PCORI Funding Awards: Cycle III and Inaugural Improving Methods for Conducting PCOR

Announced September 10, 2013

PCORI Funding Announcement (PFA) Cycle III awards were approved by PCORI’s Board of Governors on September 10, 2013, pending a business and programmatic review by PCORI staff and completion of formal award contracts. More information on each awarded project, including award amounts, will be posted on PCORI’s website as award agreements are completed.
### Assessment of Prevention, Diagnosis, and Treatment Options

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Lupus is a serious disease where the immune system attacks normal parts of the body, including the kidneys, heart, brain, lungs, joints, and skin. Lupus most commonly affects young women. It occurs more frequently in minority women. African-American and Hispanic women have more severe disease and are more likely to die of lupus compared to white women. Kidney disease caused by lupus (also called lupus nephritis) can lead to kidney failure and the need for dialysis if not treated early with strong medications. Thankfully, there are several medications available to treat kidney disease in lupus, but choosing which medication is best for each person can be challenging. This research study will develop a computer tool, called a decision aid, to help African-American and Hispanic lupus patients with kidney disease and their doctors choose the best individual treatment for each individual patient. To do this, we will compare all published studies on the treatments available for kidney disease in lupus [patients] (sic). We will then use state-of-the-art statistics to come up with the best estimates of the risks and benefits for lupus medications. The decision aids will be developed with input from patients at all stages of our study to be sure that the information created is helpful, practical, and relevant to patients facing treatment decisions for lupus nephritis. The decision aids will be available in both English and Spanish languages. Once we have developed the decision aids, we will test whether or not they work by comparing how patients and their doctors make decisions using the decision aids with patients and doctors who do not. Our long-term goal is to make sure that minority patients with lupus have the information they need to make informed decisions, at the right time, so they may actively participate in their health care. Use of decision aids will improve patient care and decrease racial/ethnic disparities for lupus patients in the United States. We will make the decision aids publicly available free of cost. Our method of developing decision aids for minority women will use the best science combined with a great deal of patient input at every step of the development process. Our decision aids can easily be used for other diseases that use similar medications, and that have risks and benefits patients need to balance before they decide what to choose.
California

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KAISER FOUNDATION RESEARCH INSTITUTE
Balancing Treatment Outcomes and Medication Burden among Patients with Symptomatic Diabetic Peripheral Neuropathy

Painful diabetic peripheral neuropathy (DPN) affects more than 5.5 million people with diabetes. People with painful DPN have trouble sleeping, participating in social events, and conducting daily activities such as going to the store. The following vignette describes the challenges of balancing treatment outcomes and burden in DPN. A 67-year-old woman with DPN is prescribed a tricyclic antidepressant after nearly 8 months of persistent pain that interferes with her ability to sleep. Soon after starting treatment, she begins to experience dizziness that she believes is caused by her new drug and is considering stopping treatment. Several prescription medications are available for the treatment of DPN symptoms, but none work perfectly and all have side effects that may be difficult for some patients. When patients report their symptoms and side effects to their doctor, they are providing the doctor with important information to help him make adjustments to treatment that will help with symptoms and that the patient can tolerate in terms of side effects. In some cases, doctors may encourage patients to make these changes on their own at home based on their experience with therapy. However, patients may have a long time between visits to their doctor and may have trouble describing their symptoms to their doctor during a brief 10 to 15-minute visit. This proposal will explore the possibility of computerized telephone calls to patients to gather information about treatment experiences that can then be reported to the doctor, or used to guide patients to make changes in how they take the medication. The following question will be addressed: Can routinely asking patients about their experiences with medications and using that information to encourage clinically appropriate titration improve patient quality of life? We believe that asking patients about their experiences can encourage better communication between patients and doctors about treatment, as well as encourage treatment changes that improve patient outcomes.

Christine E. Dehlendorf, MD, MS
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Patient-Centered Support for Contraceptive Decision Making

Approximately 50% of pregnancies in the United States each year are unintended, which leads to poor health and social outcomes for both women and their children. One factor contributing to the high rate of unintended pregnancy is the fact that many women use birth control that is less effective, or stop using their method shortly after initiating it. The family planning visit provides an opportunity to assist women to achieve their reproductive goals through providing adequate information and helping women to choose the birth control method that is best for them. Decision support tools are interventions designed to help ensure that individuals have the information and support they need to make difficult health care decisions. Because choice of a birth control method is a complex decision, with many methods being an option for the majority of women, these tools can help women to think through their options and make the best choice. We have developed a patient-centered, tablet-based tool designed to help women with their choice of a birth control method, with the ultimate goal of helping them to be able to continue their chosen method and decrease their risk of unintended pregnancy. In this research, our aims are as follows: (1) to determine the impact of a decision support tool on whether a woman continues her chosen method, as well as her experience with birth control counseling; (2) to compare
the birth control counseling provided to patients who have used the decision support tool prior to their visit with those who have not used the tool, through audio recordings of clinic visits; and (3) to assess the experience of providers and clinics that use the intervention through observation in clinics, surveys, interviews, and focus groups. We will accomplish these aims using a cluster randomized trial with approximately 700 patients, with women either using the tool before their visit or receiving usual care. We will survey women after their visit, and at 3 and 6 months, to assess their experience of counseling and continuation of her chosen birth control method. In addition, we will audio record a sample of visits before and after the tool is introduced into clinics to assess differences in the process of counseling, including whether patients and providers are more likely to engage in shared decision making after the patient has used the tool. Finally, we will compare waiting time and total clinic visit time for patients using the tool and those not using the tool, and perform interviews and surveys of providers and clinic staff about their experience with the tool, as well as their assessment of the effect of the tool on quality of care and on clinic operations. If this tool is found to be effective, we will be prepared to disseminate a patient-centered, tablet-based birth control counseling intervention designed to improve birth control counseling and women’s ability to achieve their reproductive goals.

De-Kun Li, MD, PhD
KAISER FOUNDATION RESEARCH INSTITUTE
Comparing Effectiveness of Treating Depression With and Without Comorbidity to Improve Fetal Health

Depression during pregnancy is prevalent (15%–20%) and has an adverse impact on fetal outcomes, including preterm delivery (PTD) and low birthweight (LBW). Currently, significant confusion exists about if and how depression during pregnancy should be treated given the unknown risk–benefit profiles of various treatments. Kaiser Permanente Northern California has implemented a large-scale universal peripartum depression screening program, annually screening more than 35,000 pregnant women. Taking advantage of this unique infrastructure, we propose to conduct a two-stage prospective cohort study to determine if treating depression in pregnancy is effective in improving fetal outcomes, and which treatment is most effective: pharmacotherapy, psychotherapy, or a combination. The risk–benefit of the treatments will be examined separately for two depression types: pregnant women with depression only, and those with other psychiatric comorbidities, to evaluate possible differences in treatment effectiveness between the two groups. Stakeholders (patients, advocacy groups, and providers) are an integral part of the research team. Four cohorts with different treatment options, including untreated, will be formed within each depression type (with or without comorbidity): (A) antidepressant only: screen positive for depression and use only antidepressants during pregnancy; (B) psychotherapy only: screen positive and receive psychotherapy only; (C) combination therapy: screen positive and receive both antidepressants and psychotherapy; and (D) untreated depression: screen positive and receive no treatment. A total of eight cohorts will be formed. We will also form a final cohort for baseline comparison: (E) no depression: screen negative and receive no treatment. Information on depression treatment and PTD and LBW will be available for all 88,000 women in the Stage 1 sample. We will form Stage 2 subcohorts by randomly selecting 400 women from each cohort (total of 3600 subjects) and interview them to obtain detailed information on treatment compliance and confounders. Within each depression category, comparison of Cohort A, B and C to D, respectively, will determine if treating depression is effective. Pair-wise comparisons among Cohorts A, B and C will determine the comparative effectiveness of treatment regimens. Comparison of Cohort D to E provides baseline fetal risks of untreated depression. Findings will provide answers to longstanding stakeholders’ questions of how to treat depression in pregnancy and which treatment is most effective with the best risk–benefit profile in improving fetal outcomes. Selecting an effective treatment could reduce PTD or LBW, thus, reducing infant mortality and morbidity, and medical costs.
Comparison of Peer-Facilitated Support Group and Cognitive Behavioral Therapy for Hoarding Disorder

Background: Hoarding disorder (HD) is a common syndrome that can cause significant problems for individuals, families, and communities. HD is defined as (1) ongoing problems with discarding or parting with personal possessions, even items with no clear value; (2) strong urges to save items, and distress or indecision about what to discard; and (3) the accumulation of so many items that the space cannot be used for its usual purposes. HD can cause increased social isolation (due in part to public and self-stigma associated with hoarding challenges), anxiety and depression, and physical safety risks. However, treatment options for HD are limited. One of the best treatments is cognitive behavioral therapy (CBT) with a mental health provider who is trained to treat HD. However, not everyone has access to CBT. Additionally, some people with HD may be unable to go to a mental health provider for treatment. Instead, they may join support groups or contact consumer advocacy groups for help. Therefore, alternative and more accessible forms of treatment are needed. There is some evidence suggesting that support group treatment led by individuals from the community (usually with peers who are in recovery from HD), using a workbook for hoarding, may work as well as CBT to reduce symptoms; however, this treatment has not been well studied, and it has never been compared to CBT.

Objectives: This study will compare the effectiveness of group CBT to peer-facilitated support group treatment based on the workbook Buried in Treasures (BiT). We are interested in answering several questions that are important to individuals with hoarding challenges, as well as to their families and care providers: (1) Is peer-led BiT group treatment for HD as effective as group CBT led by a trained mental health professional? (2) Are specific individual characteristics (for example, gender or presence of depressive symptoms) associated with treatment response? (3) Do individuals with HD have strong preferences for a particular type of treatment, and do those preferences influence how well people respond to treatment?

Methods: This study is a partnership between researchers at UCSF and the Mental Health Association of San Francisco (MHASF). Three hundred adults with HD will be randomly assigned to participate in 16 weeks of either CBT or BiT group treatment. A series of questionnaires and tests will be given to each person before and after they get treatment to look at how severe their hoarding symptoms are, and whether they have other important symptoms such as anxiety, depression, or problems processing information. We will compare participants in the two groups to see how much improvement they made in reducing their hoarding symptoms after treatment. We will also look at whether we can predict who will respond to these treatments based on the findings from the tests and questionnaires.

Quality of Life in Allogeneic Hematopoietic Stem Cell Transplant Patients Is Improved When Their Caregiver’s Distress Is Reduced

Hematopoietic stem cell transplants (HSCT) are a treatment option for diseases of the blood such as leukemia. The patient is conditioned by removing (ablatting) their blood cells, either in whole or in part by radiation and/or chemotherapy. Their cancerous blood cells are replaced (transplanted) with either
some of their own blood cells that were “cleaned” and preserved (autologous HSCT) or those from a closely matched donor (allogeneic HSCT). An allogeneic transplant is an extraordinarily challenging experience for both the patient and the caregiver, who must be available 24/7 for at least the first 100 days following transplant. Not surprisingly, quality of life (QOL) of the patient is significantly reduced during this process. Caregivers also report increased stress, depression, and anxiety. Patients and caregivers represent a team in cancer survivorship with tightly woven influences. The challenges, moods, and health of one impact the other. It is our contention that if caregivers are given training that helps them build coping skills, they can better attend to patient needs and consequently patients will have improved QOL. We found that allogeneic HSCT caregivers randomly assigned to a behavioral intervention that taught coping and stress management skills were significantly less distressed (reduced stress, anxiety, and depression) compared to treatment as usual (TAU). Caregivers who refused to participate or dropped out reported feeling overwhelmed by caregiving challenges. These caregivers may actually be in greater need of support services (e.g., high distress or living in a remote area). Over 40% of the patients and caregivers lived outside of the immediate vicinity of the transplant program. The impact on the patient of the caregiver’s intervention was not assessed in the initial study. We propose that patient quality of life will be enhanced by providing the caregivers with an intervention that also incorporates greater flexibility, accessibility, and ease of use. We propose to test patient outcomes associated with our caregiver intervention, which incorporates state-of-the-art smartphone technologies and video chat meetings with the interventionist when face-to-face meetings cannot be arranged. This is a randomized controlled trial of 225 patient/caregiver dyads recruited from the only two regional sites using multiple interventionists to demonstrate overall program feasibility in preparation for wide dissemination. By enhancing the reach of this intervention with the use of state-of-the-art smartphone approaches, the QOL of more patients will be enhanced significantly because their caregivers can provide improved care that is reflected in their loved one’s QOL. This relatively simple use of technology, if shown effective in reducing distress and enhancing quality of life for both the patient and caregiver, can be disseminated to other patient-caregiver dyads with other illnesses.

