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Transitions, Risks, and Actions in Coronary Events – Center for Outcomes Research and Education (TRACE-CORE): Design and Rationale

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Abstract

Background—Cardiovascular disease continues to cause significant morbidity, mortality, and impaired quality of life, with unrealized health gains from the underuse of available evidence. The Transitions, Risks, and Actions in Coronary Events Center for Outcomes Research and Education (TRACE-CORE) aims to advance the science of acute coronary syndromes (ACS) by examining the determinants and outcomes of the quality of the transition from the hospital to the community and by quantifying the impact of potentially-modifiable characteristics associated with decreased quality of life, rehospitalization, and mortality.

Methods and Results—TRACE-CORE is composed of a longitudinal multi-racial cohort of patients hospitalized with ACS, two research projects, and development of a nucleus of early stage investigators. We are currently enrolling 2,500 adults hospitalized for ACS at 6 hospitals in the northeastern and southeastern United States. We will follow these patients for 24 months after hospitalization through medical record abstraction and six patient interviews focusing on quality of life, cardiac events, rehospitalizations, mortality, and medical, behavioral, and psychosocial characteristics. The Transitions Project studies determinants of and disparities in outcomes of the quality of patients' transition from the hospital to the community. Focusing on potentially modifiable factors, the Action Scores Project will develop and validate action scores to predict recurrent cardiac events, death, and quality of life, describe longitudinal variation in these scores, and develop a dashboard for patient and provider action based on these scores.

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Disclosures
None of the authors have conflicts of interest to disclose.

Conclusions—In TRACE-CORE, sound methodologic principles of observational studies converge with outcomes and effectiveness research approaches. We expect that our data, research infrastructure, and research projects will inform the development of novel secondary prevention approaches and underpin the careers of CVD outcomes researchers.

Keywords

angina; infarction; risk factors; follow-up studies

Introduction

Despite improvements in hospital survival following acute coronary syndromes (ACS), mortality remains elevated in the first several years after hospital discharge,[1, 2] between one-quarter to one-third of patients hospitalized with ACS experience a recurrent event,[1, 3] and repeat hospitalization is common.[3] Evidence-based interventions for post-discharge ACS patients exist,[4] but are often under-prescribed or not followed by patients. As part of a broader initiative to bridge the profound translational gap between clinical trials and real-world settings, in 2010 the National Heart Lung and Blood Institute (NHLBI) funded three Centers for Cardiovascular Outcomes Research (RFA-HL-10-008). The NHLBI has a strong history of supporting large, longitudinal observational cohorts[5] such as the Framingham Heart Study, the Coronary Artery Risk Development in Young Adults (CARDIA) study, the Atherosclerosis Risk In Communities (ARIC) study, and the Cardiovascular Health Study (CHS), population-based surveillance studies such as the Worcester Heart Attack Study,[6] and registries for acute cardiac conditions such as the Translational Research Investigating Underlying Disparities in Acute Myocardial Infarction Patients' Health Status (TRIUMPH).[7] One of the Centers for Cardiovascular Outcomes Research, the Transitions, Risks, and Actions in Coronary Events – Center for Outcomes Research and Education (TRACE-CORE), builds on the strengths of these studies and uses a number of their well-established methods, with an added dimension of patient-reported outcomes collection and of quality of healthcare measurement to advance the science of prognosis following hospitalization for ACS. The aim of this paper is to describe the design of and rationale for TRACE-CORE.

Methods and Design

TRACE-CORE is a Center for Cardiovascular Outcomes Research with the following research and training aims: (1) to establish a longitudinal cohort of patients hospitalized with ACS, (2) the Transitions Project, (3) the Actions Scores Project, and (4) the development of a nucleus of early stage investigators. Table 1 details the Aims and associated research activities and hypotheses. TRACE-CORE uses a multi-site prospective cohort design to follow an eventual total of 2,500 individuals hospitalized with ACS for 24 months after hospital discharge. Data are collected through patient interviews during hospitalization and at 1, 3, 6, and 12 months following hospital discharge and abstraction of medical records through 24 months post-discharge. The study is led and coordinated by faculty and staff at the University of Massachusetts Medical School (UMMS; PI: CIK). The Committee for the Protection of Human Subjects at UMMS and Institutional Review Boards at each participating recruitment site approved this study. All participants provide informed consent.

Study sites

There are six individual recruitment and data collection sites. In Massachusetts, the participating sites are the two teaching hospitals (University and Memorial) that comprise the UMass Memorial Medical Center (UMMMC), a large academic medical center, and St. Vincent Hospital, a large community hospital. These three hospitals provide services to the

vast majority of residents hospitalized with ACS in central Massachusetts. In Georgia, the participating sites are Northside and Piedmont Hospitals, community hospitals in Atlanta affiliated with Kaiser Permanente Georgia, and the Medical Center of Central Georgia, the major cardiac referral hospital for central and southern Georgia located in Macon. These sites serve a heterogeneous patient population, represent both community hospitals and academic medical centers, and were purposely selected for their ethnic/racial, socioeconomic, urban/rural, and other sociodemographic diversity.

