmouth Institute for Health Policy and Clinical Evaluation, and a member of the Institute of Medicine of the National Academy of Sciences. Among his research interests is the development and testing of approaches to performance measurement and payment reform that can support improved quality of care. He is currently studying the development and evolution of ACOs working with Dr. Shortell and the Berkeley team. As Co-investigator he will assist in interpreting the results of the patient reported outcome measures and the clinical measures and will participate in at least one site visit.

Glyn Elwyn, MD, PhD (Co-Investigator)

Dr. Elwyn is a physician-researcher, Professor, and Senior Scientist at The Dartmouth Health Care Delivery Science Center and The Dartmouth Institute for Health Policy and Clinical Practice, Dartmouth College. He leads interdisciplinary research examining the implementation of shared decision-making, user-centered design of patient decision support interventions, and the integration of these into routine health care. As Co-investigator he will participate in the development of the site visit interview instruments and in some of the site visits. He will play a lead role in analysis and interpretation of the site visit material.

PRINCIPAL INVESTIGATOR (LAST, FIRST, MIDDLE): Shortell, Stephen M.

Patricia Ramsay, MPH (Project Director)

Patricia Ramsay, MPH, is the Administrative Director of the Center for Healthcare Organizational and Innovation Research (CHOIR) at UC Berkeley's School of Public Health. Ms. Ramsay has more than twenty years of experience in public health and health services research at the UC Berkeley, School of Public Health, and the Departments of Epidemiology and Biostatistics and Medicine at UC San Francisco. Her focus has been on study management, data quality control, and data analysis of CVD and related chronic illnesses. As project director, she will oversee all aspects of the day-to-day operation of the study, working closely with Drs. Shortell and Rodriguez and the study team as a whole. She will be the primary contact with the survey research firm and will oversee all aspects of data collection, quality control, and preparation for analysis. She will participate in the various analyses related to the study aims and will, as needed, participate in site visits.

RESEARCH ENVIRONMENT

The University of California, Berkeley, is renowned worldwide for the distinction of its faculty and students, the scope of its research and publications, and the quality of its libraries. Its academic departments consistently rank among the top five in the country. The faculty, renowned for both teaching and scholarship, includes over 20 Nobel Laureates and a number of MacArthur Fellows. In recent fiscal years UC Berkeley has received over \$600 million in research funding per year.

Since its founding, the UC Berkeley School of Public Health has become one of the world's preeminent public health schools dedicated to the health promotion and protection in human populations. The school's research excellence is strengthened by between \$40 - \$80 million in extramural funding per year. The Division of Health Policy and Management, the administrative home for Dr.'s Shortell and Rodriguez, is nationally recognized for its contributions to health services and health policy research. Five of seven core faculty hold endowed chairs. Its interdisciplinary PhD program in Health Services and Policy Analysis is ranked by the National Research Council (NRC) as among the top five in the country. Its faculty are frequently called upon for their expertise both in California and nationally where they have served on the President's Council of Economic Advisers and task forces that worked with the Obama administration on the Affordable Care Act.

Center for Healthcare Organizational and Innovation Research (CHOIR)

Through practice-based research and dissemination of evidence, The Center for Healthcare Organizational and Innovation Research (CHOIR), directed by Dr. Stephen Shortell and Associate Director Hector Rodriguez, aspires to help make the U.S. healthcare system among the most responsive in the world, characterized by high quality, efficient, and patient-centered care. CHOIR currently has approximately \$8 million of extramural funding across 8 concurrent projects. CHOIR faculty and staff are located together centrally on the UC Berkeley campus to facilitate communication.

Health Research for Action (HRA) Center at UC Berkeley

Health Research for Action is one of the UCB School of Public Health's initiatives to translate research findings into successful resources and programs for the public. The HRA Director of Research is Dr. Susan L. Ivey, MD, MHSA. The Center works with communities, foundations, and government agencies to reduce health and health care disparities and create more hopeful, empowered communities through research-driven health promotion services and programs. The Center's resources and programs have reached over ten million people in the United States and around the world.

Office

The offices of the faculty of the SPH CHOIR are situated in University Hall on the UC Berkeley campus. Library and conference facilities are also available in University Hall, as well as other support facilities, including mail, fax, photocopying, and IT support.

Other

All the support services of a major University campus are available to this project: library, computer center, materials management, accounting, business and financial services, and human resources.

G. Research Engagement Plan

CRITERION 5 - PATIENT AND STAKEHOLDER ENGAGEMENT

There will be a patient advisory group at each study site that will actively participate in all aspects of the research including the development of instruments, assessment and review of findings throughout the study, making recommendations for improvement of practices' PA&E activities, and assisting in dissemination and implementation of findings. In addition, at least two prominent patient engagement advocates (Sue Edgman-Levitan and Elizabeth Helms) are included on our overall study advisory committee. They will help to insure that the study design, and analysis stays focused on the patient-centered study aims. They will also assist in the dissemination of study findings.

Importance of Patient-Centered Approaches:

This proposal reflects the importance of examining patient-centered approaches for their potential to improve patient-reported outcomes of care and related clinical measures. Patient Centered Outcomes Research (PCOR) recognizes the expertise of patients, families, and community health organizations as collaborators in research, and has emerged as an increasingly important approach in conducting health services research projects. We can leverage the expertise of patients, including underserved patient populations, to help guide development, implementation and feedback of our measures and findings; the patient advisory groups will address these issues. We believe this participatory approach will be key to successful study implementation and yield important, high quality patient-centered health services research findings.^{83, 84}

Plan for meaningful engagement of patients:

As previously indicated we include patient advisory group input throughout the study. Our goal is to have the patient advisory groups provide input in the first few months of the study with these groups to then meet 2-3 times annually and to undertake tasks that will include, but not be limited to: input into research design, instrumentation, review of preliminary results, interpretation of those results, and advising on dissemination of results.