Illinois

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THE ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY FOUNDATION
Patient-Centered, Risk-Stratified Surveillance after Curative Resection of Colorectal Cancer

Nearly 14 million Americans are alive today having survived their battle with cancer. Colorectal cancer (CRC) survivors make up the second largest group of cancer survivors, and the current population of 1.4 million colorectal cancer survivors is expected to grow nearly 25 percent by 2022. To these survivors and their family members and caregivers, as well as their physicians, the most pressing issue is determining the best way to monitor the survivor in the future. Cancer surveillance has been identified as a top priority by organizations such as the Institute of Medicine and the Agency for Healthcare Research and Quality. Despite differences in patients’ tumors and preferences, the available colorectal cancer surveillance guidelines take for the most part a one-size-fits-all approach. As a result, the quality of care, patient experience, and use of healthcare resources are compromised, and research to generate evidence and tools for improving colorectal cancer surveillance is greatly needed. This proposal will address the critical question: “Based on my individual tumor characteristics, conditions, and preferences, what is the best way to monitor for recurrence?” We hypothesize that by tailoring the strategy for monitoring to the individual CRC
survivors—taking into account their risk for recurrence, eligibility for salvage treatment, and personal preferences—the effectiveness of cancer monitoring would be improved and the burden on patients and the healthcare system would be reduced. We specifically will 1) determine how effective CRC surveillance is and measure the risk and time to recurrence and death—taking into account different patient and tumor characteristics—through detailed analysis of surveillance data from CRC clinical trials conducted by the ALLIANCE network, as well as from the National Comprehensive Cancer Network (NCCN) and the National Cancer Database (NCDB); 2) identify key issues about CRC surveillance important to patients and clinicians through stakeholder engagement within the ALLIANCE network, as well as among patients at the University of Texas MD Anderson Cancer Center; and 3) integrate the recurrence risk and patient priorities into a patient-centered, risk-stratified surveillance strategy by creating an interactive decision aid that can be easily accessed by patients and clinicians. We will then design future studies to measure the impact of this tailored surveillance strategy, including the benefits, harms, and changes in resource utilization that occur when it is used in real-world situations. With a growing population of CRC survivors, the impact of cancer surveillance on patients and caregivers, physicians, and the healthcare system is great. The proposed research addresses an urgent and critical question these stakeholders now face each day with little information to guide their decisions. The knowledge gained by this proposal will provide important new tools to guide patients and their clinicians in making individualized decisions regarding cancer surveillance.

**Caprice C. Greenberg, MD, MPH**

THE ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY FOUNDATION

*Post-Treatment Surveillance in Breast Cancer: Bringing CER to the Alliance*

Background: Nearly 3 million women living today have survived breast cancer. Physicians rely on clinical practice guidelines to make decisions on follow-up care. Among other things, the goal is to monitor for recurrence or side effects of treatment among survivors. It is unclear whether these guidelines represent the best approach for any given patient as they do not take into account differences in disease or patient preferences and may not consider recent advances in imaging and treatment options.

Objectives: We seek to develop a new approach to surveillance following breast cancer treatment that will be more patient-centered and effective than the existing one-size-fits-all approach and will consider individual risk factors. Our project has three primary goals: 1) use existing data from clinical trials sponsored by one of the leading cancer cooperative groups to evaluate how risk of recurrence and side effects of treatment vary based on patient and cancer characteristics; 2) use existing data to evaluate the effectiveness of the latest imaging technology for improving survival in patients previously treated for breast cancer; and 3) engage cancer survivors, providers, and health outcomes researchers in the development of an improved patient-centered approach to guide post-treatment care, as well as to identify the highest-priority strategies for prospective randomized trials.

Methods: Our methods have been developed based on input from patients and other stakeholders that identified the need for a large-scale observational study. The goal is to produce timely results and guide the development of an improved approach to surveillance that recognizes individual patient risk factors and allows for design of future prospective studies. This study analyzes recurrence data and treatment side effects on over 22,000 patients involved in past clinical trials on breast cancer care. The project also involves the analysis of existing data from a national cancer registry to evaluate whether new imaging
technology, beyond mammography, is able to detect recurrence earlier and improve survival. Finally, we will engage cancer survivors, health care providers, and researchers to develop new guidance for the care and monitoring of breast cancer survivors and to guide and prioritize future prospective trials. This proposal builds on existing leadership, infrastructure, and resources, while engaging patients, providers, and researchers in all phases including design, guideline development, and sharing of new knowledge.

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Comparative Effectiveness of Peer-Led Supplemental O2 Infoline for Patients and Caregivers (PELICAN)

Background: About 1 million individuals in the United States have a prescription for supplemental oxygen (O2). Using O2 can prolong life and increase quality of life. Patients often do not use their oxygen as prescribed, which means that they are not benefiting as much as they could be from this therapy. In focus groups, patients with chronic obstructive pulmonary disease (COPD) and their caregivers emphasized their need for reliable information about O2, including information about O2 delivery systems, social aspects of O2 use such as embarrassment about using O2 in public, and concerns such as fear of becoming addicted to O2. They expressed a strong interest in getting help from peers who can coach them through the process of adjusting to O2. Data from studies in other populations suggest that peer coaching by phone can help patients improve self-management skills and outcomes. However, the effectiveness of peer coaching in helping patients with COPD use O2 is unknown. We expect that a Peer-Led O2 Infoline for Patients and Caregivers (PELICAN) will increase adherence and improve health. We have developed a broad-based team that includes patients and caregivers, the COPD Foundation, a national O2 supplier, and others to test whether PELICAN leads to increased O2 use and outcomes important to patients.

Objectives: Using input from COPD patients and their caregivers, we will develop patient-centered educational and support materials tailored to their needs, to be used in PELICAN. We will study whether PELICAN is effective and results in increased use of O2 as prescribed, more positive attitudes and beliefs about O2 use (such as confidence in the ability to use O2 despite barriers such as social discomfort), and other outcomes. The long-term goal is to help patients use their O2 as prescribed so they can be as healthy as possible.

Methods: We will meet with groups of patients with COPD who use O2 and their caregivers to help develop the materials to be used in PELICAN. We will pilot test the materials with a small number of patients, and will modify the materials based on results and feedback from participants. We will then test the effectiveness of the intervention with 450 patients with COPD. We will compare a proactive version of the intervention (peer coaches will contact patients by telephone to deliver the intervention) to a reactive version of the intervention (patients have the option of calling the peer coaches to get information about O2) and to usual care (written self-help materials).

Projected patient outcomes: PELICAN will address patients’ attitudes and beliefs about O2, including confidence in their ability to use O2 and their understanding of the benefits of using O2 as prescribed. PELICAN has the potential to greatly improve appropriate O2 use and quality of life of COPD patients, by using a non-invasive strategy tailored to their needs.
Degenerative cervical spine disease (neck arthritis) represents one of the most common indications for spinal surgery in the United States. Approximately 112,400 operations for cervical arthritis are now performed annually with hospital charges greater than $2 billion per year. Utilization of cervical spine operations has increased 100% over the last decade. Recent data from administrative databases clearly demonstrate that surgery for cervical arthritis has many early complications as well as late failures, leading to many re-operations. Advanced cervical arthritis can lead to narrowing (stenosis) of the spinal canal and compression of the spinal cord. This compression coupled with repetitive motion can injure the spinal cord, resulting in gait instability, bladder dysfunction, and difficulty with fine motor movements in the hands, a clinical syndrome known as cervical spondylotic myelopathy (CSM). CSM represents the most common cause of spinal cord injury in the United States. There is a significant need for new clinical trials on surgery for CSM. Surgical decompression for CSM can improve its disabling symptoms. The optimal surgical treatment, however, remains controversial, with disagreement among proponents of three main approaches: ventral decompression and fusion, dorsal decompression and fusion, or dorsal laminoplasty. Because we do not know which operation for CSM is optimal, it is likely that many patients with this disease are not receiving the best treatment. There is a growing consensus among spinal surgeons that a randomized clinical trial (RCT) comparing these three approaches is necessary. Our objective is to conduct an RCT comparing ventral decompression with fusion versus dorsal decompression with fusion or dorsal laminoplasty for patients with multi-level CSM with the following specific goals: 1) to determine whether one type of surgery is associated with better overall quality of life for patients with CSM and 2) to determine whether different surgical approaches to treating CSM are associated with different out-of-pocket expenses or differences in productivity after surgery. We propose to conduct a multi-center RCT comparing ventral versus dorsal approaches in patients with multi-level CSM. Valid outcomes instruments will be used to assess patients' overall health-related quality of life. In addition, complication rates, re-operation rates, and out-of-pocket expenses will be collected. One hundred fifty-nine randomized patients will be recruited from 10 sites over an accrual period of 1.5 years with one-year minimum follow-up. The overall goal of the study is to define the optimal treatment for CSM. The study’s results will reduce harm from surgery from CSM, optimize patient-oriented health-related quality of life outcome, and provide information about complications and loss of productivity following surgery that will empower patients to make more informed decisions about their own health care.

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Improving Informed Consent for Palliative Chemotherapy: Development of a Regimen-Specific Multi-Media Informed Consent Library to Promote Patient-Centered Decision Making about Treatment of Advanced Gastrointestinal Cancers

A substantial body of research indicates that many patients with incurable cancer harbor significant misconceptions about the benefits of palliative chemotherapy. In a large population-based cohort of patients with metastatic colorectal and lung cancers, we found that the vast majority failed to recognize that chemotherapy was unlikely to cure their disease. This misunderstanding indicates pervasive
deficiencies in how cancer patients are informed about fundamentals of their disease and treatment options. The root of this problem is undoubtedly complex, but likely relates to deficiencies in patient-doctor communication about incurable cancer. At the outset of treatment, it is important for oncologists to establish trust, a strong rapport, and convey hope even when prognosis is poor. As a result, oncologists may describe difficult information about prognosis and the limitations of chemotherapy in a telescopic or vague manner that makes it difficult for patients to understand what lies ahead. While this approach may initially provide solace, downstream it can impede patients’ ability to make truly informed choices about how to allocate their limited time and energy. Patients are routinely asked to sign an “informed consent” document prior to starting chemotherapy, indicating they understand the risks and benefits of treatment. Although this could be a strategic moment to equip patients with information they need to make truly informed medical decisions, many patients and caregivers note that these conversations are less useful than they could be. The informed consent process and its associated documents suffer several limitations: 1) Risks are emphasized over benefits; 2) Educational materials focus on individual drugs instead of regimens; 3) Information is presented in written instead of alternative written/audiovisual format; and 4) The patient perspective is lacking. The overarching objective of this project is to develop a library of communication tools for the five most common chemotherapy regimens used to treat metastatic colorectal cancer. Tools will include video clips and written documents that can be readily distributed, modified, and customized. This toolkit will be crafted in collaboration with oncologists and patients living with gastrointestinal cancer and will improve upon existing resources in several ways: 1) balanced discussion of benefits as well as risks, 2) focus on regimens rather than drugs, 3) use of both written and video format, and 4) inclusion of the patient perspective (e.g., video clips of patients describing their experience). A panel of oncologist and patient stakeholders will evaluate the acceptability of the tools. We will then conduct a randomized clinical trial to demonstrate if the informed consent toolkit improves the quality of informed consent for palliative chemotherapy. If effective, the tools will be amenable to broad dissemination via patient-accessible cancer education websites and oncology clinics.

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HARVARD UNIVERSITY (SCH OF PUBLIC HLTH)

Benchmarking the Comparative Effectiveness of Diabetes Treatments Using Patient-Reported Outcomes and Socio-Demographic Factors

Diabetes affects 25.6 million individuals in the United States aged 21 years and older, or 11.3% of this population. Diabetes causes high blood glucose, which often results in serious health problems including blindness, heart disease, stroke, and amputations of the foot and toes. While diet and exercise can lower blood glucose, most individuals with diabetes need medications such as pills or insulin, proper diet and exercise, and at-home glucose testing. There are many factors that influence how well patients are able to comply with these requirements including age, education, income, and cultural and lifestyle issues. Often, the way an individual responds to treatment, in terms of negative side effects and the burden of the treatment, impacts compliance. In addition, persons with diabetes might also be depressed or have other diseases and conditions that make treatment with a particular medication or regimen more difficult. While diabetes patients act and respond differently to treatment due to many reasons, healthcare providers often cannot advise patients as to how they might respond given their personal characteristics simply because they do not have the required information. While drug research studies can tell us on the average how effective a particular treatment will be in terms of lowering blood glucose, they cannot tell us how any one individual will respond. Moreover, while they can tell us how variable the response in blood glucose lowering is for different patients, they do not identify why patients respond differently. The reason for this is that typically no one clinical study can separate out
the results by all the patient characteristics that might affect treatment. In addition, clinical drug trials have not typically measured how patients feel or how satisfied they are with their assigned treatment. In most clinical trials, the “true voice” of the patient is usually silent. During the past 25 years, we have asked patients in clinical trials to tell us how they feel during their treatment. For our proposed research, we have combined the strengths of our pooled diabetes clinical trials quality-of-life database and one of the largest and most comprehensive healthcare electronic medical records databases in existence in an attempt to predict patient-centered characteristics that impact diabetes treatment effectiveness. The purpose of our study is to compare the quality of life and treatment satisfaction responses to different therapies, and determine to what extent factors such as age, gender, employment status, education, income, race, language, ethnicity, clinical characteristics, and other conditions impact these responses. We will incorporate the results of our analysis into a web-based application that will allow clinicians to predict how likely a patient will be to respond given their individual characteristics, and allow patients and physicians to benchmark their progress against others with similar characteristics to improve the quality of care.