Participant screening, eligibility determination, and enrollment

Active surveillance for case identification is used to identify eligible patients admitted to participating medical centers. Site coordinators review computerized hospital admission logs on a daily basis for a standardized list of admission diagnoses related to ACS. The site coordinators also review lists for planned percutaneous coronary intervention (PCI)/ coronary artery bypass graft (CABG) procedures, Cardiac Catheterization Lab lists, lists by hospital floor, and lists of patients with elevated troponin levels to ensure that all potentially eligible patients are identified. Site coordinators then use additional medical record information (i.e., laboratory records, electrocardiogram [ECG] reports, and history and physical examination findings) to confirm the patient's eligibility status (Table 2). Because of rapidly changing criteria for acute hospitalization, we also include patients admitted for "elective" PCI or CABG, provided that they have symptoms of acute coronary ischemia within 72 hours of admission. Inclusion criteria include symptoms consistent with ACS and one of the following: serial EKG changes, elevated biomarkers of myocardial necrosis, or cardiac catheterization findings revealing >70% stenosis in a coronary artery (Table 2). Following discharge, each participant's discharge summary is reviewed to confirm an ACS diagnosis of either unstable angina, ST-elevation myocardial infarction (STEMI), or non-ST-elevation myocardial infarction (non-STEMI). Questionable cases are adjudicated by two cardiologists. After eligibility confirmation, a study-trained research assistant approaches the patient in the hospital to introduce them to the study. During this interaction, the research assistant completes the Confusion Assessment Method (CAM)[8] to screen for delirium and determine the patient's ability to provide informed consent. After obtaining informed consent, the baseline interview is conducted. Patients who are unable to complete the baseline interview prior to discharge are called within 72 hours of discharge to complete the interview. As of May 31, 2012, we have enrolled 1,365 participants towards our target of 2,500.

Data collection

TRACE-CORE's rich data are derived from patient interviews and abstraction of participants' medical records; measures are described in more detail below and are outlined in Table 3. The computer-assisted 60-minute baseline interview is conducted in-person during the patient's index hospitalization for ACS or by phone within 72 hours of discharge by trained interviewers. Computer-assisted 45- to 60-minute follow-up telephone interviews at 1, 3, 6, and 12 months after hospital discharge for participants at all sites are conducted by trained interviewers at the UMMS. At least 10 calling attempts are made to each participant for each assessment at varying times of weekdays and weekends to maximize interview completion. Baseline and follow-up interviews are conducted using systems that allow for skip patterns based on responses to previous questions within the current interview and from previous interviews, thus reducing participant burden by easily avoiding redundant or irrelevant questions. Participants receive monetary incentives in the form of gift cards for completing study interviews; total incentives for completing the study range from $45-75 based on differences in living costs and IRB-designated guidelines at each site.

Trained staff at each study site abstract participants' medical records into an online data entry system with built-in quality and consistency checks using standardized procedures. There are three components to medical record data collection: (1) medication use is abstracted from the medical record soon after discharge and is used to pre-populate medication information for the 1-month follow-up interview; (2) a comprehensive baseline medical record abstraction occurs post-discharge; and (3) follow-up medical record reviews occur following events reported by participants during the follow up phone interviews (e.g., re-hospitalization) and at 6-, 12-, 18-, and 24-months to check for hospitalizations at the study hospitals (Table 3). Source data, such as laboratory and medication records, are used in preference to interpreted data, such as those summarized in physician or nursing progress notes. For information that has been interpreted by a care provider, the note that is deemed most complete or the note that was written closest in time to the ACS event is used when there are discrepancies. Study staff conduct duplicate abstractions on 5% of randomly-selected charts to determine inter-rater reliability of medical record abstractions. Additionally, during site visits, audits are conducted of all study-related documentation to ensure appropriate record keeping and adherence to established protocols.

In addition, a sub-sample of participants from central Massachusetts are also having blood samples drawn and stored for future use in ancillary studies. This is made possible though a collaboration between the TRACE-CORE investigators and the UMMS's Conquering Diseases Biorepository Core funded through the University of Massachusetts' Clinical and Translational Science Award (CTSA).

Measures

Data collected for use by both the Transitions and Action Scores projects includes transition quality, quality of life, clinical outcomes, and medical, behavioral, psychosocial, and demographic characteristics. A list of domains measured along with the mode and timing of data collection and Projects utilizing each measure are shown in Table 3.

Our main measure of care transitions is the Care Transition Measure (CTM15), a 15-item measures assessing the quality of care transitions from the patient's perspective.[9] The measure has good psychometric properties and has been demonstrated to have predictive validity for rehospitalizations.[9] During each follow-up interview, participants report the quality of their care transition for their most recent hospitalization by completing the 3-item Care Transition Measure (CTM3).[10] We also include several questions to evaluate the general discharge environment context, including questions on hearing and visual impairment and level of caregiving support, including unmet caregiving needs.