Further, this proposal has been informed by years of research involving health care teams and their patients and most recently from interviews with patients and caregivers on our related preliminary study of ACO Patient Activation and Engagement funded by the Gordon and Betty Moore Foundation.

Experience in Patient and Stakeholder Engagement:

Dr. Shortell is currently the PI on the study funded by the Moore Foundation to assess what ACOs are currently doing in regard to PA&E activities, and to identify some of the barriers and facilitators to further involvement. In addition to the survey which has been informed by patient input, the study team is making two site visits, interviewing patients and their caregivers to learn more about what appears to be working and not working in regard to PA&E.

Dr. Ivey and her colleagues at Health Research for Action have many years of experience using participatory processes in research projects. Nearly every research project at HRA contains a community advisory board, and for those projects based within clinical sites, includes a group of patient advisors. Our work in this proposal will benefit from this experience.

As noted above we will draw on our overall study advisory committee and the site-specific patient advisory groups. We will ask for direct input from the site-specific patient groups in the first few months of the study with a goal for these advisory groups to meet 2 to 3 times annually and to undertake tasks that will include, but not be limited to: input into research design, instrumentation, review of preliminary results, interpretation of those results, and advising on dissemination of results.

DISSEMINATION AND IMPLEMENTATION POTENTIAL

Describe the potential for disseminating and implementing the results of this research in other settings.

There is great potential for disseminating and implementing the results of this research in other settings due to the established relationships which we have with many stakeholders in the field. This includes, but is not limited to: 1) All of the ACOs throughout the country through the ongoing work funded by the Commonwealth Fund; 2) through serving on the Advisory Board (Shortell) of the Kaiser-Permanente Institute for Health Policy that convenes roundtables and other dissemination forums for the results of such research; 3) in California, through our leadership of the Right Care Initiative focusing on reducing strokes and CVD in San Diego, Sacramento, and Los Angeles through greater patient and provider engagement; and 4) through our ties to the CDC Million Hearts campaign. All of this is in addition to the usual publication of study findings in journals, and at conferences and professional meetings. We look forward to working with PCORI on an overall dissemination and implementation strategy and determining the necessary resources involved.

Describe possible barriers to disseminating and implementing the results of this research in other settings.

There are two major barriers to disseminating and implementing the results of this research in other settings. The first is the challenge of adapting the study results to new and different contexts; the “we are different – it will never work here” challenge. The second is having sufficient time and resources to spread the study results to other settings. If the current proposal is funded and the results are promising, we look forward to submitting a subsequent dissemination proposal to be considered which will address our approach to these issues.

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REPRODUCIBILITY AND TRANSPARENCY OF RESEARCH

Describe the ability to reproduce potentially important findings from this research in other data sets and populations.

As large scale delivery systems begin to form and as electronic health records become more prevalent it becomes more possible for organizations like Advocate Health Partners and HealthCare Partners to work with their patient populations to improve process and outcomes of care. The instruments from our study can be made available to other delivery systems to conduct such research in addition to what we learn about the role of patient activation and engagement in the research process.

PROTECTION OF HUMAN SUBJECTS

PROTECTION OF HUMAN SUBJECTS – University of California, Berkeley

Risks to Human Subjects

Human Subjects Involvement, Characteristics, and Design

This research seeks to determine whether patients with diabetes or cardiovascular diseases (CVD) who receive care from provider practices affiliated with accountable care organizations (ACOs) with high involvement in patient activation and engagement (PA&E) experience better patient-reported outcomes, better experience of care, and improved clinical process measures compared with adult patients with diabetes or CVD who receive care from teams with low involvement in PA&E activities. These and related chronic conditions represent an estimated 75 percent of all U.S. health care expenditures.¹⁴ In addition, we will examine: (1) whether this effect is stronger for patients who score higher on the patient activation measure (PAM) than those who do not¹⁰; and (2) whether this effect is stronger for patients who improve their PAM scores over time than for those who do not. We will also assess the characteristics of practice teams associated with both high and low involvement in PA&E activities in regard to their degree of relational coordination, perceived team effectiveness, leadership, and team culture that they exhibit. Finally, we will examine the impact of feeding back the T1 patient outcome and teamwork assessment results to both caregivers and patient advisory groups on subsequent T2 measures of both patient outcomes and teamwork assessments.

We will engage patients and primary care teams within two ACOs. The two selected to participate in this research are Advocate Health in Chicago, Illinois and HealthCare Partners in Torrance, California. Within each ACO, we will select four practices that are highly involved in PA&E and four that are less or not at all involved. We will make this determination based on a broad definition of PA&E activities that will include: (1) patient care outreach in regard to disease prevention and health promotion; (2) changes in the clinician-patient relationship, particularly in the areas of communication, motivational interviewing, and involvement in treatment care plans; (3) shared decision-making; (4) patient self-management of their condition(s); (5) end of life/advanced serious illness care patient engagement and family involvement; and (6) patient involvement in the overall design of care and in organization-wide efforts to improve the quality of care.

From among those practices we will select 273 patients with diabetes and/or CVD from each of eight practices at each ACO – a total of four practices with high involvement in PA&E and four practices with low PA&E involvement. Given two ACOs, we will have data from 4,368 patients with these chronic conditions. We will follow them as cohorts over a two-year period. We will obtain measures of blood pressure, HbA1c and LDL-C at 12 months and 24 months from the EHR. Patients selected for the study will be mailed a survey including the 13-item PAM measure at baseline (0-3 months). Patients will complete patient-reported outcomes (PROMIS) and experience of care measures between 7-12 months and again at between 19-24 months. Patients who do not complete and return the survey by mail will be contacted by phone (up to 8 attempts) and offered an opportunity to complete the questions by computer-assisted telephone interview (CATI). We will survey and follow-up with patients in both English and Spanish, according to their stated primary language preference. Patients will be offered a \$20 incentive to complete the survey by mail or by CATI. The calculations provided below for the PROMIS self-reported measures and for blood pressure provide evidence of sufficient statistical power to detect meaningful differences between practices on these key variables of interest.