**Michigan**

Nancy Birkmeyer, PhD
UNIVERSITY OF MICHIGAN AT ANN ARBOR
Improving Patient Decisions about Bariatric Surgery

At least 15 million Americans are more than 100 pounds overweight. While weight loss surgery is a very effective treatment for these patients, it also has risks. There are four different types of weight loss surgery and the risks and benefits of these procedures vary widely and are strongly affected by patient factors such as age, sex, race, and the amount of excess body weight. The treatment options also vary in other ways (such as the type of diet that must be followed after surgery) that should be considered when deciding whether or what type of surgery to have. The goals of this research proposal are to develop and test a decision support tool for morbid obesity patients considering weight loss surgery. This tool will be based on data regarding the risks (complications and death) and benefits (weight loss, patient satisfaction, and improvements in quality of life after surgery) from 35,000 patients that have previously had weight loss surgery. The final decision tool will be in the form of a website where patients will enter data about themselves and receive a customized report of the expected risks and benefits of the different types of weight loss surgery based on their personal characteristics. This tool will also provide patients with information about other attributes of the treatment options that should be considered based on data from interviews with bariatric patients and providers. We will test the effects of our decision tool on patient decisions and outcomes by comparing it with usual care at all of the weight loss surgery programs in Michigan. This decision support tool will provide patients with an independent assessment of the risks and benefits of the treatment options, not to replace physician’s clinical judgments but rather to help guide communication between the patient and physician and encourage shared medical decision making.
Missouri

Kim G.E. Smolderen, PhD
SAINT LUKE’S HOSPITAL
Patient-Centered Outcomes Recovery from Treating Peripheral Arterial Disease: Investigating Trajectories (PORTRAIT)—Phase II

An estimated 8 million individuals in the United States are affected by peripheral arterial disease (PAD), blockages of the leg arteries that can cause excruciating calf pain when walking. PAD can have a major impact on patients’ quality of life. It is also associated with high rates of heart attacks and premature death. While there are a number of treatments, there have been few previous studies that have prospectively examined treatment patterns for PAD or sought to systematically identify opportunities to improve care. Most importantly, there have been no rigorous studies examining the impact of the disease from patients’ perspectives—their symptoms, function, and quality of life—as a function of different patient characteristics and treatments. The PORTRAIT study (Phase II) will systematically document the treatments and health-status outcomes (symptoms, function, and quality of life) of 840 US patients from nine centers over the course of one year to address these gaps in knowledge. It will illuminate whether disparities in treatment or health-status outcomes exist as a function of a patient’s age, gender, race, or socioeconomic or psychological characteristics. As a direct deliverable, it will translate its findings—expected health status changes following PAD treatments over the course of one year—directly to patients through the development of education tools for patients with PAD who need to make a choice with regard to their treatment. As it is PCORI’s mission to assist patients, clinicians, purchasers, and policy makers in making informed health decisions with regard to diseases like PAD, PORTRAIT will substantially elevate the field and identify critical gaps in the way PAD is currently managed, including potential disparities in care, so that the quality of care can be improved. PORTRAIT will also be a critical first step in designing efficient, effective disease management programs for PAD in the future that are based on more personalized and healthcare system-oriented approaches to increase the use of evidence-based guidelines. Finally, as patients have been closely involved in the design of this study in Phase I and continue to be engaged as active advocates and experts on their disease throughout the current study, PORTRAIT will also empower patients and let them decide on what information and outcomes are most relevant for them while dealing with this burdensome condition of PAD.

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UNIVERSITY OF MISSOURI KANSAS CITY
Developing and Testing a Personalized, Evidence-Based, Shared Decision-Making Tool for Stent Selection in PCI

Background: Patients undergoing percutaneous coronary intervention (PCI) to open up blocked heart arteries have a choice to receive either drug eluting (DES) or bare metal stents (BMS) to keep the artery open. This is an important decision because, while DES reduces the risk of needing a repeat procedure, patients receiving a DES must take a “super-aspirin” for at least one year, as compared with a month for BMS. This medicine can increase the risk of bleeding, delay elective surgeries, and increase patients’ medication costs. Currently, 80% of patients receive drug-coated stents, but less than a third discuss stent choices with their doctors.
Objectives: We will create a shared decision-making (SDM) tool that will describe the benefits, drawbacks, and costs associated with DES and BMS. Importantly, the benefits of avoiding a repeat procedure will be individualized for each patient, based upon a validated prediction model. We will use this SDM tool at two US hospitals and train hospital staff to improve SDM. We will then find out whether the use of the SDM tool increases the frequency and quality of the discussions between patients and their doctors about stent choices.

Methods: To create the SDM tool, we will interview patients and healthcare providers to identify the most important information and optimal presentation mode for SDM discussions. After developing the tool, we will introduce it into routine clinical care. Patients undergoing PCI, before and after introduction of the tool, will complete questionnaires to measure the frequency and quality of their discussions with their doctors about stent choice. If successful, we will be able to rapidly disseminate our tool, and the accompanying staff training materials, to increase its use in the 600,000 PCI procedures performed each year in the United States.

New York

Jose Alejandro Luchsinger, MD, MPH
COLUMBIA UNIVERSITY HEALTH SCIENCES
Northern-Manhattan Hispanic Caregiver Intervention Effectiveness Study (NHiCE)

Background: The number of people with dementia, such as Alzheimer's dementia, is increasing. There is no cure or prevention for dementia. Thus, the burden of dementia on caregivers is also increasing. Hispanics have a higher prevalence of dementia than non-Hispanic whites (NHW), have higher caregiving burden, and may have fewer economic resources to cope with the caregiving burden. However, there is little evidence on whether caregiver interventions work for Hispanics in the real world. We propose to compare two interventions that have been proven to work in research settings: the New York University Caregiver Intervention (NYUCI) and the translated Resources for Enhancing Alzheimer’s Caregivers Health (REACH OUT). The NYUCI is a family-centered counseling intervention that focuses on reducing negative family interactions and improving family support of the primary caregiver. REACH OUT focuses on caregiver skills training through action-oriented formal problem solving, goal setting, and written action plans. These interventions have never been compared in the real world, in Hispanics or any other ethnic group. Thus, caregivers and the agencies that cater to caregivers have no information on whether the NYUCI or REACH OUT is better for them.

Objectives: Our research question is which intervention, NYUCI or REACH OUT, is better for Hispanic relative (any relative) caregivers of persons with dementia. An additional question is, among Hispanic caregivers, are there some that benefit more from the NYUCI or REACH OUT? Our objective is to obtain information that will help caregivers and health providers to make decisions about which intervention to choose. We will compare how effective the implementations of NYUCI and REACH OUT are in reducing burden and depression symptoms. We will also explore what characteristics of Hispanic caregivers predict success with NYUCI and REACH OUT. We will also explore additional outcomes such as caregiver stress and physical health, and outcomes related to the person with dementia.

Methods: We will conduct a study in which 200 relative caregivers of persons with dementia will be assigned to the NYUCI or REACH OUT at random. This study will take advantage of a Dementia Caregiver Research program at Columbia University Medical Center. The total duration of the intervention will be
six months, with assessments at baseline and follow-up. All interventions and questionnaires will be conducted in both English and Spanish. The total duration of the study will be three years.

Patient outcomes (projected): The primary outcomes will be changes in caregiver depressive symptoms and in caregiver burden using existing scales. These outcomes are important to caregivers because depressive symptoms and caregiver burden are the main comorbidities of caring for a person with dementia.

North Carolina

Adrian Felipe Hernandez, MD, MS
DUKE UNIVERSITY
Patient-Centered Research into Outcomes Stroke Patients Prefer and Effectiveness Research (PROSPER)

Strokes occur when blood vessels to the brain become clogged with either a plaque or a clot, cutting off blood flow. Approximately 800,000 people in the United States will have a stroke each year and one-fourth will have another stroke. It is the fourth leading cause of death and a leading cause of disability in the United States. Once a patient has a stroke, the major goals are two-fold: recovery and prevention of another stroke or other complications. Common therapies after a stroke include anticoagulants (a blood thinner), statin therapy (cholesterol lowering) and periodically an antidepressant. For many, the benefits and risks of these different therapies are unknown, especially among stroke survivors 65 years and older, women, and minorities. Anticoagulants come in different forms, such as warfarin, which requires frequent lab tests and a restricted diet. There are newer anticoagulants without these issues, but there is much less experience with their use. Statin therapy, especially high doses, may have side effects such as muscle aches, and it is unknown whether the benefits seen in younger, healthier patients translate to older stroke survivors. Depression after stroke is common and is associated with higher risk of death. Antidepressants may improve depressive symptoms, but it is unknown whether they may help stroke survivors live longer with a better quality of life. For all of these therapies, there is wide variation in when and to whom physicians prescribe them. More importantly, the prior studies have not addressed the full range of benefits or harms given the personal characteristics, conditions, and preferences of most stroke survivors. To address these gaps, we will conduct a series of novel comparative effectiveness studies. We will compare the effectiveness and safety of anticoagulation with warfarin versus nothing and compared to novel oral anticoagulants. Similarly, we will compare statin therapy versus nothing and different intensities of statin therapy. Finally, we will evaluate the effectiveness of antidepressant therapy. These studies will use data from the nation’s largest clinical registry for stroke (American Heart Association Get With The Guidelines—Stroke) linked with Medicare claims for long-term outcomes and with telephone interviews after discharge for patient-reported outcomes (AVAIL Registry). Our stroke survivor focus groups and stakeholders have selected “home-time” or days alive and well outside an institution as the primary outcome. Other outcomes include recurrent stroke, readmission, survival, functional status, depression, fatigue, and quality of life. To do these observational effectiveness studies, we will use advanced analytic methods including inverse propensity weighting. Results will inform treatment decisions through online tools that present stroke survivors the trade-offs of benefits and risks on a range of outcomes based on their personal preferences, values, and characteristics.
Pennsylvania

Jennifer S. Brach, PhD
UNIVERSITY OF PITTSBURGH AT PITTSBURGH

On the Move: Optimizing Participation in Group Exercise to Prevent Walking Difficulty in At-Risk Older Adults

Community-dwelling older adults fear loss of independence and nursing home placement more than death. Walking difficulty often leads to loss of independence. Exercise is beneficial to physical and mental health and may prevent walking difficulty and promote independence. Recognizing the importance of exercise, senior housing facilities offer exercise programs to their residents. The exercise programs are often group-based, seated range-of-motion exercises that do not challenge the older adult; consequently, participation rates and resident satisfaction are low. If the goal is to improve walking to promote independence, then the exercise program should specifically target walking. Therefore, we developed a challenging group exercise program entitled “On the Move” which focuses on the fundamentals of walking. In this research study, we will determine if the On the Move program is better than a standard program at improving walking and promoting independence and if the same benefits can be obtained if the On the Move program is delivered by staff of the senior living facilities instead of an exercise leader. To answer these questions, 560 community-dwelling older adults living in 28 different Independent Living Facilities and Senior High Rises will be randomly assigned to either the 12-week On the Move group exercise program or the standard group exercise program delivered by either an exercise leader or staff activity personnel. Participants’ walking and reported ability to carry out everyday activities (functional ability) will be assessed before and after the 12-week program. We will also assess participant safety and satisfaction with the exercise program and instructor. The findings from this research study will provide evidence for the value of the On the Move group exercise program and will better inform patient choices regarding participation in exercise programs. If successful in improving walking and promoting independence and acceptable to older adults, the On the Move program could be incorporated into exercise programming for older adults in community centers, health clubs, and senior residences across the country.