Quality of life is an important outcome for both the Transitions Project and the Action Scores Project (Table 3); we measure both general and disease-specific quality of life. General quality of life is measured by the physical and mental component scores (PCS and MCS) of the SF-36,[11]. The SF-36 has been recommended as a most appropriate generic QoL instrument for patients with cardiovascular disease. To reduce participant burden, the 12-item version (SF12) is collected during the 12-month interview.[12] Disease-specific quality of life is measured the Seattle Angina Questionnaire (SAQ),[13] and the disease impact scale (DIS-7). The SAQ is a 19-item questionnaire measuring five dimensions of coronary artery disease: physical limitation, angina stability, angina frequency, treatment satisfaction, and disease perception.[13] The DIS-7 is a newly-developed scale measuring the disease-specific impact on quality of life; this measure is standardized to enable comparisons across different therapeutic areas. The DIS-7 includes an item assessing the global impact of ACS on the patient's wellbeing and six items measuring fatigue, general health outlook and worry, mental health, physical functioning, role participation, and social activities (personal communication with Dr. John E. Ware, Jr., 8/15/11).

Participants self-report emergency room visits and readmissions during the follow-up interviews. We confirm these reports when possible by reviewing admission logs at study hospitals. Medical records review at 6, 12, 18, and 24 months following discharge from the index hospitalization also provide data on timing and reason for rehospitalization. All-cause mortality will be ascertained from proxy report when attempting follow-up interviews and review of medical records and local, state, and national vital statistics records.

Behavioral characteristics are assessed during the baseline and follow-up interviews (Table 3). Frequency, intensity, and duration of physical activity is assessed through a series of questions used in the Women's Health Initiative.[16] Diet is briefly assessed using Starting the Conversation, an 8-item simplified food frequency questionnaire designed for use in primary care and health-promotion settings.[17] Alcohol consumption, smoking, and use of smokeless tobacco products are assessed using items from TRIUMPH.[7] Participants self-report weight changes occurring between follow-up interviews. At the 1- and 3-month interviews we ask participants whether a doctor or nurse suggested that they make a series of lifestyle changes, whether they intend to make these changes, and how confident they feel in their ability to make these changes. At every interview, medication adherence is assessed by the Morisky scale;[18] cost-related non-adherence is assessed at baseline and 12 months using questions included in the Medicare Current Beneficiary Survey.[19]

We assess several psychosocial characteristics for use in both Projects. Cognitive impairment is measured using the Telephone Interview for Cognitive Status (TICS), a telephone assessment of cognitive function.[20] At baseline and 1 month, participants complete the 9-item Patient Health Questionnaire (PHQ-9), which assesses depressive symptoms and can be used to make criteria-based diagnoses of depressive disorders,[21] and the Generalized Anxiety Disorder (GAD7), a 7-item valid scale for identifying probable cases of generalized anxiety disorder.[23] At later interviews, the 2-item PHQ2 and GAD2 provide brief screens for depression and anxiety, respectively.[22, 24] We have included a set of measures assessing patients' engagement in their health care: a 5-item scale measuring trust in physicians,[25] the Patient Activation Measure (PAM6) which assesses patient knowledge, skill, and confidence for self-management,[26] preferences for shared decision making between the patient and provider,[27] and brief screens of low health literacy[29] and numeracy.[28] Also included in baseline and follow-up interviews are measures of perceived stress and social support: the Perceived Stress Scale (PSS4), a 4-item measure designed to measure the degree to which situations in one's life are appraised as stressful,[30] 6 questions from the Medical Outcomes Study Social Support Survey,[31] and the 6-item Lubben Social Network Scale (LSNS6) which asks about social ties to family and friends.[32]

Methods and Activities Specific to the Research Projects

Transitions Project—Activities and hypotheses to be tested as part of the Transitions Project are listed in Table 1. We have engaged an expert advisory panel to determine critical measures of transition quality, and we aim to describe transitions from the hospital to the community for ACS patients and to examine the determinants and outcomes of care transition quality. The panel consisted of 6 international experts in transitional care and included cardiologists, health economists, and health services researchers. The group provided feedback on items from the proposed survey assessing transitional care and quality and identified areas of deficiency. In addition to the Care Transition Measure[9] as our main measure of transition quality, based on panel recommendations, we included several psychosocial measures in the baseline and 1-month interviews (e.g., depression and cognitive impairment) and consider several patient clinical characteristics that have not been previously examined with respect to care transitions such as vision or hearing impairment. Potential behavioral and psychosocial determinants of transition quality were also discussed

by the panel and are outlined in Table 3. We will also examine outcomes of transition quality, including quality of life (as measured by the SF-36,[11] the Seattle Angina Questionnaire (SAQ),[13] and the disease-specific impact scale) and rehospitalizations. The expert advisory panel will convene again following the completion of data collection activities to discuss the findings regarding transition quality and the implications of these findings.