To project the sample size requirements given 16 practices (8 high PA&E and 8 low PA&E), we estimated the design effect (DE) to account for the clustering of patients within practice sites. While PROMIS data from participating ACO patients are presently unavailable, recent studies of change over time on the PROMIS physical functioning measure informed our sample size estimates for the PROMIS measure⁴⁷. Having been selected using item-response theory (IRT) methods and extensive testing, the PROMIS physical functioning measure is a precise measure that is sensitive to small changes in physical functioning over time.

Quantum Market Research, a survey firm in Oakland, CA, will be hired to administer the patient survey. Given the published estimates and a range of design effect estimates (intraclass correlation (ICC)=0.01-0.04) to account for the clustering of patients within practices, a clinically meaningful change (a 3-5 point change out of 100) on the PROMIS physical functioning measure can be detected with 50-65 patients per practice. Based on prior experience, we expect a minimum 50% response rate for completing the first patient survey and a 65% response rate for the second survey. We

PRINCIPAL INVESTIGATOR (LAST, FIRST, MIDDLE): Shortell, Stephen M.

expect a 3% undeliverable addresses and a 20% drop out rate between the two survey periods based on our previous research. Patient-level blood pressure data from adult diabetic patients at HealthCare Partners practices were used to calculate the design effect ($ICC=0.01-0.02$). Previous research suggests that population-level improvements in blood pressure on the order of 3-5mm Hg are clinically meaningful.^{48, 49} Based on a two-sided difference of means with a power of 0.90, we estimate that an average of 140 patients per practice are needed to detect a 3 mm Hg difference in change in systolic blood pressure over time between the high ($n=8$) vs. low ($n=8$) PA&E practices. Based on these calculations, we will randomly select 273 patients per practice ($n=4,368$) with diabetes or CVD diagnoses from each of the practice sites and teams in the two ACOs for inclusion in the study. Given the assumptions of response rates and attrition noted above, this will yield a final total of 1102 patients with two time points for analysis of the PROMIS (69 patients per site). In addition we expect to receive retrospective clinical outcomes data for all sampled patients ($n=4,368$) from the electronic health record. Thus, even with slightly lower than expected survey response rates, our study will be sufficiently powered to detect clinically meaningful differences between high and low PA&E practices on both patient-reported (PROMIS) and clinical, e.g., blood pressure, outcome measures.

Two site visits to each of the two ACOs will be conducted at two points in time to gain an insight to the strategic goals of the ACOs in improving patient activation and engagement and fostering high functioning interdisciplinary primary care teams: (1) during the 0-6 month start-up phase of the study, and again (2) during the period of 18-24 months.

Sources of Materials

Patients selected for the study will be mailed a survey including the 13-item PAM measure, patient-reported outcomes (PROMIS), and experience of care measures between 7-12 months and again between 19-24 months. Please see Appendix III for examples of questions to be included in the patient survey. We will obtain measures of blood pressure, HbA1c and LDL-C at 12 months and 24 months from the EHR at Advocate Health and HealthCare Partners.

Advocate Health and HealthCare Partners will be responsible for linking patients' EHR data to their study ID, and thus the data transmitted will not be identifiable to any researchers or staff at UC Berkeley. All such de-identified data will be housed at Berkeley on password-protected, secure servers accessible only by Principal Investigator Shortell and the Co-Investigators and staff under his direction.

Quantum Market Research (QMR) will be responsible for contacting patients to complete the survey. They will receive identifiable patient information such as name, address, and phone number directly from Advocate and HealthCare Partners only for the purposes of administering the survey.

Primary care team members from each of the 16 practices will complete the following instruments that we refer to as "teamwork assessment instruments." These are: (1) team culture, (2) team leadership, (3) relational coordination, and (4) perceived team effectiveness. These will be completed at baseline (0-3 months) and then again at 18 months. UC Berkeley will manage and administer the staff survey.

Only the Investigators at Advocate and Health Care Partners site will have the key linking survey data to names of their own patients completing the survey. No investigators at UC Berkeley or Dartmouth or staff on the project besides the ACOs will have access to a key allowing linkage of collected data to identifiable patient information.

Potential Risks

There are no physical, financial, or legal risks to patients selected for participation in this project. The principal risks from this study concern the potential for loss of confidentiality.

With respect to the site visits and staff surveys performed at the 16 ACO practices, the information collected through the survey and in-depth interviews with physicians and other ACO executives pertains to each organization's professional activities only and does not pertain to any personal matters. The collection of these survey data do not pose any physical, financial, or legal risks to the ACO practice team members.

Adequacy of Protection Against Risks

Recruitment and Informed Consent

Informed consent will be obtained from all selected patients before completion of the survey. A written consent letter will be included with the mailed surveys and phone consent will be specifically obtained at the beginning of each follow-up CATI interview.

PRINCIPAL INVESTIGATOR (LAST, FIRST, MIDDLE): Shortell, Stephen M.

Informed consent will also be obtained from the team members surveyed during administration by UC Berkeley investigators.

Protections Against Risk

To minimize the risk of loss of confidentiality, all information with the potential to identify study participants will remain housed at Advocate Health and Health Care Partners, respectively, only accessible to Advocate Health and HealthCare Partners staff.

Potential Benefits of the Proposed Research to Human Subjects and Others

Patients may benefit from the feedback of the time one findings which could enable some of the practice sites to make changes which directly benefit some patients subsequent to time 2. Furthermore, the knowledge gained from this study at the participating ACOs could potentially benefit all enrolled patients. As large scale delivery systems begin to form and as the electronic health record becomes more prevalent, it becomes more possible for organizations to work with their patient populations to improve process and outcomes of care. The instruments from our study can be made available to other delivery systems to conduct such research in addition to what we learn about the role of PA&E in the research process.