Jeffrey Gerber, MD, PhD
CHILDRENS HOSPITAL OF PHILADELPHIA

Comparative Effectiveness of Broad vs. Narrow Spectrum Antibiotics for Acute Respiratory Tract Infections in Children

Antibiotics are the most common medicines prescribed to children. Children often receive antibiotics from their primary care provider for acute respiratory tract infections (ARTI) such as strep throat, ear infections, or sinus infections. Although providers have many choices of antibiotics for treating these infections, the principle that experts recommend to guide antibiotic selection is to start treatment with narrow-spectrum drugs, and to reserve broad-spectrum drugs for the few infections that do not respond to narrow-spectrum drugs or more severe infections that may be resistant to the narrow-spectrum antibiotics. However, providers do not always follow this principle. In fact, broad-spectrum drugs are used first nearly 50% of the time, and given how common these infections are, consequences could be serious: Experts worry that these drugs may not always be effective, result in more side effects, and their use could lead to antibiotic resistance. The obvious question is, “Why?”, and the explanation is complicated. It may be that parents and children prefer broad-spectrum drugs for their convenient dosing schedule and flavor. It may be that providers believe that the drugs are more effective. To help
clarify this, more research is needed to compare the effectiveness of narrow-spectrum and broad-spectrum antibiotics—research that includes outcomes relevant to families. To that end, we are proposing a two-part study that will be conducted in one of the largest primary care pediatric practice networks in the United States, including more than 200 providers who care for more than 200,000 children. First, we will interview children and their caregivers who bring them to the pediatrician for an ARTI and ask them what factors are most important to them when it comes to antibiotic use for these infections. These interviews will help us understand which outcomes to include in future comparisons of antibiotics. Second, we will survey parents of children who received antibiotics for an ARTI to compare narrow-spectrum and broad-spectrum antibiotics in terms of their ability to cure the infection and the type and amount of side effects they caused. This study will help inform pediatric providers and parents of the risks and benefits associated with the treatment of these very common infections, and assist providers and parents in arriving at the best decisions for children.

Lakshmanan Krishnamurti, MD
UNIVERSITY OF PITTSBURGH AT PITTSBURGH
Patient-Centered Comprehensive Medication Adherence Management System to Improve Effectiveness of Disease Modifying Therapy with Hydroxyurea in Patients with Sickle Cell Disease

Sickle cell disease (SCD) is an inherited, chronic, multi-organ system disorder that affects approximately 100,000 individuals in the United States, mostly belonging to minority, underserved populations. SCD is associated with substantial morbidity, premature mortality, individual suffering, healthcare costs and loss of productivity. Hydroxyurea (HU), the only disease modifying therapy for SCD, is efficacious in reducing complications such as pain crisis and acute chest syndrome, and improving survival. It is, however, vastly underutilized and poorly adhered to because of barriers at the system, provider, treatment, socioeconomic, and patient levels. Our overarching hypothesis is that barriers to acceptance and adherence to HU are multi-factorial, and that a structured set of interventions can lead to improved adherence to medication and patient-centered outcomes. To test our hypothesis we propose the following specific aims: Aim 1: To determine in a randomized clinical trial if individualized structured interventions will improve adherence with HU and will be acceptable to patients with SCD. Children, adolescent and adult subjects with SCD will be randomized in a multi-center study to adherence intervention arm or standard of clinical care. Interventions will be individualized to patient barriers, and preferences and will consist of improved access to care through virtual clinic visits and in-home testing, adherence management through a novel cell phone, video-based, directly observed therapy (Mobile-DOT), and patient support using text and telephone follow-up. The standard arm will consist of the usual clinical care. We will measure adherence through review of pharmacy records, and in patients on the intervention arm through direct video record of adherence, as well as by validated measures of self-reported medication adherence. We will [conduct] (sic) qualitative interviews [with] (sic) patients to explore attitudes toward acceptability, and utility to patients of structured interventions to improve HU adherence. Aim 2: To determine the impact of adherence with HU on clinical and patient reported outcomes, and patient burden of care. A randomized clinical trial will generate detailed measures of the level of adherence among patients in the intervention and standard of care arms. Using standardized survey instruments, we will determine; patient-reported outcomes of physical functioning; fatigue, pain and sleep; pediatric and adult quality of life; clinical and laboratory parameters; healthcare utilization; functioning at school and work; individual and system financial savings; and burden of implementing the interventions. This will help determine the impact of adherence with HU on patient-reported, clinical, laboratory, and health services outcomes. The completion of these aims will help define factors which predict adherence to HU in SCD, and determine the effectiveness of a set of structured interventions in improving both adherence and patient related outcomes.
Texas

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UNIVERSITY OF TEXAS SW MED CTR/DALLAS
Collaborative Assessment of Pediatric Transverse Myelitis: Understand, Reveal, Educate (CAPTURE) Study

The proposed study, entitled the Collaborative Assessment of Pediatric Transverse Myelitis: Understand, Reveal, Educate, or CAPTURE study, will be the first to combine assessments from healthcare providers and patients relative to TM outcomes. The collaboration will involve multiple healthcare centers across North America, the Transverse Myelitis Association and most importantly, patients. It will assess the current state of Pediatric TM in terms of diagnosis, treatment and outcomes. Ultimately, it will lead to an improved understanding of the current status of care for individuals afflicted with TM, and reveal what are the current best practices. Patients will educate clinicians and the study will educate the broader healthcare system about what outcomes are important and achievable. It will develop a multi-metric outcome measure, based on combined patient-generated and provider-generated data that can be used in future controlled trials. Of critical significance is the specific aim to make the data available for use by patients and practitioners via a Web-based program to determine how comparable their specific case is to the studied population. Unlike other clinical research endeavors that report findings primarily in peer-reviewed publications or presentations, this study will provide its data to a controlled program that can be accessed while a patient is being evaluated for TM, to determine if the data exists to guide decision making for that individual patient. This study will work with the Web-based program Traitwise™, to enable their platform to inform a patient or practitioner about the percent homology of their patient to [other] (sic) studied patients. When complete, this study could serve as a model for other rare disease communities, allowing them to leverage vital assets and accelerate understanding of various conditions. The proposed research will lead to meaningful improvements in patient health and quality of care in multiple ways. It will identify which treatments were the most effective and safe for patients. This data will be used to guide future acute care and controlled clinical trials. Currently, there are wide variations in clinical practice, which is evidence of the pervasive uncertainty surrounding best practices. Previous studies examining the impact of acute care treatments in TM have identified a differential response to various therapeutic options. Recognizing which patients respond to the various therapies available would be of immense value to clinicians and individual patients, by helping them navigate the acute therapy environment with more scientific guidance. The largest patient advocacy organization for TM, the Transverse Myelitis Association, has identified improved diagnostic algorithms, treatment options, and outcome measures as a critical priority for the patients they serve.

Patricia A. Parker, PhD
UNIVERSITY OF TEXAS MD ANDERSON CAN CTR
Contralateral Prophylactic Mastectomy and Breast Cancer: Clinical and Psychosocial Outcomes

When diagnosed with breast cancer, there are many decisions that women and their physicians must make regarding treatment. One of these decisions that women are faced with making is whether to have contralateral prophylactic mastectomy (CPM)—surgery to remove the breast without cancer, in addition to the breast with cancer. The frequency with which this surgery is performed has increased dramatically, despite the fact that there is little evidence to demonstrate that it improves patients’ outcomes. Accordingly, the goal of our project is to collect the information needed to help women and their healthcare practitioners make this important medical decision. To do this, we will: (1) prospectively assess the psychosocial outcomes of women who have CPM and those who do not. We will examine
how characteristics of the women (e.g., age, ethnicity, education) and those of the physician (gender, age) influence outcomes; and (2) conduct a decision analysis to provide estimates of how CPM affects life expectancy. We will use the results of the decision-analytic model to develop and field test an innovative online decision tool that will promote shared physician and patient decision making about CPM. This study will provide women with important information that is necessary to make an informed decision about whether or not to have CPM. Our study team is multidisciplinary and includes physicians from medical oncology, surgery and reconstruction, as well as behavioral scientists, decision scientists and biostatisticians, as well as women with breast cancer. Throughout the development and conduct of the study we will obtain input and feedback from patients with breast cancer [as well as] (sic) their spouses and physicians, so that our work reflects the needs of those who must make these difficult healthcare decisions. Our findings will provide women and clinicians with the critical information they need to improve decision making about CPM, and the quality of life of women with breast cancer.

Washington

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FRED HUTCHINSON CANCER RESEARCH CENTER

Tools and Information to Guide Choice of Therapies in Older & Medically Infirm Patients with AML

Acute myeloid leukemia (AML) is an aggressive, life-threatening disease, and its risk increases with age. However, older AML patients (60 [+ (sic) years) have shorter survival after diagnosis compared to younger patients, mainly because of suboptimal treatment of their leukemia. Physicians may not recommend intensive initial treatments that have the potential of curing the disease because they believe their patients may die from the treatment itself. Likewise, while investigators have developed minimally toxic chemotherapy regimens to prepare patients for a potentially curative procedure, [namely] (sic) blood or marrow transplantation from a donor, there has been reluctance in offering this procedure to older patients. Physicians often use an age cutoff of 60 years to determine whether a patient is likely to benefit from curative treatments. But age above or below 60 years [in itself] (sic) is not an accurate assessment of risks, since some patients in their 60s are healthier than others in their 50s. Organ dysfunctions (comorbidities) are probably more relevant in determining how patients will tolerate treatment than age itself. We have shown that measuring comorbidities before blood or marrow transplantation can help more accurately predict whether a patient will survive the transplant. We would now like to test whether measuring comorbidities in AML patients can predict whether treatment will be successful, and provide physicians, patients and their families with a better understanding of the risks and benefits of their treatment options. We will then use comorbidities and other risk factors to assess new patients for the appropriateness of marrow transplantation and how it compares to chemotherapy in regards to survival and quality of life. We will conduct a series of three studies to address these issues. One study will review the charts of 2,000 people with AML treated at four hospitals. This information will allow us to develop a comorbidity index that is specific for AML patients, and to incorporate this index with other factors [such as] (sic) AML disease features, into a risk-stratification strategy for mortality. A second study will enroll 1,000 people who are [recently] (sic) diagnosed with AML. We will follow this group very closely and ask them and their physicians questions over time to understand how they are making their treatment decisions, and whether their chosen treatments are successful. The final study will compare the survival and quality of life between those who choose the most intensive treatments and those who choose less intensive treatments. The results of these studies will significantly advance our knowledge about how to tailor treatments so that we recommend intensive treatments to those who can tolerate them, but suggest less intensive treatments.
to those whom we will only harm. It will also provide a better understanding of how successful the different treatments are in curing AML, and the quality of life people experience during and after treatment.

Karen Joanne Wernli, PhD, MS
GROUP HEALTH COOPERATIVE
Comparative Effectiveness of Surveillance Imaging Modalities in Breast Cancer Survivors

Background: In 2013, about 232,000 women will be diagnosed with breast cancer. More than 90% of them will survive the first 5 years after diagnosis. This is a result of improvements in care that help doctors detect breast cancer earlier and provide more effective treatments. After treatment, breast cancer survivors enter a phase of care called surveillance—which means they are regularly checked for new signs of breast cancer. Surveillance mammography is a proven way to reduce deaths when breast cancer recurs. However, many patients and their doctors are now using Magnetic Resonance Imaging (MRI) for surveillance—even though there is no evidence that it is more effective than mammography. Both tests have pros and cons.

Goals: Our overall aim is to find out how well MRI works compared to mammography for surveillance in women who have had breast cancer. Specifically, our goals are to: (1) understand doctors’ and patients’ experiences with surveillance mammography and MRI; (2) provide evidence on which outcomes are more or less likely to occur; and (3) develop patient decision aids to help women and their doctors choose the surveillance method that is right for them.

How we will conduct the study: We will work with patients, doctors, policymakers, advocacy groups, and researchers to improve surveillance for women who have had breast cancer. Through focus groups with patients and interviews with doctors, we will gain insights into women’s experience with surveillance mammography and MRI. We will also compare mammography to MRI using data from the Breast Cancer Surveillance Consortium—the largest collection of breast cancer surveillance data in the nation. We will use data from more than 36,000 women diagnosed with breast cancer between 2005 and 2012 to determine how well both tests work. We will measure the tests’ effectiveness at finding second cancers, and estimate the likelihood of different outcomes. We will also determine whether one test appears to work better than the other to prevent death from second breast cancers among different groups of women. We will then develop patient decision aids to help women and their doctors make more informed choices about surveillance.