Action Scores Project—Activities and hypotheses to be tested as part of the Action Scores Project are listed in Table 1. We will develop two sets of Action Scores to predict (1) recurrent cardiac events and all-cause mortality and (2) quality of life as measured by the physical and mental component scores (PCS and MCS) of the SF-36,[11] the Seattle Angina Questionnaire (SAQ),[13] and the disease-specific impact scale. We will build upon the Global Registry of Acute Coronary Events (GRACE) model for predicting death within 6 months after discharge for ACS; this risk score includes only factors not modifiable by the patient or his/her health care team (i.e., age, medical history, clinical presentation, and in-hospital cardiac procedures).[33] Action Scores will be based on statistical models that include both these non-modifiable factors and modifiable factors, but with particular emphasis on factors potentially amenable to intervention (e.g., physical activity, diet, weight, smoking cessation, medication adherence). We also include factors that may not be amenable to intervention (e.g., cognitive impairment, low health literacy, vision or hearing impairment), but might provide information on subgroups where targeted interventions would be most effective. Additional behavioral and psychosocial predictors are listed in Table 3.

We will use procedures widely accepted for clinical prediction rules[34, 35] to develop these Action Scores. We will develop Action Scores based on information from patient interviews during hospitalization and at 1 and 3 months post-discharge. If new events occur after the index ACS, we will account for the fact that more recent events affect future risk more than remote events. We will develop score sheets based on the beta coefficients of the variables included in the final regression model for use in clinical practice. Next, we will describe longitudinal variation in the Action Scores and test the hypothesis (Table 1). Finally, we will develop a “Dashboard (control panel) for CVD Action” that represents the blueprint of a future tailored measurement system. Calculations based on our regression models will populate the Dashboard. The Dashboard is intended as graphical display of factors potentially modifiable by patients and providers; interface and content of the dashboard will be developed following the completion of the first stages of this Project.

Development of early stage investigators

The fourth Aim of TRACE-CORE is the development of four early stage investigators (MEW, JSS, MDA, DDM) as cardiovascular outcomes researchers (Table 1). By implementing structured mentoring, engaging them as Co-PIs of the two research projects, and assisting them in preparing K- and R-type applications, TRACE-CORE goes beyond the experiential learning common to many large research studies. The early stage investigators have leadership roles in the design and implementation of the longitudinal cohort and in convening the national consensus panel to discuss measures of transition quality. These investigators will lead the writing groups of manuscripts detailing the main results of the two research projects and other important manuscripts.

Potential for Ancillary Studies

The rich clinical and patient-reported data collected in TRACE-CORE provide a valuable resource to the community of cardiovascular outcomes researchers. Plasma, DNA, and RNA are also being obtained from TRACE-CORE participants hospitalized at the UMMMC in Worcester, MA. TRACE-CORE aims and projects do not include analysis of these

biological samples; these data are collected to facilitate future ancillary studies. Also possible are studies linking the rich clinical and patient-reported TRACE-CORE data to claims data such as that from Medicare, or to U.S. Census or geographic information system (GIS) data. We welcome proposals for ancillary studies not only from TRACE-CORE investigators but also from investigators at other institutions.

Summary and conclusions

TRACE-CORE builds on the NHLBI's strong history of longitudinal observational research[5-7] by adding a dimension of patient-reported outcomes collection and of quality of healthcare measurement that bridges epidemiology with outcomes and effectiveness research. Using data from the large, diverse cohort of adults with ACS established as part of this Center for Cardiovascular Outcomes Research, the two research projects aim to advance the science of prognosis post-ACS by increasing our understanding of the determinants and outcomes of the quality of the transition from hospital to the community and by quantifying the impact of potentially-modifiable characteristics associated with decreased quality of life, rehospitalization, and mortality.

The Transitions Project aims to enhance our understanding of the determinants and outcomes of ACS specific transition quality over the extended post-discharge period. Shortened hospital stays and fragmented care across settings make the transition following hospitalization for ACS a high-risk period. Problematic transitional care includes poor patient readiness, conflicting advice for self-management, minimal patient input into care planning, medication errors, inaccurate information transfer, and inadequate follow-up.[36-39] Care coordination interventions may be ineffective in the absence of a transitional care component beyond the time of discharge.[40] The Transitions Project will address important gaps in the literature by characterizing the transition from the hospital to the community. We will examine determinants and outcomes of transition care quality, especially among patients vulnerable to poor-quality transitions due to race/ethnicity, socioeconomic status, comorbidities, or psychosocial factors such as cognitive impairment, enhancing our understanding of the complex relationship between transitional care and ACS health disparities.[41-43] By examining novel patient factors, such as cognitive impairment and comorbidity burden, as risk factors for poor transition quality, the Transitions Project may identify groups of patients who require tailored discharge planning or modified follow-up schedules, thus laying the groundwork for the development of interventions to improve transitional care for patients following ACS.