Importance of the Knowledge to be Gained

This research is important as relatively little is known about the impact of actively engaging patients on such outcomes of care. Further, there are major gaps in knowledge and understanding of what practice team characteristics are associated with achieving better outcomes from more fully engaged patients. Thus the research is directly relevant to practices working on PA&E as well as payers and policy makers interested in encouraging engagement. The risk of the loss of confidentiality combined with the planned procedures to minimize that risk are reasonable in relation to the importance of the knowledge that is reasonably expected to result from this study.

INCLUSION OF WOMEN AND MINORITIES

Detailed Study Enrollment Table

Racial Categories	Not Hispanic or Latino		Hispanic or Latino		TOTAL
	Female	Male	Female	Male	
American Indian/ Alaska Native	11	11	0	0	22
Asian	178	171	0	0	349
Native Hawaiian or Other Pacific Islander	11	11	0	0	22
Black or African American	356	342	0	0	699
White	913	878	702	674	3167
More than One Race	56	54	0	0	109
TOTAL	1526	1466	702	674	4368

INCLUSION OF CHILDREN

Individuals under 18 will be excluded from the proposed research as the chronic adult conditions proposed for study for this project are not relevant to children.

PROTECTION OF HUMAN SUBJECTS – Dartmouth College

Risks to Human Subjects

Human Subjects Involvement, Characteristics, and Design

The investigators at Dartmouth College will participate in the design of the research and will participate in the site visits to Advocate Health care and HealthCare Partners to interview practice staff, as described above.

Sources of Materials

Dartmouth will not participate in the selection of patients and will receive de-identified data only after the conclusion of data collection. No Dartmouth investigators or staff will have any access to identifiable patient data. Dartmouth will have access only to de-identified practice team staff assessment data. Dartmouth will participate in the site visit interviews.

Potential Risks

The information collected by Dartmouth investigators through the in-depth interviews with physicians and other ACO executives pertains to each organization's professional activities only and does not pertain to any personal matters. Data collected will be maintained confidentially. The collection of these data do not pose any physical, financial, or legal risks to the ACO practice team members.

Recruitment and Informed Consent

Consent will be obtained from all ACO practice staff prior to beginning site visit interviews.

Protections Against Risk

The collection of the site visit interview data does not pose any physical, financial, or legal risks to the ACO practice team members. Nevertheless names of interviewees will be kept confidential and will not be made public.

Potential Benefits of the Proposed Research to Human Subjects and Others

Data gained and summarized in feedback reports from the site visits may benefit Advocate Health Care and HealthCare Partners by enable some of the practice sites to make changes which directly the delivery of care at these organizations.

Importance of the Knowledge to be Gained

Please see above under Protection of Human Subjects – UC Berkeley.

INCLUSION OF WOMEN AND MINORITIES

Please see above under Protection of Human Subjects – UC Berkeley.

INCLUSION OF CHILDREN

Please see above under Protection of Human Subjects – UC Berkeley.

PROTECTION OF HUMAN SUBJECTS – Advocate Health Care and HealthCare Partners

Risks to Human Subjects

Human Subjects Involvement, Characteristics, and Design

Protection of human subjects considerations are identical for the two ACOs participating in this project. Advocate Health Care and HealthCare Partners will each securely transmit names, addresses, and contact information for adult patients with diabetes and/or cardiovascular diseases with at least 2 visits in the baseline year (2013) from each of eight primary care practices affiliated with our Accountable Care Organization (ACO) to the patient survey vendor selected for the project, Quantum Market Research. The four primary managerial and supervisory staff members at the survey firm have all completed the Collaborative Institutional Training Initiative (CITI) modules relating to Human Subjects Protection training, as have a number of other QMR staff, including interviewers. Although all QMR employees have followed strict procedures with regard to human subjects throughout their careers, this formalizes the training.

The two ACOs will also securely transmit a de-identified patient-level data to the UC Berkeley research team in Months 7 and 19 covering 2014 and 2015 period, respectively. The dataset will include adult patients with diabetes, cardiovascular disease, and/or asthma with at least 2 visits in the baseline year (2014) and the data elements include select sociodemographic information and clinical care process and outcome data using Healthcare Effectiveness Data Information Set (HEDIS) definitions for measures of chronic illness care.

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For analysis of all patient-level data at UC Berkeley, we will create unique subject identifiers that do not include date of birth, social security number, or medical record number. The ACOs will be responsible for linking each patient's EHR data to their study ID, and thus the data transmitted will not be identifiable to any researchers or staff at UC Berkeley. All such de-identified data will be housed at Berkeley on password-protected, secure servers accessible only by Principal Investigator Shortell and the Co-Investigators and staff under his direction.

Advocate Health Care and HealthCare Partners will also provide the UC Berkeley research team with the names, emails, and mail contact information for all primary care clinicians and staff of the eight practices so that a survey of team culture, leadership, relational coordination, and perceived team effectiveness can be conducted at two points in time (between months 0-6 and between months 13-18).

These two ACOs will also work with the UC Berkeley team to coordinate two site visits lasting two to three days for the research team to interview key people, some patients, and to observe meetings. Finally, the ACOs will assist with recruiting five patient representatives from the target population to serve on an advisory board that will provide recommendations and feedback for the ACO practices to consider as they refine and improve their PA&E efforts.

Sources of Materials

Advocate Health and HealthCare Partners will be responsible for linking patients' EHR data to their study ID, and thus the data transmitted will not be identifiable to any researchers or staff at UC Berkeley.

As described above, Quantum Market Research (QMR) will receive identifiable patient information such as name, address, and phone number directly from Advocate and HealthCare Partners only for the purposes of administering the survey.