What we hope to achieve: We hope this study will improve medical decision making and care for the 3 million women in the United States who have a history of breast cancer. Specifically, our results will help women and their doctors make clearer, better choices about the surveillance method that is right for them. Our patient advisory board identified outcomes of most interest to patients when comparing mammography to MRI, including: (1) patient-reported pain and anxiety; (2) number of cancers detected versus number of cancers missed; (3) likelihood of false positives and biopsies; and (4) differences in radiation exposure. The advisory board also recommended that we use our results to develop a patient decision aid.
Improving Healthcare Systems

California

Mary Whooley, MD
UNIVERSITY OF CALIFORNIA SAN FRANCISCO
Improving Delivery of Patient-Centered Cardiac Rehabilitation

Many patients feel nervous about transitioning from hospital to home after being hospitalized for a myocardial infarction (heart attack), percutaneous coronary intervention (stent placement), or coronary artery bypass surgery. This period immediately after hospital discharge, when patients feel particularly vulnerable and highly motivated to make lifestyle changes, represents a huge opportunity to improve health. Teaching patients new habits for keeping active and eating healthy foods during the weeks following a myocardial infarction, stent placement, or bypass surgery can have a formative impression that results in lifelong changes. Exercise-based cardiac rehabilitation (CR) programs decrease mortality and improve quality of life after hospitalization for coronary heart disease by providing individually tailored exercise training, education, risk factor management, and psychosocial support. However, CR programs are vastly underutilized, with less than a third of eligible patients participating in the United States. The largest barrier to patient participation is that CR must be provided in a physician’s office or hospital setting to qualify for reimbursement. Virtually all existing CR programs require that the patient travel to a CR center three times per week for 12 to 36 weeks. Most patients live too far from a CR center to enroll, and even when nearby programs are available, few patients have the time, flexibility, transportation, social support, and/or financial resources to attend. A recent Presidential Advisory from the American Heart Association concluded, “The remarkably wide treatment gap between scientific evidence of the benefits of cardiac rehabilitation and clinical implementation is unacceptable.” One promising solution to the problem of CR under-utilization is greater implementation of home-based CR programs. Both home- and center-based CR programs have equal benefits on cardiovascular risk factors, mortality, and quality of life. However, similar efficacy does not necessarily translate into similar effectiveness. If patients are more likely to participate in home- versus center-based therapy, then greater participation could lead to greater effectiveness. We are therefore proposing to compare the clinical effectiveness of home- versus center-based CR following hospitalization for myocardial infarction, percutaneous coronary intervention, or coronary artery bypass surgery. We hypothesize that referral to home-based CR will have greater effectiveness than center-based CR as measured by (a) greater participation; (b) similar patient-centered outcomes; and (c) similar cost. Our ultimate goal is to demonstrate that administering a 12-week home CR program will cost less than (and prevent at least) one day of re-hospitalization per patient.

Connecticut

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YALE UNIVERSITY
Increasing Healthcare Choices and Improving Health Outcomes Among Persons with Serious Mental Illness

Adults with serious mental illnesses (SMI) die an average of 25 years earlier than other Americans due, in part, to untreated or poorly treated medical conditions such as obesity, hypertension, and diabetes.
Several strategies for improving the physical health of this population have been developed that show promise, including screening for risk factors, co-location of primary care in mental health settings, coordination of physical and mental health care, and using peers to help people access the healthcare system and take better care of themselves. What we do not yet know is who will choose to use these practices when they are implemented in real-world settings, in what combinations, with what short-term effects, and with what health outcomes. We also do not know whether additional strategies may be needed for persons for whom these strategies are not effective. This proposal seeks to answer these questions by comparing the use and effectiveness of different evidence-based practices that are being implemented as part of a newly established Wellness Center—an integrated primary and behavioral healthcare center—at our local community mental health center. In addition to offering primary care on-site, the Wellness Center will facilitate screening of up to 360 poor, urban adults with serious mental illnesses for risk factors and medical conditions, and offer care coordination and access to peer health navigators, combining the four strategies above. Phase 1 will involve evaluating the use of and outcomes generated by the different components of this center, while Phase 2 will involve developing and piloting an augmentation strategy to improve the health of clients who have yet to derive any benefits from the Wellness Center. Using both qualitative and quantitative methods, our specific aims are to: understand more about who chooses to use which Wellness Center services and in what combinations, with what short-term effects, and leading to what health outcomes; identify barriers to and facilitators of access, service use, and improvements in person-centered outcomes and elicit suggestions for changes and additional interventions to improve the quality and effectiveness of the Wellness Center; and collaborate with persons in recovery to develop and pilot a new peer-led, community-based intervention to enhance access and choice, and improve person-centered health outcomes, among 40 clients who show no improvement in 12-month outcomes from using the Wellness Center. Findings from this comparative effectiveness study will be used to inform policy makers and practitioners about the practices that work best for different subgroups of persons with SMI on the health outcomes that matter to them most. This model can then be disseminated to mental health centers around the country to improve the physical health and extend the longevity of this under-served population.

District of Columbia

Richard Jeffrey Katz, MD
GEORGE WASHINGTON UNIVERSITY
Changing the Healthcare Delivery Model: A Community Health Worker/Mobile Chronic Care Team Strategy

Diabetes is a complicated disease that can cause heart attack, stroke, kidney failure, and eye problems. Patients with diabetes need to monitor their blood sugar, follow a diabetic diet, exercise regularly, take multiple medications, and get regular checkups of their blood pressure, cholesterol, eyes, and feet. To assist with organizing these tasks, a community health worker, attached to a patient’s clinic, can help patients understand the care of their diabetes and keep patients in contact with their doctors. In addition to a community health worker, there are new cell phone systems that have programs to assist with diabetes care. The cell phone system can provide immediate feedback to diabetes patients on how they are doing and send advice to their healthcare team on how to do better. The cell phone system information will be regularly reviewed by the healthcare team community health worker to provide patients with added advice. This study will compare the benefit of providing patients with diabetes with a cell phone system alone versus providing patients with both a community health worker and a cell phone with an electronic system for following their diabetes and, if needed, blood pressure. As
participants in this study, 200 diabetes patients with Medicaid insurance will be followed for 12 months in the medical clinics at George Washington University, Howard University, or the Washington Hospital Center. Participants will be assigned to one of three groups. Group 1 will use the diabetes cell phone system alone. Group 2 will be assigned a community health worker, and group 3 will have both the cell phone system and a community health worker. Those patients using the cell phone system will be taught how to use the phone to monitor their blood sugar and other diabetes needs and keep in contact with their community health worker and their medical team. All participants will be asked to fill out questionnaires at the first visit and 6 and 12 months later. Patients using the cell phone will be asked to enter their blood sugar and blood pressure readings on the system. Patients can use their own cell phone or can be provided with a free phone and service. Those using their own phone will be reimbursed for SMS texting services. Those study subjects not using the cell phone will receive $15 every month for their participation. At the end of the study, we will compare the patients who used the cell phone system alone and the community health worker alone to those who had both a community health worker and the cell phone diabetes program to see which approach is most helpful for patients to improve wellness behaviors and clinical outcome goals.

Illinois

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Computerized PAINRelieveIt Protocol for Cancer Pain Control in Hospice

Unrelieved cancer pain at the end of life is a major health problem and inconsistent with patient-centered goals. Building on a successful approach in outpatient oncology clinics, we propose a study testing PAINRelieveIt, a system-level intervention of computerized tools with patient-reported pain outcomes (available in English, Spanish, Chinese languages), decision support for clinicians (English), and multimedia education tailored to each cancer patient and lay caregiver. Using a one-week randomized design in patients receiving care provided by two Chicago-area hospices, we will compare effects of usual hospice care and PAINRelieveIt on pain outcomes. The tablet-based PAINRelieveIt includes valid and reliable pain tools (PAINReportIt), a summary of the patient’s pain data with decision support for hospice nurses to obtain recommendations for analgesic therapies (PAINConsultN), and multimedia education tailored to the patient’s and lay caregiver’s pain management misconceptions (PainUCope). Patient’s/caregiver’s answers are automatically stored in an electronic database, from which the system generates information for patients/caregivers and hospice nurses. All patients will receive usual hospice care. All patients/caregivers will complete PAINReportIt at pre-test and one week later (post-test); patients also complete parts of it daily. Via daily e-mail updates, the control-group hospice nurses will receive a PAINReportIt Summary, and experimental-group hospice nurses will receive a PAINConsultN. Additionally, experimental-group patients/caregivers will view multimedia educational materials via PAINUCope to help patients report pain and adhere to prescribed analgesics. Specific aims are to compare usual hospice care and PAINRelieveIt groups for effects on: 1) patient outcomes (analgesic adherence, worst pain intensity, satisfaction, and misconceptions) and lay caregiver outcome (pain misconceptions) in a diverse sample of 250 cancer patient-caregiver dyads receiving hospice care; and 2) nurse outcomes (obtained appropriate analgesics for patient) in a sample of hospice nurses. We hypothesize that at post-test, controlling for pre-test data and compared to the usual care group, the PAINRelieveIt group will: a) report decreased scores for worst pain intensity and pain misconceptions; b) have increased analgesic adherence (primary outcome); and c) have a larger proportion who report satisfaction with pain intensity and whose nurses obtained appropriate analgesics for the patients’ pain. Findings will guide future system-level research to implement PAINRelieveIt in a multi-site, longitudinal
trial that will test the effect of disseminating this technology on clinical decisions for managing pain and patient/caregiver pain outcomes in a national sample of hospices. This approach offers improved pain control for dying patients and other populations.

Indiana

Michelle Salyers, PhD
INDIANA UNIV-PURDUE UNIV AT INDIANAPOLIS
The Impact of Burnout on Patient-Centered Care: A Comparative Effectiveness Trial in Mental Health

Healthcare providers play an important role in helping patients be actively involved in treatment and recover from mental illness. But mental health clinicians, like other healthcare providers, are at risk for experiencing burnout—feeling emotionally drained from their work, having cynical thoughts toward patients and others, and feeling little accomplishment in their work. Burnout can lead to problems for the clinician including poor overall health, depression, and lower job satisfaction. Burnout also can impact how clinicians perform on the job; for example, people with high levels of burnout take more time off, show lower commitment to their job, and are more likely to quit or be fired. There is some evidence that burnout can affect the quality of care for patients, but very little rigorous research has tested this assumption. The purpose of our study is threefold. First, we will investigate how patients perceive burnout in clinicians and whether (and/or how) burnout impacts the care they receive. Next, we will test an intervention to reduce clinician burnout called Burnout Reduction: Enhanced Awareness, Tools, Handouts, and Education (BREATHE). BREATHE brings together tools that mental health clinicians are already familiar with, including relaxation and mindfulness exercises, setting boundaries, using social supports, and changing negative thought patterns and replacing them with more helpful ways of thinking. We have found this intervention effective in reducing burnout in other organizations, but have yet to study whether it also can improve patient outcomes. Clinicians (approximately 200) who participate will receive either the BREATHE intervention or training in motivational interviewing, which could also improve patient involvement in treatment and patient outcomes, but is unlikely to significantly reduce clinician burnout. We will also recruit 600 adult patients served by participating clinicians. We will survey clinicians and interview patients over a 12-month period after the intervention to determine how the intervention impacts clinician burnout and patient perceptions of care (relationship with the clinician, degree of autonomy in decision making), patient involvement in care, and outcomes (confidence in managing mental health, symptoms, functioning, and hope). Finally, this study will use a statistical procedure called Structural Equation Modeling to test a theoretical model of the relationship between burnout and patient outcomes. Findings from this study will show whether reducing clinician burnout can improve patient outcomes and the quality of care that patients receive. Our intervention will have the potential to be easily implemented in a variety of settings where burnout is a problem. Knowing how clinician burnout impacts patient outcomes, and whether improving burnout can improve patient care, can help improve the healthcare system.
Maryland

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JOHNS HOPKINS UNIVERSITY

An Integrative Multilevel Study for Improving Patient-Centered Care Delivery among Patients with Chronic Obstructive Pulmonary Disease

The transition from hospital to home is a high-risk period for patients. When patients, or their families, are not well prepared for discharge, they are at risk for adverse events and may subsequently need to use the emergency department (ED) or get readmitted. Transitional care interventions, developed to support patients being discharged from the hospital, have been shown to result in reduced use of the hospital or ED. These interventions mainly focus on following patients for 30 days post discharge, addressing medication and outpatient follow-up issues. There is little evidence on the effect of these interventions on meaningful outcomes to patients, such as reduced shortness of breath and improved ability to walk or climb stairs. In this study, we propose to develop and evaluate a comprehensive patient- and family-centered transitional care intervention to improve patient-centered outcomes among hospitalized patients. We will focus the study on Chronic Obstructive Pulmonary Disease (COPD) patients, given that these patients commonly experience severe symptoms and frequently visit the ED or get hospitalized. The study will answer the following: Among patients hospitalized due to COPD, would patient/family engagement in a hospital-initiated three-month transitional care program that addresses the patient’s biopsychosocial needs and advances the patient/family caregiver ability to manage the disease improve the patient’s health-related quality of life and reduce number of hospitalizations and ED visits? Would this program improve family caregiver coping skills and reduce caregiver stress? Specifically, we aim to: 1) develop and pilot-test a Patient- and Family-Centered Transitional Care Intervention (PFI) that starts within hospital and continues for three months. The program will help meet hospitalized patients’ individual needs and build capacity of COPD patients/family caregivers to manage this disease and advance their problem-solving and coping skills; 2) conduct a randomized controlled trial, recruiting 214 patients admitted to one academic center, to measure the effects of PFI on health-related quality of life, survival, and rates of re-hospitalizations and ED visits, compared to usual care; 3) evaluate PFI impact on patient activation, confidence, and behaviors; and 4) evaluate impact on family caregiver confidence, stress, and coping skills. COPD patients dread getting severe shortness of breath that requires them to go to the ED or hospital. Many patients suffer from symptoms that limit their ability to perform their daily activities. Our primary study outcomes are to measure patients’ quality of life and the combined number of hospital and ED visits per patient over the six months post discharge. Other study measures that are highly relevant to patients and family caregivers include patient survival, symptom burden, and experience of care and family caregiver stress and coping skills.