The Action Scores project aims to advance the science of CVD risk assessment by separating modifiable from non-modifiable risk, and by predicting the important patient-centered outcome of quality of life. The development of models to predict quality of life following discharge for ACS represents one of the unique contributions of TRACE-CORE to the literature. We will build on the model predicting prognosis in the GRACE study[33] by including factors potentially amenable to intervention, and by constructing risk scores to predict rehospitalization and quality of life following discharge for ACS. The Action Scores may also identify patterns of sub-optimal management in particularly vulnerable groups, the remediation of which could lead to reducing health disparities. To help guide provider and patient action, we will develop a dashboard (control panel); dashboards are increasingly being used as a way to summarize complex data to improve patient care.[44, 45] The value of the Action Scores will be enhanced by a user-friendly measurement system allowing for recommendations for action, and the final product of this Project will be a roadmap for such a system to be further developed in future work.

In summary, TRACE-CORE represents a convergence of (1) sound principles of primary data collection for observational studies and their analyses, which have been developed through decades of NHLBI-funded large epidemiological cohort studies and (2) outcomes and effectiveness research approaches to collecting and interpreting patient-centered outcomes data. We expect that our data, research infrastructure, and results of our two research projects will improve our understanding of the natural history of patients hospitalized with ACS, lead to the development of novel secondary prevention approaches, and underpin the careers of CVD outcomes researchers.

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References

1. Roger VL, Go AS, Lloyd-Jones DM, Benjamin EJ, Berry JD, Borden WB, Bravata DM, Dai S, Ford ES, Fox CS, Fullerton HJ, Gillespie C, Hailpern SM, Heit JA, Howard VJ, Kissela BM, Kittner SJ, Lackland DT, Lichtman JH, Lisabeth LD, Makuc DM, Marcus GM, Marelli A, Matchar DB, Moy CS, Mozaffarian D, Mussolini ME, Nichol G, Paynter NP, Soliman E, Sorlie PD, Sotoodehnia N, Turan TN, Virani SS, Wong ND, Woo D, Turner MB. on behalf of the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart Disease and Stroke Statistics - 2012 Update: a Report from the American Heart Association. Circulation. 2012; 125:e2–e220. [PubMed: 22179539]
2. McGovern PG, Jacobs DRJ, Shahar E, Arnett DK, Folsom AR, Blackburn H, Luepker R. Trends in acute coronary heart disease mortality, morbidity, and medical care from 1985 through 1997: the Minnesota Heart Survey. Circulation. 2001; 104:19–24. [PubMed: 11435332]
3. Bernheim SM, Grady JN, Lin Z, Wang Y, Wang Y, Savage SV, Chat KR, Ross JS, Desai MM, Merrill AR, Han LF, Rapp MT, Drye EE, Normand ST, Krumholz HM. National patterns of risk-standardized mortality and readmission for acute myocardial infarction and heart failure: update on publicly reported outcomes measures based on the 2010 release. Circ Cardiovasc Qual Outcomes. 2010; 3:459–467. [PubMed: 20736442]
4. Smith SC, Allen J, Blair SN, Bonow RO, Brass LM, Fonarow GC, Grundy SM, Hiratzka L, Jones D, Krumholz HM, Mosca L, Pasternak RC, Pearson T, Pfeffer MA, Taubert KA. AHA/ACC Guidelines for Secondary Prevention for Patients with Coronary and Other Atherosclerotic Vascular Disease: 2006 Update. Circulation. 2006; 113:2363–2372. [PubMed: 16702489]
5. National Heart Lung and Blood Institute (NHLBI). [May 20, 2012] BioLINCC: Biologic Specimen and Data Repository Information Coordinating Center. Available at: https://biolincc.nhlbi.nih.gov/home/
6. Floyd KC, Yarzebski J, Spencer FA, Lessard D, Dalen JE, Alpert JS, Gore JM, Goldberg RJ. A 30-year perspective (1975-2005) into the changing landscape of patients hospitalized with initial acute myocardial infarction: Worcester Heart Attack Study. Circ Cardiovasc Qual Outcomes. 2009; 2:88–95. [PubMed: 20031820]