Only the collaborating investigators and data coordinator located at each the Advocate and Health Care Partners sites will have the key linking survey data to names of their own patients completing the survey.

Potential Risks

As described above, there are no physical, financial, or legal risks to patients selected for participation in this project. The principal risks from this study concern the potential for loss of confidentiality.

Adequacy of Protection Against Risks

Recruitment and Informed Consent

Informed consent will be obtained from all selected patients before completion of the survey. As described above, a written consent letter will be included with the mailed surveys and phone consent will be specifically obtained at the beginning of each follow-up CATI interview.

Protections Against Risk

All information with the potential to identify study participants will remain housed at Advocate Health and HealthCare Partners, respectively, only accessible to Advocate Health and HealthCare Partners staff.

Potential Benefits of the Proposed Research to Human Subjects and Others

Please see above under Protection of Human Subjects – UC Berkeley.

Importance of the Knowledge to be Gained

Please see above under Protection of Human Subjects – UC Berkeley.

INCLUSION OF WOMEN AND MINORITIES

Please see the detailed enrollment table above under Protection of Human Subjects – UC Berkeley.

INCLUSION OF CHILDREN

Individuals under 18 will be excluded from the proposed research as the chronic adult conditions proposed for study for this project are not relevant to children.

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CONSORTIUM CONTRACTUAL ARRANGEMENTS

Describe the proposed research projects that will be performed by subcontracted organizations. Explain the strengths that these partners bring to the overall project.

Dartmouth College (The Dartmouth Institute)

Our faculty and staff have worked closely with colleagues at The Dartmouth Institute for the past several years on an ongoing research project involving ACOs,^{46, 85} which will facilitate our collaboration on site visits to the clinical sites selected for participation in this project.

Elliott Fisher, MD, MPH (Co-Investigator)

Dr. Fisher is the director of The Dartmouth Institute for Health Policy and Clinical Evaluation, and a member of the Institute of Medicine of the National Academy of Sciences. He is a national leader in the development of accountable organizations. Among his research interests is the development and testing of approaches to performance measurement and payment reform that can support improved quality of care. He is currently studying the development and evolution of ACOs working with Dr. Shortell and the Berkeley team. As Co-investigator he will assist in interpreting the results of the patient reported outcome measures and the clinical measures and will participate in at least one site visit.

Glyn Elwyn, MD, PhD (Co-Investigator)

Dr. Elwyn is a physician-researcher, Professor and Senior Scientist at The Dartmouth Health Care Delivery Science Center and The Dartmouth Institute for Health Policy and Clinical Practice, Dartmouth College. He has considerable expertise in patient activation and engagement, an area in which he is considered an international expert. He leads interdisciplinary research examining the implementation of shared decision-making, user-centered design of patient decision support interventions, and the integration of these into routine health care. As Co-investigator he will participate in the development of the site visit interview instruments and in some of the site visits. He will play a lead role in analysis and interpretation of the site visit material.

Advocate Health Partners and HealthCare Partners

Advocate Health Care (Advocate) and Advocate Physician Partners (APP) operate both a commercial and a Medicare ACO. In 2011, Advocate joined with its largest commercial insurance partner to create AdvocateCare, providing care to 370,000 covered lives. In 2012, Advocate was chosen to participate in the Medicare Shared Savings Program (MSSP), becoming one of the largest Medicare ACOs in the country, serving an estimated 106,000 beneficiaries. They are leads in providing clinically integrated care. As indicated by their letter of support, they are highly committed to this study.

HealthCare Partners ACO was formed in 2010 as one of the early Dartmouth-Brookings demonstration ACOs⁴⁶. They hold both CMS and private payer risk-based contracts collectively accountable for 50,000 lives. They serve high proportions of Medicaid patients in low-income communities who tend to face many social and financial barriers to self-management of diabetes and CVD. Approximately 55% of HCP's Southern California patients are Latino. HCP and the HCP Institute for Applied Research and Education have extensive expertise leading patient-centered HIT development and research projects. For the past 3 years, the HCP Institute through earned, competitive grant funding, has been refining the application of remote patient monitoring of chronic disease in older adult patients using interactive voice response technology (IVR). Based on a third-party evaluation by the Center for Connected Health at Partners Healthcare in Boston, HCP's IVR system resulted in significant improvements in appropriate care⁸⁶. HCP's implementation of patient-centered HIT, particularly focused on integrating informal caregivers⁸⁷, are important patient activation and engagement innovations to study in the context of improving patient-reported outcomes, as there is considerable variation in the use of patient-centered HIT across HCP's practices. They are highly committed to this study as indicated by their letter of support and related materials in this proposal.

PRINCIPAL INVESTIGATOR (LAST, FIRST, MIDDLE): Shortell, Stephen M.

Both Advocate and HealthCare Partners will subcontract with UC Berkeley to perform the following tasks:

Securely transmit names, addresses, and contact information for 273 adult patients with diabetes and/or cardiovascular disease with at least 2 visits in the baseline year (2013) from each of eight primary care practices affiliated with our Accountable Care Organization (ACO) to the patient survey vendor selected for the project.

Securely transmit a de-identified patient-level data to the UC Berkeley research team in Months 7 and 19 covering 2013 and 2014 period, respectively. These datasets will include adult patients with diabetes and cardiovascular disease with at least 2 visits in the baseline year (2014) and the data elements include select sociodemographic information and clinical care process and outcome data using Healthcare Effectiveness Data Information Set (HEDIS) definitions for measures of chronic illness care.

Provide the UC Berkeley research team with the names, emails, and mail contact information for all primary care clinicians and staff of the eight practices so that a survey of team culture, leadership, relational coordination, and perceived team effectiveness can be conducted at two points in time (at baseline, between months 0-6, and again between months 13-18). The data manager at each ACO will facilitate the completion of the surveys by coordinating implementation with practice managers and ensure that participants have time during work hours to complete the survey.