Carla S. Alexander, MD
UNIVERSITY OF MARYLAND BALTIMORE
CASA: Care and Support Access Study for Implementation of a Palliative Approach with HIV Treatment

Background: Effective outcomes for persons living with HIV/AIDS depend upon strict adherence to antiretroviral therapy. HIV-positive young men who have sex with men (YMSM) may have a history of childhood abuse or other predisposing factors, such as age and emerging homosexual identity. Emerging sexual identity predisposes young men to less engagement in care and limited ability to adhere with chronic HIV management. Support groups and outreach workers have been partially effective in addressing this issue, but little attention has been paid to
educational strategies for the health delivery team related to changing their approach to care management for these patients.

Objectives: Using translational methods, combined with implementation science, our key objectives are to: 1) refine, deliver, and determine the acceptability and applicability of an interdisciplinary professional education program that will prepare a site-based multidisciplinary health care team to deliver patient-centered care integrated with ongoing outpatient HIV care; 2) document critical mechanisms for integration of care and support when patients have multidimensional needs beyond the scope of routine outpatient care delivery; 3) demonstrate impact on patient outcomes (e.g., mental health, quality of life [QOL]), retention in care, and adherence to treatment (e.g., achievement of viral suppression) of early integration of multidimensional care strategies for vulnerable populations with HIV not easily engaged in care; and 4) detail use of self-care strategies for staff during integration of new care strategies and explore their impact upon patient-centered outcomes.

Methods: Care and Support Access (CASA), the intervention delivered, uses an iterative teaching method followed by onsite mentored training of site-specific CASA teams, including a patient representative (PR), to introduce palliative approaches into outpatient HIV care. This study will offer team training incorporating PRs during the full process and documenting key techniques that can be translated for use with any difficult-to-engage population. Using an interdisciplinary team approach steered by needs of the patient, PRs on the team will advise on approaches, services, and outcomes. Individualized care is time-consuming and undervalued in current health delivery, yet patients with competing lifestyles and comorbidities require additional assistance. CASA is expected to improve patient outcomes in vulnerable populations by facilitating patient-centered care and enhancing retention in care and adherence to complex treatment to impact QOL, mental health, and survival (e.g., achievement of viral suppression). CASA will be delivered at two clinics; 204 YMSM with HIV/AIDS will be enrolled and followed longitudinally. Patients and clinic staff will complete surveys and qualitative interviews. The project will inform policy and care related to the patient-centered benefits of implementing multidimensional care strategies for populations difficult to engage and retain in care.

Massachusetts

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MASSACHUSETTS GENERAL HOSPITAL
Improving Childhood Obesity Outcomes: Testing Best Practices of Positive Outliers

Overweight affects over one-third of children in the United States and is more common among racial and ethnic minorities and those living in disadvantaged communities. Overweight children often suffer from chronic medical problems like diabetes and also from conditions that are often unseen, such as poor quality of life. Programs within healthcare settings, such as primary care offices, can help children who are overweight because families often have a long-standing, trusting relationship with their primary care clinicians. However, clinical programs do not always pay close attention to the many non-medical issues that can interfere with families trying their best to follow their doctors’ recommendations. Many things can get in the way, such as financial trouble leading to inability to buy healthy foods, not recognizing which foods are contributing to their child’s weight gain, or not knowing about the availability of low-cost resources in their communities to help their children exercise. Therefore, it is unlikely that the primary care setting can address the vexing problem of childhood overweight without understanding and addressing social issues that influence weight. The goal of this study is to work with parents and children to develop a new program for the management of childhood overweight. The
program will build on the resources available in primary care and provide linkages to community resources to support behavior change. This program is intended to improve children’s weight, body mass index, quality of life, and parents’ experiences with their child’s care. We will conduct this study in Massachusetts primary care offices that care for a large number of children at high risk for being overweight. This study has two parts. First, we will work with pediatricians to identify children from disadvantaged communities who have achieved a healthier weight. We call these children and their families “positive outliers” because they stand apart from their peers by managing to succeed under conditions where many fail. Learning from these families by using interviews and group discussions will help us determine what worked and how we can incorporate their strategies into a new program. Next, we will design and test a new clinical program to improve the care of overweight children 2–12 years old. The program will involve health coaches who will assist children in improving their health behaviors and will link children and families to existing resources in their community. Health coaches will study communities by using cutting-edge technology that can tell them where families can shop for healthy foods, find safe places for children to play, and use public transportation to get there. In addition, health coaches will use text messages and other mobile technology to reach families. By creating clinical-community linkages and attending to the social issues that influence weight, this program can have a significant impact on childhood overweight.

**Tennessee**

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Baptist Memorial Hospital-Tipton

*Building a Multidisciplinary Bridge Across the Quality Chasm in Thoracic Oncology*

The Building a Multidisciplinary Bridge Across the Quality Chasm in Thoracic Oncology project will examine the effectiveness of a coordinated multidisciplinary model of treatment for thoracic oncology at a regional hospital system. Baptist Memorial Health Care offers a full continuum of care to communities throughout the MidSouth that have the highest lung cancer incidence and death rates in the country. Lung cancer rates in this area reflect the disease’s socioeconomic disparity, disproportionately affecting low-income people, African-Americans, and both rural and inner-city inhabitants. Low lung cancer survival rates are thought to be partially due to the failure of the traditional serial model of care, in which multiple specialists independently screen, diagnose, and treat the patient through a sequence of referrals. This model can result in poor patient outcomes as a result of inconsistency, inefficiency (duplication and incompleteness), non-timeliness, and a lack of oversight. In addition, the model presents barriers to access for disadvantaged patients and limits opportunities for direct patient input. With PCORI funding, we propose to rigorously test the comparative impact of a multidisciplinary care model, in which key specialists concurrently provide early input and execute a consensus plan of care developed in collaboration with patients and their families, who will be the ultimate beneficiaries of this research project. Potential improvement in patient outcomes will result in more timely healthcare delivery, a higher rate of stage-appropriate treatment, and more direct patient involvement in decision making. Our objective is to provide high-level evidence of the comparative impact of multidisciplinary care on patient outcomes. The key research method will be a matched cohort comparative effectiveness study of patients receiving serial versus multidisciplinary care. Model design will incorporate input from a series of patient/stakeholder surveys and focus groups and use computer simulation modeling to optimize the efficiency of patient flow. We will measure patient-centered endpoints including survival, satisfaction with the medical care experience, timeliness and appropriateness of care, and quality of staging. Significantly, the study will be one of the first to explore the multidisciplinary care model in a regional hospital system. Although the model is strongly advocated
by experts and clinical practice guidelines, there are few examples of successful implementation, mostly in academic tertiary care centers. Findings will broadly apply to any complex healthcare delivery environment in which multiple specialists manage patients with complex, debilitating, and life-threatening health problems.

Texas

Dawn I. Velligan, PhD
UNIVERSITY OF TEXAS HLTH SCI CTR SAN ANT
Improving Transitional Care Experience for Individuals with Serious Mental Illness

The cost of serious mental illness (SMI) in the United States is $317 billion annually. This translates to more than $1,000 for every man, women, and child in the United States. Hospitalization and Emergency Room (ER) visits have the highest costs. Outpatient services are overburdened. There is a push to get people out of hospitals quickly, while they are still quite ill. These factors cause patients to be lost in the transition from inpatient to outpatient care. Many individuals are repeatedly rehospitalized or continue to clog emergency rooms in an attempt to receive care. The importance of transitional care between inpatient/ER facilities and outpatient services to prevent this revolving door phenomenon has been continually stressed. There is little research on the best way to accomplish smooth transition to outpatient care. We developed a 90-day transitional care clinic (TCC) to address this need. We propose a randomized treatment outcome study comparing two transitional service packages within our TCC: a Standard Care package versus an Engagement-Focused package that features a novel intake procedure and a Shared Decision-Making intervention. Access Group is an intake procedure designed to address many of the problems of traditional approaches to post-acute treatment engagement, including failure of patients to reach intake appointments. Shared Decision-Making (SDM) is a structured approach to provider-patient communication that has been shown to increase patient involvement in care and improve outcomes. Despite SMI patients’ desire to be more involved in their treatment decisions and promising early evidence of SDM’s effectiveness in SMI, SDM has not been systematically evaluated in transitional psychiatric care. In the proposed study, patients referred to TCC will be randomized to either Engagement-Focused Care or Standard Care. The relative benefit of these two approaches will be evaluated in 300 individuals who will be randomized to these two treatments in a 2:1 ratio. We will examine attendance at intake and subsequent appointments at the TCC as well as their initial appointment once referred for long-term services in the community. We will examine reported satisfaction and shared decision making as well as quality of life in the two treatments. Results will be important in addressing the public health problem of rehospitalization in mental health. The new treatment package is designed to get individuals into treatment quickly and to teach them how to be good consumers of mental health treatments going forward.

Washington

Dawn Marie Ehde, PhD
UNIVERISTY OF WASHINGTON
Improving the Quality of Care for Pain and Depression in Persons with Multiple Sclerosis

Background: It is common for people with multiple sclerosis (MS) to have depression and chronic pain. Individuals with MS who have depression and/or pain often use more healthcare services, benefit less from treatment, and have poorer quality of life. While evidence-based medical and behavioral
treatments for depression and pain exist, they are often not offered or accessible to persons with MS. As a result, chronic pain and depression are under-treated in people with MS. One way to better treat these problems is through a “Collaborative Care” approach. In this approach, a care manager (nurse supervised by expert physicians, psychiatrists, and psychologists) helps coordinate and provide high-quality, evidence-based treatments for depression and pain. The care manager also makes sure that the care is focused on the patient’s goals and preferences. The care is provided by phone or in person based on the patient’s preference. Although this approach has been used successfully with patients with many different conditions, it has never been tested in patients with MS, pain, and depression.

Objectives: Our objectives are to 1) test the benefits of the patient-centered collaborative care treatment approach for persons with MS who also have depression and/or pain; and 2) test whether this approach improves quality of life, patient satisfaction, adherence to other treatments, and quality of care in the MS care system.

Methods: Participants will be 200 outpatients with MS from a specialty MS Center who have depression and/or chronic pain. Half of the participants will receive the treatment that is typical for patients in the MS Center (“usual care”), while the other half will receive treatment using the Collaborative Care approach. Participants in the collaborative care group will meet regularly in person or by telephone with a nurse who coordinates their depression and pain treatments and provides strategies for better managing their symptoms. All participants will be involved in the treatment phase of the study for 16 weeks. Participants will also complete telephone interviews before treatment begins, immediately after, and six months after the treatment ends. During these interviews, participants will be asked questions about their pain, depression, satisfaction with care, and quality of life to compare the two care approaches.

Projected patient outcomes: We anticipate that those in the collaborative care approach will have better-controlled pain and depression and better quality of life, satisfaction with care, adherence to other MS treatments, and quality of care compared to those in the usual care approach. The results of this study may help patients, clinicians, healthcare system leaders, and policy makers make decisions about the benefits of this type of coordinated care approach for depression and pain in MS care.