7. Arnold SV, Chan PS, Jones PG, Decker C, Buchanan DM, Krumholz HM, Ho PM, Spertus JA. for the Cardiovascular Outcomes Research Consortium. Translational Research Investigating Underlying Disparities in Acute Myocardial Infarction Patients' Health Status (TRIUMPH): Design and Rationale of a Prospective Multicenter Registry. Circ Cardiovasc Qual Outcomes. 2011; 4:467–476. [PubMed: 21772003]
8. Inouye SK, van Dyck CH, Alessi CA, Balkin S, Siegal AP, Horwitz RI. Clarifying confusion: the Confusion Assessment Method: a new method for detection of delerium. Ann Intern Med. 1990; 113:941–948. [PubMed: 2240918]
9. Coleman EA, Mahoney E, Parry C. Assessing the quality of preparation for posthospital care from the patient's perspective: the Care Transitions Measure. Med Care. 2005; 43:246–255. [PubMed: 15725981]
10. Parry C, Mahoney E, Chalmers SA, Coleman EA. Assessing the quality of transitional care: further applications of the Care Transitions Measure. Medical Care. 2008; 46:317–322. [PubMed: 18388847]
11. Ware JEJ, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). 1. Conceptual framework and item selection. Medical Care. 1992; 30:473–483. [PubMed: 1593914]
12. Ware JEJ, Kosinski M, Keller SD. A 12-item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. Medical Care. 1996; 34:220–233. [PubMed: 8628042]
13. Spertus JA, Winder JA, Dewhurst TA, Deyo RA, Prodzinski J, McDonell M, Fihn SD. Development and evaluation of the Seattle Angina Questionnaire: a new functional status measure for coronary artery disease. JACC. 1995; 25:333–341. [PubMed: 7829785]
14. Anatchkova MD, Bjorner JB. Health and role functioning:the use of focus groups in the development of an item bank. Qual Life Res. 2011; 20:745–758. [PubMed: 21153710]
15. Anatchkova MD, Ware JEJ, Bjorner JB. Assessing the structure of a role functioning item bank. Qual Life Res. 2011; 20:745–758. [PubMed: 21153710]
16. Manson JE, Greenland P, LaCroix AZ, Stefanick ML, Mouton CP, Oberman A, Perri MG, Sheps DS, Pettinger AB, Siscovick DS. Walking compared with vigorous exercise for the prevention of cardiovascular events in women. N Engl J Med. 2002; 347:716–725. [PubMed: 12213942]
17. Paxton AE, Stryker LA, Toobert DJ, Ammerman AS, Glasgow RE. Starting the Conversation: performance of a brief dietary assessment and intervention tool for health professionals. Am J Prev Med. 2011; 40:67–71. [PubMed: 21146770]
18. Morisky DM, Ang A, Krousel-Wood M, Ward HJ. Predictive validity of a medication adherence measure in an outpatient setting. J Clin Hypertens. 2008; 10:348–354.
19. Pierre-Jacques M, Safran DG, Zhang F, Ross-Degnan D, Adams AS, Gurwitz J, Rusinak D, Soumerai SB. Reliability of new measures of cost-related medication nonadherence. Med Care. 2008; 46:444–448. [PubMed: 18362826]
20. Brandt J, Spencer M, Folstein M. The Telephone Interview for Cognitive Status. Neuropsychiatry, Neuropsychology, and Behavioral Neurology. 1988; 1:111–117.
21. Kroenke K, Spitzer RL, Williams JBW. The PHQ-9: validity of a brief depression severity measure. J Gen Intern Med. 2001; 16:606–613. [PubMed: 11556941]
22. Kroenke K, Spitzer RL, Williams JBW. The Patient Health Questionnaire-2: validity of a two-item depression screener. Medical Care. 2003; 41:1284–1292. [PubMed: 14583691]
23. Spitzer RL, Kroenke K, Williams JBW, Lowe B. A brief measure of assessing generalized anxiety disorder: the GAD-7. Arch Intern Med. 2006; 166:1092–1097. [PubMed: 16717171]
24. Lowe B, Wahl I, Rose M, Spitzer C, Glaesmer H, Wingenfield K. A 4-item measure of depression and anxiety: validation and standardization of the Patient Health Questionnaire-4 (PHQ-4) in the general population. Journal of Affective Disorders. 2010; 122:86–95. [PubMed: 19616305]
25. Dugan E, Trachtenberg F, Hall MA. Development of abbreviated measures to assess patient trust in a physician, a health insurer, and the medical profession. BMC Health Services Research. 2005; 5:64. [PubMed: 16202125]
26. Hibbard JH, Mahoney ER, Stockard J, Tusler M. Development and testing of a short form of the Patient Activation Measure. HSR. 2005; 40:1918–1930. [PubMed: 16336556]