Provide feedback to the UC Berkeley team on the individual practice feedback reports that will include key comparisons from the patient and clinician/staff surveys. These reports will be shared with primary care clinicians, staff, and patient advisory group members after each data collection period.

Work with the Berkeley team to coordinate two site visits lasting two to three days for the research team to interview key people, some patients, and to observe meetings. The purpose of these visits is to learn more about the successes and challenges of delivering more patient-activated and engaged care and to help the research team better understand the quantitative data being collected.

Assist with recruiting six patient representatives from the target population to serve on an advisory board that will review study instruments and provide recommendations and feedback for the ACO practices to consider as they refine and improve their PA&E efforts. The ACOs will provide institutional support to the patient advisory board and will provide patient advisors with project stipend support for their participation each year.

PRINCIPAL INVESTIGATOR (LAST, FIRST, MIDDLE): Shortell, Stephen M.

APPENDIX (Optional)

(Use continuation pages as needed. You may provide an appendix of up to 10 pages to include additional materials that you think may be useful to describe, e.g., survey instruments, interview guides, etc. Note, however, that reviewers are not required to include the appendix when they review and assess your application.)

Appendix I. Patient Activation and Engagement Site Assessment Survey

For most items below, the response categories will be:

Yes, fully implemented	Yes, partially implemented	Yes, but not regularly	No
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Begin survey:

Please indicate the extent to which your practice site uses the following patient activation and engagement strategies for patients with diabetes and/or CVD.

A. Patient care outreach in regard to disease prevention and health promotion

1. Conducts a Health Risk Assessment (HRA) Survey
2. Feedback to patients on results of their HRA
3. Ongoing monitoring of HRA results (assess over time changes)
4. Refer patients to a disease prevention or health promotion program as a result of the HRA
5. Sponsor or participate in a community-based Healthy Eating Program
6. Sponsor or participate in a Community-based Physical Activity Program
7. Sponsor or participate in a Farmers Market
8. Have a Employee Health Promotion/Prevention/Wellness program
9. Sponsor or participate in School Health Clinic interventions

B. Changes in the clinician-patient relationship, particularly in the areas of communication, motivational interviewing, and involvement in treatment care plans.

10. HRA results available electronically to care team members (through EHR registry) at the point of care
11. Clinicians are trained in motivational interviewing techniques
12. Clinicians consistently use motivational interviewing techniques in communicating with patients, e.g. encourage patients to ask questions
13. Clinicians consistently encourage patients to discuss their work, home life, and social situation
14. Staff note patient preferences for treatment in the patient's record
15. Staff are trained in motivational interviewing techniques
16. Staff consistently use motivational interviewing techniques in communication with patients, e.g., encourage patients to ask questions
17. Select staff serve as "health coaches" for patients seeking to modify their lifestyle
18. Patients can routinely provide information on their care and their health via a patient portal (not just access)
19. Telehealth is consistently made available to patients with diabetes

20. Telehealth is consistently made available to patients with cardiovascular disease

C. Shared decision-making

- 21. Clinicians consistently involve patients in developing treatment goals
- 22. Goal-setting for behavioral changes with patients as a result of their HRA
- 23. Provide eligible patients with shared decision making videos
- 24. Physicians consistently have follow up discussions with patients regarding their treatment options and preferences
- 25. There is a formal evaluation of the impact of shared decision making on patient care choices, outcomes of care, and patient experience with their care
- 26. There exists an organized follow up program to assist patients in managing their medications at home, e.g., pharmacist-led medication management
- 27. Shared medical appointment (group visits) are available for patients with diabetes
- 28. Shared medical appointment (group visits) are available for patients with cardiovascular disease
- 29. Peer to Peer (Patient to Patient) programs are available for patients with diabetes
- 30. Peer to Peer (Patient to Patient) programs are available for patients with cardiovascular disease
- 31. Programs to improve family participation and support for patients with diabetes
- 32. Programs to improve family participation and support for patients with cardiovascular disease

D. Patient self-management of their condition

- 33. At home monitoring devices and/or tools to assess medication management, blood pressure, blood sugar, and lipids are made available to patients

E. End of life/advanced serious illness care patient engagement and family involvement

- 34. Clinicians consistently discuss the importance of patient advanced directives (Care for Older/Vulnerable Adults)
- 35. Clinicians consistently discuss hospice care options with patients (Care for Older/Vulnerable Adults)
- 36. Clinicians consistently discuss the availability of both hospital based and community based palliative care with patients (Care for Older/Vulnerable Adults)

F. Patient involvement in the overall design of care and in organization-wide efforts to improve the quality of care

- 37. Patient advisory councils exist for patients with diabetes
- 38. Patient advisory councils exist for patients with cardiovascular disease
- 39. Patients consistently participate in quality improvement teams
- 40. Patients are involved in helping to govern the clinic/practice

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Appendix II. Patient Activation, Self-Reported Outcomes of Care, and Patient Experience

(Number of questions = 65)