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UNIVERSITY OF WASHINGTON
A Comparative Effectiveness Trial of Optimal Patient-Centered Care for US Trauma Care Systems

The nation’s trauma care system, which includes trauma center hospitals and emergency departments, is where over 30 million Americans receive care after traumatic injuries each year. Injury victims are diverse patients who suffer from complications of the initial injury as well as from multiple complex medical and mental health conditions. Currently, high-quality patient-centered care is not the standard of care throughout US trauma care systems. Injured trauma survivors treated in trauma care systems frequently receive fragmented care that is not coordinated across hospital, emergency department, outpatient, and community settings. Post-injury care is frequently not individualized to integrate the patient’s most pressing post-traumatic concerns and preferences into medical decision making. We, as a group of front-line trauma center providers, patients, researchers and policy makers, have been working together for over a decade to integrate patient-centered care into US trauma care systems. We began this work by asking large groups of injured patients the key patient-centered question: “Of everything that has happened to you since your injury, what concerns you the most?” We developed scientifically sound assessment tools that allowed us to follow patient concerns after injury hospitalization. In May of
2011, our team convened an American College of Surgeons’ policy summit that addressed mental health and patient-centered care integration across US trauma care systems. As part of this policy summit, patient members of our team presented in their own words their experiences of traumatic injury and recovery. While giving injured patients a “voice” at the summit, these narratives did not move surgical policy makers to develop mandates or guidelines for patient-centered care. In contrast, presentations that included information from randomized comparative effectiveness trials and standardized outcome assessments convinced surgical policy makers to develop US trauma care system policy mandates and best practice guidelines for post-traumatic stress disorder and alcohol use problems. Our team now realizes that in order to optimally integrate patient-centered care into US trauma care systems, we must use the best scientific methods that capture the highest-quality data. This PCORI proposal aims to demonstrate that a patient-centered care management treatment that addresses patient’s post-injury concerns and integrates patient concerns and preferences into medical decision making, while also coordinating care, can improve outcomes of great importance to patients and their caregivers, front-line providers and policy makers. This proposal directly addresses two PCORI patient-centered research questions: “After a traumatic injury, what can I do to improve the outcomes that are most important to me?” and “How can front-line providers working in trauma care systems help me make the best decisions about my post-injury health and health care?”

Wisconsin

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UNIVERSITY OF WISCONSIN MADISON
Family-Centered Tailoring of Pediatric Diabetes Self-Management Resources

It is easy to take your pancreas for granted. When you eat, your pancreas makes insulin, a hormone necessary for your cells to use sugar from food. For 175,000 children with type 1 diabetes (15,000 newly diagnosed annually), the pancreas does not make insulin, so sugar accumulates in the blood. Unlike type 2 diabetes, type 1 diabetes cannot be prevented, cured, or treated solely with better diet and exercise. The only way for these children to survive is with multiple daily insulin injections. Not taking enough insulin can cause serious health problems, like kidney failure and blindness. Taking too much insulin can cause seizures or even death. Managing diabetes can reduce child and parent quality of life (QOL), negatively affecting school/work attendance and participation in activities. Diabetes care is also costly, approximately $14.9 billion annually in the United States. Although help is available, most families struggle to control their child’s diabetes. Each family faces a different set of challenges in managing the disease. Taking a family-centered approach to diabetes management, in which resources are tailored to each family’s unique challenges, could result in better health. Currently, there is no convenient way for providers to identify families’ challenges in managing diabetes, so families are often referred to resources that do not address their needs. Families become frustrated and may not get the services needed to successfully manage diabetes. PRISM (Problem Recognition in Illness Self-Management), a 10-minute survey, can identify the best resources to help families, based on their specific needs. In preliminary testing, using PRISM to select resources resulted in substantial improvements in blood sugar control. This project’s long-term goal is to provide families with the best help for managing diabetes, to improve blood sugar control and QOL. In partnership with parents, children, clinicians, clinic administrators, and the Juvenile Diabetes Research Foundation, this study will examine whether families who use PRISM to select resources to improve diabetes management will have better blood sugar control and child/parent QOL than families receiving usual care. About 200 children (8 to 16 years old) with diabetes and their parent(s) will be enrolled at two sites. Families who agree to participate will
complete the PRISM and QOL surveys and have their child’s A1c (blood sugar control) measured. Families will be randomly assigned to receive either resources that are matched to their needs by PRISM or their usual care (100 in each category). Resources will be delivered in group sessions scheduled to coincide with children’s routine diabetes visits, making participation easier for families. Children’s blood sugar control will be measured every three to six months while child/parent QOL will be measured every six months. If PRISM improves blood sugar or QOL, the tool could be incorporated into the care of all children with diabetes.

**Communication and Dissemination Research**

**California**

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*Randomized Trial to Increase Adherence to Cervical Cancer Screening Guidelines for Young Women*

Cervical cancer screening (CCS) with cytology has saved thousands of women’s lives. However, because cytology is not perfect, thousands of women get extra tests they don’t need, including biopsies (taking a piece of tissue out of the cervix) and treatments that result in removing large portions of the cervix. We now know that these treatments in young women are often unnecessary, since the dysplasia will go away all on its own. In addition, these treatments can affect the strength of the cervix that may result in babies being born [prematurely] (*sic*). Many women also experience emotional stress because of treatments. As a result, recent US guidelines recommend CCS every 3 years instead of every year, and they recommend not treating young women with dysplasia but [rather] (*sic*) to follow them closely every 6–12 months until it goes away. Studies show this is safe and helps women avoid getting overtreated. Unfortunately, many doctors do not follow the guidelines. This might be because they are unaware of the guidelines, or that women insist on screening and treatments. This study will examine three different doctor- and patient-based interventions that will help prevent [unnecessary] (*sic*) screening and treatments in young women less than 30 years of age. We picked this age since these are the women most likely to want to get pregnant and [who are likely to] (*sic*) be negatively affected by overscreening. We will select clinics from California that serve underinsured women, [comprising] (*sic*) the Family PACT provider network [in which] (*sic*) 40% of the women are Latina. We chose to work in this network since we can follow how many women get cytology, and get treatments based on how they are billed. We will randomly assign these clinics to one of four interventions: (1) provider-based feedback (PBF) intervention alone; (2) mobile phone application (APP-based) intervention for providers plus PBF; (3) patient-centered approach (PCA) intervention plus PBF; and the three arms will be compared to: (4) no intervention arm (control). PBF will be written messages on cytology lab reports that will spell out the guidelines. The APP will guide providers through the guidelines. The PCA will be focused on educating women and helping them understand the guidelines, as well as the choices for treatment. The intervention will occur before they see the doctor, to help them ask questions of the doctor and to assist them with treatment choices. Interventions will be developed with direct input from women from the community who are members of the National Cervical Cancer Coalition and the Latina Contra Cancer group. Organizations including the American Congress of Obstetricians and Gynecologists, the State Office of Family Planning, the American Society for Colposcopy and Cervical Pathology, and Quest [Diagnostics] (*sic*) laboratories will help us develop the doctor-based interventions. We plan to enroll about 10,000 women. We will examine the average interval between
cytology specimens, and the number of dysplasia treatments before and after the interventions, to see if the interventions [were effective] (sic).

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UCSF CT Radiation Dose Registry to Ensure a Patient-Centered Approach for Imaging

Despite how frequently computed tomography (CT) is used—75 million CT examinations are conducted annually in the United States—and the high doses of radiation it delivers (up to 500 times higher than a chest x-ray), there are few standards for the conduct of CT examinations. This has resulted in excessive variation in the doses patients receive when they undergo CT, and the routine use of doses higher than needed for medical diagnoses, the doses associated with increased cancer risk. Although there has been increasing attention paid to CT use from consumer advocates, medical groups, quality organizations, and state and national legislators around improving the safety of medical imaging, little progress has been made. The manufacturers are developing lower dose devices, but these [will not] completely replace existing machines for decades or longer, [as there are] (sic) over 10,000 CTs currently in operation in the United States, thus, the current machines need to be made safer. The proposed research is focused on developing and implementing strategies to standardize and optimize the protocols and doses used for CT across a large number of institutions, to improve patient safety and lower the risk of future cancers related to CT imaging. The goals of the proposed collaboration include: collect detailed data to assess current CT practice; to use these data to develop meaningful metrics to summarize dose at the facility level; to create benchmarks for assessing the appropriateness of dose; to develop and test interventions to improve dose optimization; to test organizational strategies for optimizing dose; and then to disseminate and implement the successful strategies to the larger healthcare community. Our project will be conducted in partnership with diverse healthcare delivery organizations in the US, the UK, and Canada, and in collaboration with Radimetrics, [Inc.], a medical imaging radiation dose monitoring software company that has commercial relationships with each of these partners. By purchasing Radimetrics services, each organization has demonstrated an interest, and commitment of financial resources, in optimizing the radiation doses used for CT. Each is therefore an ideal partner for our proposed project, as there is organizational support and a champion at each institution for dose optimization, even if not the expertise to do this. By organizing our project around these existing relationships, where the details of how to collect data in a secure fashion from across a range of platforms [have] already been established (one of the main hurdles that must be overcome to develop a widely implementable quality improvement program), we can focus our project on the proposed aims without having to focus on the complexity of the data collection.

Illinois

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CHILDREN’S MEMORIAL HOSPITAL (CHICAGO)
Improving Communication in the Pediatric Intensive Care Unit for Patients Facing Life-Changing Decisions

Pediatric Intensive Care Units (PICUs) are places of tragedy and hope. Approximately 16,000 children die annually in PICUs, forcing traumatized parents to make challenging end-of-life decisions. Even the parents of children who return home often face serious life-changing decisions in the PICU. For every PICU parent the experience is unforgettable, emphasizing the importance of high quality communication
during the most intense decision-making (DM) moments. Research shows that current communication is inadequate between parents and healthcare team members (HTMs) and among HTMs. There is clear a need to improve PICU communication and care coordination. Despite the obvious need for high quality PICU communication and care coordination, no stakeholder-driven, empirically tested interventions to improve PICU communication exist. Without a formal process for managing communication, critical decisions are often made at hastily assembled family meetings, and may be based on disorganized, often conflicting information. This lack of a consistent process compromises the quality of care and magnifies anxiety already felt by emotionally and physically exhausted parents. This work will improve the quality of communication, enabling parents to make the best possible decisions for their children. We will test the impact of an intervention, PICU Supports, on the quality of the DM process. PICU Supports uses a navigator to aid parental DM by addressing parents’ needs, removing communication barriers, enhancing care coordination, and providing emotional support. Our primary research question is how much does PICU Supports improve parental satisfaction with DM. We will also obtain novel data about PICU communication and DM needs for future efforts to ease the detrimental impact of pediatric critical illness. We have the following specific aims: (1) develop PICU Supports by adapting an established, navigator-guided intervention tested in an adult ICU; (2) test the impact of PICU Supports on parent outcomes (DM satisfaction/regret, psychological morbidity, and health-related quality of life) 3–5 weeks following PICU discharge; and (3) test the impact of PICU Supports on parent and HTM assessments of communication and team collaboration during admission. Stakeholders (parents and HTMs) will participate in focus groups and working groups to adapt a previously developed intervention into PICU Supports. We compare the experiences of parents and HTMs who receive PICU Supports to those who receive an education brochure. Our study will be conducted at two sites and involve the parents of 404 patients. During the PICU admission we will obtain questionnaire data from parents and HTMs, and collect navigators’ descriptions of PICU communication. After PICU discharge parents will be interviewed and complete an additional questionnaire. Stakeholders will collaborate to implement the study, analyze the data, disseminate results, and plan for future communication improvements.

Massachusetts

Lewis Mitchel Cohen, MD
BAYSTATE MEDICAL CENTER
Shared Decision Making and Renal Supportive Care

While most of us think of dialysis as a life-saving treatment for people who develop kidney failure, the unfortunate reality is that more than one-fifth of those who receive this arduous and time consuming therapy will die each year. This is not a tragic consequence of dialysis, but rather reflects [the fact] (sic) that most of the people are quite elderly and have diseases like diabetes that continue to take a toll on their hearts, brains, limbs, eyes, and other organs, in addition to the kidneys. It is tragic that we now can predict which individuals are most likely to die within the next 6 months, and yet dialysis staff rarely sit down with them and their loved ones to discuss the situation. They die without completing advance directives, appointing healthcare proxies, or knowing they have the right to stop dialysis. They die in intensive care units, hospitals, and nursing homes, and are never given the opportunity to discuss the possibility of receiving hospice services and dying at home surrounded by friends and loved ones. This study is based on preliminary research that started with patient, family, and caregiver focus groups, created a tool for predicting mortality, and went on to develop a communication intervention that successfully increased the use of hospice services in several Massachusetts dialysis clinics. We now wish, with our PCORI patient-partners and stakeholders, including hospices and dialysis companies, to
improve the intervention and [demonstrate] (sic) its effect on additional dialysis clinics in New Mexico, [in addition to] (sic) New England. We believe that this innovative clinical model can then be [disseminated] (sic) throughout the country.