27. Deber RB, Kraetschmer N, Irvine J. What role do patients wish to play in treatment decision making? Arch Intern Med. 1996; 156:1414–1420. [PubMed: 8678709]
28. Lipkus IM, Samsa G, Rimer BK. General performance on a numeracy scale among highly educated samples. Med Decis Making. 2001; 21:37–44. [PubMed: 11206945]
29. Powers BJ, Trinh JV, Bosworth HB. Can this patient read and understand written health information? JAMA. 2010; 304:76–84. [PubMed: 20606152]
30. Cohen, S.; Williamson, GM. Chapter 3: Perceived Stress in a Probability Sample of the United States. In: Spacapan, S.; Oskamp, S., editors. The Social Psychology of Health. Newbury Park, CA: Sage; 1988. p. 31-67.
31. Sherbourne CD, Stewart AL. The MOS Social Support Survey. Soc Sci Med. 1991; 32:705–714. [PubMed: 2035047]
32. Lubben J, Blozik E, Gillman G, Iliffe S, von Renteln Kruse W, Beck JC, Stuck AE. Performance of an abbreviated version of the Lubben Social Network Scale among three European community-dwelling older adult populations. The Gerontologist. 2006; 45:503–513. [PubMed: 16921004]
33. Eagle KA, Lim MJ, Dabbous OH, Pieper KS, Goldberg RJ, Van de Werf F, Goodman SG, Granger CB, Steg PG, Gore JM, Budaj A, Avezum A, Flather MD, Fox KAA. for the GRACE Investigators. A validated prediction model for all forms of acute coronary syndrome: estimating the risk of 6-month postdischarge death in an international registry. JAMA. 2004; 291:2727–2733. [PubMed: 15187054]
34. Laupacis A, Sekar N, Stiell IG. Clinical prediction rules: a review and suggested modifications of methodological standards. JAMA. 1997; 277:488–494. [PubMed: 9020274]
35. McGinn TG, Guyatt GH, Wyer PC, Naylor CD, Stiell IG, Richardson WS. for the Evidence-Based Medicine Working Group. Users' guide to the medical literature - XII: how to use articles about clinical prediction rules. JAMA. 2000; 284:79–84. [PubMed: 10872017]
36. van Walraven C, Seth R, Austin PC, Laupacis A. Effect of discharge summary availability during post-discharge visits on hospital readmission. J Gen Intern Med. 2002; 17:186–192. [PubMed: 11929504]
37. Moore C, Wisnivesky J, Williams S, McGinn T. Medical errors related to discontinuity of care from an inpatient to an outpatient setting. J Gen Intern Med. 2003; 18:646–651. [PubMed: 12911647]
38. Coleman EA. Falling through the cracks: challenges and opportunities for improving transitional care for persons with continuous complex care needs. J Am Geriatr Soc. 2003; 51:549–555. [PubMed: 12657078]
39. Strunin L, Stone M, Jack B. Understanding reshospitalization risk: can hospital discharge be modified to reduce recurrent hospitalization? J Hosp Med. 2007; 2:297–304. [PubMed: 17935257]
40. Peikes D, Chen A, Schore J, Brown R. Effects of care coordination on hospitalization, quality of care, and health care expenditures among Medicare beneficiaries. JAMA. 2009; 301:603–618. [PubMed: 19211468]
41. Canto JG, Allison JJ, Kiefe CI, Fincher C, Farmer R, Sekar P, Person S, Weissman NW. Relation of race and sex to the use of reperfusion therapy in Medicare beneficiaries with acute myocardial infarction. N Engl J Med. 2000; 342:1094–1100. [PubMed: 10760310]
42. Rao SV, Padma K, Newby LK, Lincoff MA, Hochman J, Harrington RA, Mark DB, Peterson ED. Poverty, process of care, and outcome in acute coronary syndromes. J Am Coll Cardiol. 2003; 41:1948–1954. [PubMed: 12798563]
43. Pamboukian SV, Funkhouser E, Child IG, Allison JJ, Weissman NW, Kiefe CI. Disparities by insurance status in quality of care for elderly patients with unstable angina. Ethn Dis. 2006; 16:799–807. [PubMed: 17061730]
44. Lister ED. How to drive a quality dashboard. Interview by Laurie Larson. Trustee. 2008; 61:27–28. [PubMed: 18512471]
45. Jung E, Schnipper JL, Li Q, Linder JA, Rose AF, Li R, Eskin MS, Housman D, Middleton B, Einbinder JS. The coronary artery disease quality dashboard: a chronic care disease management tool in an electronic health record. AMIA Symposium. 2007; 2007:999. [PubMed: 18694098]

Table 1

Aims and associated activities and hypotheses of TRACE-CORE

Aim 1 – to recruit and follow for two years a multi-racial cohort of 2,500 adults residing in urban, suburban, and rural areas of Massachusetts and Georgia hospitalized at 6 community teaching and non-teaching hospitals.

- Recruit and enroll patients, conduct baseline in-person interview, and review inpatient medical records of this index ACS hospitalization.
- Follow patients for two years, reviewing rehospitalization records and electronically-available outpatient records.
- Conduct follow-up interviews at 1, 3, 6, and 12 months after discharge from the index hospitalization.

Aim 2 – Transitions Project

- Engage a technical advisory panel in consensus building to assist in the selection and evaluation of measures of transition quality focused on the first 90 days after discharge, extending beyond existing systems limited to the discharge process.
- Characterize the transition from hospital to community for ACS patients
- Examine the determinants and outcomes for transition care quality, testing the following hypotheses

  H1: Better transition quality is associated with improved post-discharge quality of life.

  H2: Better transition quality is associated with longer time to first ED visit or rehospitalization.

  H3: Patients who are potentially vulnerable due to (a) race/ethnicity, (b) socioeconomic status, (c) total morbidity burden, or (d) cognitive status will have worse transition quality.

  H4: Transition quality partially mediates observed disparities in outcomes for vulnerable patients.

Aim 3 – Action Scores Project

- Develop and validate two kinds of “CVD Action Scores” to predict 1) recurrent cardiac events or death and 2) quality of life.
- Describe longitudinal variation in the Action Scores over 2 years and test the hypothesis:

  H5: Observed health disparities for populations vulnerable because of (a) race/ethnicity, (b) socioeconomic status, (c) total morbidity burden, or (d) cognitive status would be reduced if actions identified in the Action Scores were taken by patients and providers.
- Develop a dashboard for CVD action based on regression models underlying the Action Scores.