Measure	Item Count	Example Content	Internal Consistency Reliability	Why Selected (Why alternatives were not?)
Patient Activation Measure (PAM-13)	13	<ul style="list-style-type: none"> • When all is said and done, I am the person who is responsible for taking care of my health • I know how to prevent problems with my health • I am confident that I can follow through on medical treatments I may need to do at home. 	0.90+	PAM is a widely used measure that has high internal consistency, has been shown to be associated with a range of patient-reported outcomes, and is also useful to guide the quality improvement activities of participating ACO practices ¹⁰ .
Patient Assessment of Chronic Illness Care (PACIC-11)	11	<p>Over the past 6 months, when I received care for my chronic conditions. How often was I:</p> <ul style="list-style-type: none"> • Given choices about treatment to think about • Helped to set specific goals to improve my eating or exercise. • Helped to plan ahead so I could take care of my condition even in hard times. 	0.93	There are few validated measures of patients' experiences of chronic illness care. We considered using two alternate measures- the Ambulatory Care Experiences (ACES) quality of chronic illness care composite ⁸⁸ and the recently developed Integrated Patient Care measures ⁸⁹ (Singer et. al). The PACIC was preferred because of it has more extensive research highlighting the reliability and utility of the measure. PACIC was also preferred because validation studies have been conducted with the brief measure (PACIC-11) and is sensitive to change over time. ⁵⁸
Patients' Experiences of Primary Care Teams (Ambulatory Care Experiences Survey)	5	<p>Screener: Are there nurses or other providers in your personal doctor's office who play an important role in your care?</p> <ul style="list-style-type: none"> • In the last 6 months, how often did these nurses and other providers in your personal doctor's office explain things in a way that is easy to understand? 	0.70	Few validated measures of patients' experiences of primary care teams exist. The "care team" composite measure of the Ambulatory Care Experiences Survey (ACES) survey has been previously used in peer-reviewed research and has acceptable internal consistency reliability. The recently developed Integrated Patient Care measures ⁸⁹ includes 2

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Appendix II. Patient Activation, Self-Reported Outcomes of Care, and Patient Experience

(Number of questions = 65)

Measure	Item Count	Example Content	Internal Consistency Reliability	Why Selected (Why alternatives were not?)
		<ul style="list-style-type: none"> How would you rate the coordination of your care between these nurses and other providers and your doctor? Thinking about these nurses or other providers in your doctor's office, how would you rate their knowledge of you as a person, including values and beliefs that are important to you? 		items related to care team coordination and these questions have similar content as the ACES items (Rodriguez, et al, 2007). ⁹⁰
Ability to Participate in Social Roles and Activities (PROMIS Short Form 8a)	8	<ul style="list-style-type: none"> I have trouble doing all of the family activities that I want to do I have to limit my regular activities with friends. I have trouble doing all of the work that is really important to me (include work and home) 	0.85-0.94	The PROMIS social role subscale was selected because the composite covers a health domain central to patient activation and engagement. Further, the measure was developed through extensive item preparation and review, EFA-, CFA- and IRT-guided item banks help provide increased measurement precision and flexibility. ⁹¹
Patient Health Questionnaire (PHQ-4) Depression and Anxiety	4	<p>Over the past 2 weeks, how often have you been bothered by these problems:</p> <ul style="list-style-type: none"> Feeling nervous, anxious or on edge Not being able to stop or control worrying Feeling down, depressed, or hopeless Little interest or pleasure in doing things 	0.82	Compared to the PROMIS measures of anxiety and depression, the PHQ-4 is parsimonious, is used more extensively in primary care settings for quality improvement and research purposes. While the PROMIS measures are longer and cover a broader range of symptoms, research has not demonstrated the relative advantage of the PROMIS measures compared to the PHQ-9 or PHQ-4 for use in primary care settings. ⁹²

PRINCIPAL INVESTIGATOR (LAST, FIRST, MIDDLE): Shortell, Stephen M.

Appendix II. Patient Activation, Self-Reported Outcomes of Care, and Patient Experience

(Number of questions = 65)

Measure	Item Count	Example Content	Internal Consistency Reliability	Why Selected (Why alternatives were not?)
Physical Function (PROMIS Short Form 12a)	13	<ul style="list-style-type: none"> • Are you able to do yard work like raking leaves, weeding, or pushing a lawn mower? • Are you able to bend down and pick up clothing from the floor? • Are you able to push open a heavy door? 	0.86-0.95	Research indicates that the PROMIS physical function composite, which is comprised of item response theory-based items, can result in greater responsiveness and precision across a broader range of physical function compared to other physical function measures. This can reduce sample size requirements and thus study costs. ⁹³
Demographics	11	Age, gender, race, ethnicity, self-rated English literacy, preferred language, interpreter use, employment status, marital status, education, and military status		Census specifications will be used, when applicable.

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Appendix III. Primary Care Teamwork, Relational Coordination, Leadership, and Culture Survey (Number of questions= 40 excluding the team composition question)					
Measure	Level	Item Count	Example Content	Internal Consistency Reliability	Why Selected (Why alternatives were not?)
Team Composition Assessment	Team	1	Which of the following people do you consider to be members of <u>your</u> team? [List of all practice members]: Member selects “Yes, always”, “Yes, sometimes”, “No”	NEW	Recognizing that individual members sometimes have different conceptions of their team membership boundaries, we aimed to clarify differences in administratively-defined team membership and individual reports of team composition, and consider these differences when interpreting the teamwork measures.
Team Processes / Relational Coordination	Team	7	Do people on your team communicate with you in a timely way about patient care? When there is a problem with patient care, do people on your team blame others or work with you to solve the problem?	0.80	Adapted: Use a team-based referent vs. a focal workgroup (external) ⁷¹ . We chose the RC over other measures of teamwork because more extensive validation and reliability information exists for RC compared to other teamwork measures such as the new AHRQ TeamSTEPPS measures ^{71, 94} .
Team Participation	Team	7	<ul style="list-style-type: none"> • I frequently contribute information • I frequently interpret information • I can comfortably disagree with other • I usually propose alternatives 	0.90	Among teamwork measures assessed in a recent systematic review, is one of three instruments that satisfied standard psychometric criteria and associated with non self-reported outcomes. Staff participation and engagement is also central to patient activation and engagement. ⁷²
Baldrige Award Adapted – Patient Centeredness	Practice	5	The practice does a good job of assessing current patient needs and expectations; staff promptly resolve patient complaints; patients'	0.86 (2004)	Used in previous research and found to be positively associated with changes to improve chronic illness care (Shortell,