Aim 4 – Develop a nucleus of early stage investigators (ESIs)

- Implement structured mentoring for the ESIs
- Engage the ESIs as co-PIs in the two research projects (Aims 2 and 3), and encourage them to take leadership roles in the design and implementation of the cohort (Aim 1)
- Assist the ESIs in preparing K- and R-type grant applications

Table 2

Eligibility criteria.

Inclusion criteria include age 21+ years and at least one of (A), (B), (C), or (D).

- **A.** Serial ECG changes
  - **1.** ST-segment changes
  - **2.** New left or right branch bundle block changes
  - **3.** T-wave inversion
  - **4.** New Q waves consistent with ACS
- **B.** Elevation of cardiac biomarkers (above a level established by the individual hospital as a determination of cardiac myonecrosis)
  - **1.** CK-MB
  - **2.** Troponin
- **C.** Cardiac catheterization revealing greater than 70% stenosis in a coronary artery
- **D.** Admission for PCI/CABG classified as urgent, emergent, salvage, or rescue and symptoms of acute ischemia in the 72 hours prior to admission.

Exclusion criteria include:

- **A.** ACS secondary to aortic dissection
- **B.** ACS secondary to demand ischemia
- **C.** Admission from hospice or for palliative care, or under comfort measures only
- **D.** Admission for trauma
- **E.** Diagnosis of dementia
- **F.** Elective cardiac catheterization procedure (PCI/CABG without symptoms immediately preceding procedure)
- **G.** Perioperative ACS related to surgery
- **H.** Under custody of a prison system (federal or state)
- **I.** Pregnant
- **J.** Patient transferred from another hospital with a length of stay greater than 24 hours at the referring hospital.

Table 3

Domains measured in TRACE-CORE.

		Patient interviews						
Domains and measures	**Project**	**Baseline**	**1M**	**3M**	**6M**	**12M**	**Baseline**	**Medical record abstractions 6, 12, 18, and 24M**
Transition quality								
Care Transitions Measure (CTM15) for index hospitalization[9]	T		X					
Caregiving support	T, A		X					
Care Transitions Measure (CTM3) for most recent hospitalization[10]	T		X	X	X	X		
Quality of life								
Short-Form Health Survey (SF36)[11, 12]	T, A	X	X	X	X	X		
Seattle Angina Questionnaire (SAQ)[13]	T, A	X	X	X	X	X		
Disease impact scale (DIS-7)	T, A	X	X	X	X	X		
Role functioning[14, 15]		X	X	X	X	X		
Clinical outcomes								
Readmissions	T, A		X	X	X	X		X
Emergency room visits	T, A		X	X	X	X		X
Outpatient encounters	T, A		X	X	X	X		X
Mortality	A		X	X	X	X	X	X
Medical characteristics								
Vital signs and cardiac symptoms at hospitalization	A						X	
Clinical findings (including ECG findings)	A						X	
Cardiac procedures	T, A						X	X
Medical histories and comorbidities	T, A						X	X
Medications	T, A		X	X	X	X	X	X
Access to medical care	T, A	X	X	X	X	X		
Hearing and vision impairment	T, A	X				X		
Behavioral characteristics								
Physical activity[16]	A	X	X	X	X			
Diet[17]	A	X	X	X	X			
Alcohol consumption	A	X	X	X	X			
Smoking and use of smokeless tobacco products	A	X	X	X	X	X		

		Patient interviews						
Domains and measures	**Project**	**Baseline**	**1M**	**3M**	**6M**	**12M**	**Baseline**	**Medical record abstractions 6, 12, 18, and 24M**
Weight changes, weight loss attempts	A	X	X	X	X	X		
Recommendations for lifestyle change	A		X	X				
Medication adherence[18, 19]	T, A	X	X	X	X	X		
Online information-seeking behavior	T, A	X				X		
Psychosocial characteristics								
Telephone Interview for Cognitive Status (TICS)[20]	T, A	X	X	X	X	X		
Depression (PHQ9)[21, 22]	T, A	X	X	X	X	X		
Anxiety (GAD7)[23, 24]	T, A	X	X	X	X	X		
Trust in physicians[25]	T, A	X	X	X				
Patient Activation Measure (PAM6)[26]	T, A	X	X	X				
Shared decision making[27]	T, A	X						
Health literacy and numeracy[28, 29]	T, A	X						
Religiosity/spirituality	T, A	X						
Perceived Stress Scale (PSS4)[30]	T, A	X	X	X				
Social support[31]	T, A	X	X	X				
Lubben Social Network Scale (LSNS6)[32]	T, A	X	X	X				
Demographics								
Date of birth (age)	T, A						X	
Race/ethnicity and education	T, A	X					X	
Marital status, living situation	T, A	X	X	X	X	X		
Household size, annual income	T, A	X				X		

T = Transitions Project, A = Action Scores Project.