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Appendix III. Primary Care Teamwork, Relational Coordination, Leadership, and Culture Survey (Number of questions= 40 excluding the team composition question)					
Measure	Level	Item Count	Example Content	Internal Consistency Reliability	Why Selected (Why alternatives were not?)
			complaints are studied to identify patterns and prevent the same problems from recurring; the organization uses data from patients to improve services; and the organization uses data on customer expectations and/or satisfaction/ experiences when designing new services.		2004). ⁷⁴
Leadership Facilitation (Organizational Readiness for Change Assessment- leadership behavior and change culture subscales)	Practice	7	Leadership and management in your practice... ...Reward clinical innovation and creativity to improve patient care ...Solicit opinions of clinical staff regarding decisions about patient care ...Seek ways to improve patient education and increase patient participation in treatment. ...Make sure that we have the time and space necessary to discuss changes to improve care ...Strongly support practice change efforts ...Promote an environment that is an enjoyable place to work ...Create an environment where things can be accomplished	0.94	We selected the ORCA measure of leadership because it is more specific to the changes related to PA&E initiatives while the AHRQ measure is more general.
Group Practice Organizational Culture	Practice	8	Innovation and Risk-taking in our practice 1. Successful innovations are highly publicized 2. Risk taking is encouraged 3. We consider ourselves to be the testing ground for new approaches to engage patients in their care	.80	Consideration was also given to the Competing Values measure of culture but being an ipsative scale it is more difficult for respondents to complete. We therefore decided to use the more straightforward measures developed and validated by

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<u>Appendix III. Primary Care Teamwork, Relational Coordination, Leadership, and Culture Survey</u> (Number of questions= 40 excluding the team composition question)					
Measure	Level	Item Count	Example Content	Internal Consistency Reliability	Why Selected (Why alternatives were not?)
			4. We are given time to generate new ideas and innovations Group Solidarity in our practice 1. We have a strong sense of belonging to the practice 2. It would be hard for me to leave my colleagues at this practice 3. Team members openly share their patient care challenges and failures with each other 4. There is a well-defined pecking order among team members		Kralewski ⁷⁵
Demographics	Individual	6	Age, sex, race/ethnicity, occupation, years working at practice, work hours/week.		

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Appendix IV. NATIONAL STUDY OF PHYSICIAN ORGANIZATIONS III—FEEDBACK REPORT EXAMPLE

Comparison of <<Your Practice>> with all other physician practices surveyed

Note: The “your organization” column reflects your self-reported survey responses

Care Management Processes Indices Score*						
	Your Organization	Mean Scores				
		All Practices	1-7 physicians	8-19 physicians	20-99 physicians	100+ physicians
Practice provides patient educators (0-4)		1.5	1.3	1.5	1.9	2.3
Practice provides performance feedback to physicians (0-4)		1.1	1.0	1.3	1.4	2.0
Practice uses nurse care managers for chronic disease (0-4)		0.6	0.5	0.6	0.9	1.6
Practice sends patients reminders for preventive or follow-up care (0-4)		1.3	1.3	1.3	1.4	1.7
Provider receives clinical practice guideline reminders at point of care (0-4)		1.3	1.3	1.3	1.4	1.7
Practice maintains electronic registry of patients with chronic condition (0-4)		1.1	0.9	1.2	1.4	1.9
Overall Care Management Processes Index (0-24)		6.9	6.1	7.1	8.3	11.1
Care Management Process Percent Score**		28.9%	26.0%	30.2%	34.7%	46.4%

The Care Management Processes Indices are based on a “yes” response to a series of six questions regarding use of the specified processes for patients with asthma, congestive heart failure, depression, or diabetes. It is only possible to receive all points if your practice treats all conditions.

***The “Care Management Process Percent Score” takes into account that a practice may not treat all conditions and reflects the points received out of points possible regarding conditions treated at your practice,*

Enhanced Access Index Score						
	Your Organization	Percentage/ Mean Scores				
		All Practices	1-7 physicians	8-19 physicians	20-99 physicians	100+ physicians
Majority of physicians communicate with patients via e-mail		18.4%	19.1%	13.2%	13.1%	31.3%
Practice allows patients to view medical record online		24.3%	18.6%	27.0%	36.5%	56.3%

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Physicians use “advanced access” scheduling		21.4%	16.3%	27.0%	32.1%	43.8%
Practice is open extended hours or on weekends		59.3%	53.3%	61.6%	78.1%	82.5%
Practice uses group visits		16.5%	11.2%	19.5%	29.2%	42.5%
Overall Enhanced Access Index (0-5)		1.4	1.2	1.5	1.9	2.6

Care Coordination/Integration Index

	Your Organization	Percentage/ Mean Scores				
		All Practices	1-7 physicians	8-19 physicians	20-99 physicians	100+ physicians
Majority of physicians use the EMR for progress notes		64.2%	55.0%	75.5%	87.6%	95.0%
Electronic access to view emergency department records and hospital discharge summaries		75.4%	71.1%	88.1%	80.3%	86.3%
Majority of physicians send prescriptions directly to pharmacies electronically		81.5%	76.2%	91.2%	92.0%	97.5%
Overall Care Coordination/ Integration Index (0-3)		2.2	2.0	2.5	2.6	2.8

Patient-Centered Care Index

	Your Organization	Percentage/ Mean Scores				
		All Practices	1-7 physicians	8-19 physicians	20-99 physicians	100+ physicians
Assess patient needs and expectations		48.7%	54.4%	45.3%	29.9%	30.0%
Promptly resolve patients’ complaints		47.2%	52.3%	39.0%	35.8%	31.3%
Complaints studied to identify patterns and prevent recurrence		35.0%	38.4%	28.9%	27.0%	37.5%
Data from patients used to improve care		30.1%	30.2%	28.3%	27.0%	37.5%
Data from patients used to develop new services		17.4%	18.1%	14.5%	16.1%	18.8%
Overall Patient-Centered Care Index (0-5)		1.8	1.9	1.6	1.3	1.5