**Pennsylvania**

*Cynthia Chuang, MD*

**Pennsylvania State Univ Hershey Med Ctr**

*Reducing Unintended Pregnancies Through Reproductive Life Planning and Contraceptive Action Planning*

Most US families want [two] children, resulting in the average woman spending 3 decades of her life trying to avoid pregnancy. However, most women have at least one unintended pregnancy, resulting in 1.5 million abortions and 1.7 million unintended births annually. Women and couples try to avoid unintended pregnancy for a range of personal, social, and economic reasons, but also due to the increased physical and mental health effects for children that result from unintended pregnancy. Healthcare reform now requires that private health insurance companies cover all FDA-approved contraceptive methods with no copays or deductibles to the patient, creating a great opportunity for women with health insurance to get contraceptive methods they previously could not afford. In this study, women with health insurance will be randomly assigned to one of three groups: (1) Reproductive Life Planning (RLP)—women will complete a reproductive life plan that guides them to think about if and when they would want any future pregnancies, and to determine what contraceptive method(s) are best suited to them; (2) Reproductive Life Planning Plus (RLP+) which additionally includes “if–then planning,” where women determine what they will do when they encounter difficult situations that make it difficult to use their contraceptive method perfectly; or (3) an information-only control group. The online format of the study allows for the potential of wide dissemination. We expect that the RLP and RLP+ interventions will result in greater likelihood of contraceptive use, continuity of contraceptive use, and contraceptive adherence, and thus reduce overall risk of unintended pregnancy.

*Marc Williams, MD*

**Weis Center for Research-Geisinger Clinc**

*Enhancing Genomic Laboratory Reports to Enhance Communication and Empower Patients*

Most rare genetic disorders are chronic and impact patients and their families for life. The challenge for patients, families, and their providers is having ready access to the information that is necessary for appropriate management and coordination of care. Non-genetic providers are often not comfortable managing genetic disease. In most cases, patients have inadequate information to decide the best course of action for their disorders even though they are put in the position of having to become an expert in the condition. This issue will be more important as information from all of an individual’s genes (genomic information) is used to diagnose and manage medical conditions. Currently, laboratory reports only go to providers. We believe that a new type of genomic test report, tailored for provider use, will enable patients to have access to information they can understand, allowing them to be more involved in the management of their disorders, better navigate the healthcare system, and make more-informed decisions about their health and health care in conjunction with their providers. This approach has the potential to improve outcomes from both the patient and provider perspectives. We propose to study the research question, “Can a genomic laboratory report tailored for both providers and families of patients improve interpretation of complex results and facilitate recommended care by enhancing communication and shared decision making?” To do so, we propose to: 1) Use
interviews and focus groups with patients and providers to understand what is needed from both groups to interpret genomic information. The results will be used to develop a genomic laboratory report that can be used by both patients and providers. Providers and patients will use the draft report to see if it meets their needs and is easy to use. Their feedback will be used to improve the report. 2) We will test the new report by comparing a group of patients and providers using the new report to a group of patients and providers using the traditional report that is only viewed by the provider. Outcomes that are important to patients will be measured to see if the new report is more effective. 3) The new report will be further improved using the information from the study in order for it to be used routinely in the care of patients with rare disorders. We expect to determine how the proposed genomic laboratory report can help providers and patients answer patient-oriented questions. By including the patient’s perspective, we will create a laboratory report that not only will provide test results but will facilitate improved communication between providers and patients. Shared decision making will promote patient empowerment and trust, close the knowledge gap, and improve outcomes of importance to patients.

Addressing Disparities

California

John Sinclair Brekke, PhD, MS
UNIVERSITY OF SOUTHERN CALIFORNIA

Peer Health Navigation: Reducing Disparities in Health Outcomes for the Seriously Mentally Ill

The mortality rate among people with serious mental illness (SMI) is two to three times that of the general population (DeHert et al., 2011), meaning that those with a serious mental illness die, on average, 25 years earlier than those without a SMI (Parks et al., 2006). There is evidence that these deaths are largely attributed to preventable medical conditions, many of which are more common in the SMI population. System bifurcation, or the separation of mental and physical health services, has been identified as a critical factor that leads to significant health disparities for those with SMI (Bazelon Center for Mental Health Law, 2004). Grounded in patients’ experiences, needs, and voices, we seek to generate knowledge about effective interventions, uses outcomes that are central to patients and caregivers, attends to issues of implementation and dissemination, and may seek to optimize outcomes in the context of factors such as burden, technology, and stakeholder perspectives. Based on pilot work funded by the UniHealth Foundation, the goal of this PCORI proposal is to test the effectiveness of a peer health navigation intervention (The Bridge) in comparison to usual treatment. The Bridge is a peer-staffed comprehensive healthcare engagement and self-management model, situated in an outpatient mental health clinic, where clients are taught the skills to access and manage their health care for any condition. Our goal is [to] (sic) train clients to successfully engage and navigate the primary health care system as well as other needed health care services (specialty care, lab, and pharmacy). Guided by a version of Gelberg, Andersen, and Leake’s (2000) Behavioral Model of Health Service Use for Vulnerable Populations that we adapted for the seriously mentally ill (Brekke et al., in press), The Bridge combines three approaches: integrated care, patient education, and cognitive-behavioral skill building with an in vivo (real-world) focus. We will conduct a randomized controlled trial comparing two groups: (1) a treatment as usual waitlist ($n=73$), and (2) The Bridge peer navigator intervention ($n=73$). We will compare these groups across three time points (baseline, 6 months, 1 year) to examine The Bridge’s effectiveness at improving health care service use, satisfaction with care, health knowledge, health status, health-related self-efficacy, and quality of life. Outcomes will be measured through patient self-report and according to objective measures of health (medical records and insurance claims data). This
PCORI proposal relies on significant stakeholder involvement in the intervention development, project development and management, and in the plans for dissemination and implementation. The ultimate goal is to provide the field [with] (sic) a peer-delivered intervention that significantly reduces disparities in the utilization and outcome of health services for the seriously mentally ill, and thereby reduce morbidity and mortality in this highly vulnerable population.

Kathleen Ell, DPH
UNIVERSITY OF SOUTHERN CALIFORNIA

*A Helping Hand to Activate Patient-Centered Depression Care among Low-Income Patients (AHH)*

Major depression, plus other chronic illness such as diabetes, coronary heart disease and heart failure is common among low-income, culturally diverse safety net care patients. Unfortunately, many of these patients are uncomfortable about either asking their doctor questions about their illness and treatment options and their illness self-care or informing their doctors about their treatment preferences. Lack of strong engagement with medical providers occurs because patients believe they lack the knowledge to ask questions or to understand and follow recommended self-care and their concern that their medical provider lacks understanding of their treatment preferences. These factors often result in patient worry, poor adherence to prescribed treatment, and worsening illness status and even early death. The study will be conducted by a university, the Los Angeles County Department of Health Services (DHS) and a community health worker organization research team. The study will be conducted within two DHS Patient-Centered Medical Home clinics, with each patient having a designated primary care team of physician, nurse, social worker and medical assistant. Study patients with major depression and other illnesses face numerous self-care management barriers: managing concurrent symptoms (depression, pain, anxiety etc.) and cultural influences (depression stigma, diet), difficulty in navigating primary and specialty doctor and treatment plans, while at the same time experiencing daily social and economic stress. The randomized comparative effectiveness study will recruit 350 patients with major depression and a concurrent chronic illness (i.e., diabetes, heart failure, coronary heart disease) from two DHS PCMH community health centers. To enhance patient-centered research community partnerships, patients will be provided A Helping Hand (AHH) in which a community organization-based promotora aims to activate patient-centered depression self-care training and practical assistance to: a) improve and personalize major depression self-care (e.g., medication or psychotherapy preference, treatment adherence, fatigue, pain, diet, activity, stress management, family/caregiver communication); b) activate patient-provider communication, clinic appointment keeping and treatment coordination; and c) and facilitate patient navigation and receipt of needed community resources. AHH aims to improve patient self-care management and patient-provider care management relationships among underserved low-income patients, who must simultaneously cope with major depression and chronic co-morbid physical illness. Study objectives aim to determine: 1) whether community health worker promotora care management training improves patient-centered outcomes, such as self-care need and management, treatment adherence, symptom improvement, and care satisfaction over the usual team care; 2) depression symptom improvement; and 3) patient hospitalizations and ER visits frequency.
Colorado

Joan O’Connell, PhD
UNIVERSITY OF COLORADO DENVER
Improving Health Outcomes among Native Americans with Diabetes and Cardiovascular Disease

Project Background: American Indians and Alaska Natives (AI/ANs) have the highest prevalence of diabetes among all US racial and ethnic groups. In fiscal year (FY) 2010, the diabetes prevalence among AI/AN adults who obtained services through Indian Health Service (IHS) was 14.6%, nearly double the US rate. Compared to other racial groups, AI/ANs are more likely to develop type 2 diabetes at younger ages and to have more diabetes-related complications. These factors substantially increase diabetes-related mortality. Although diabetes is the seventh leading cause of death in the United States, it ranks fourth among AI/ANs. Heart disease is the leading cause of AI/AN mortality and a common complication among those with diabetes. AI/ANs have the highest rate of premature deaths from heart disease among all races; that is, they are more likely to die from heart disease before age 65 than other races. To address this need, IHS and tribes collaborated with the Centers for American Indian and Alaska Native Health (CAIANH) to create a project data set from existing data sources that are stored in different computer systems, to increase their capability to evaluate health services. We propose to use these data and the collaborations we developed as part of the previous project for this study. Project Goal: The project goal is to provide information that may be used to improve health outcomes among AI/AN adults with diabetes and cardiovascular disease (CVD).

Project Methods: The study population includes approximately 14,600 AI/AN adults with diabetes and CVD who use IHS services and lived in 15 project sites during FY2012. The data infrastructure includes data for FY2011–2012. Building on existing collaborations, we will create a collaborative network that includes CAIANH, IHS and tribal health program representatives, and patients to provide advice and guidance on all aspects of the study. First, we will conduct analyses to better understand the patients’ needs. These will include analyses of health status, service use, and treatment costs. Second, we will conduct a study to evaluate how use of education, case management, and advanced practice pharmacy services influences patient outcomes. The collaborative network will identify which patient outcomes should be studied. They may include health status outcomes based on clinical measures (e.g., blood pressure, glycemic and cholesterol levels) and health care quality outcomes such as preventable use of inpatient services and hospital readmissions. Finally, the collaborative network will use these findings to identify strategies that may facilitate patients’ ability to make informed choices about using education, case management, and advanced practice pharmacy services, and enhance the provision of these services to better address patients’ needs.

District of Columbia

Laura Gutermuth Anthony, PhD
CHILDREN’S RESEARCH INSTITUTE
A Community-Based Executive Function Intervention for Low-Income Children with ADHD and ASD

Background: Attention deficit hyperactivity disorder (ADHD) and autism spectrum disorders (ASD) are common, brain based, and associated with executive function (EF) problems. EF enables people to regulate their emotions, behaviors, and thinking. Poor EF interferes with medical care and is associated with problems in long-term health, school, and independent living. Poverty is linked to increased EF
problems, as well as reduced access to care for people with ADHD or ASD. This project addresses the disparity of fewer choices and poorer outcomes for low-income children with ADHD and ASD.

Objectives: This project will find out whether a new treatment, Unstuck and On Target (UOT), works better, worse, or the same as the best treatment that is available now, Contingency Behavioral Management (CBM), for low-income children with ADHD or ASD. We know that UOT improves problem-solving, EF, and self-control in middle-class children with ASD. It teaches children to use and understand specific scripts and skills to reduce impulsive, inflexible responses and increase on-task behaviors. It is the first school-based cognitive-behavioral treatment targeting EF and self-control. Being school instead of clinic based makes UOT unique, low cost, accessible, and much more likely to generalize to real-world settings. CBM emphasizes positive rewards for good behavior and is effective. To help parents and providers choose between the treatments, we will randomly assign schools to UOT or CBM treatment and measure their effectiveness to find out: (1) which works better for low-income children with ASD, UOT or CBM; (2) which works better for low-income children with ADHD, UOT or CBM; and (3) are the effects of UOT and CBM sustained over time?

Methods: We will make sure that the treatments are acceptable to families and schools by having parent and teacher input throughout the project. There will be 100 3rd–5th graders with ASD and 100 with ADHD in the study. They will come from Title 1 (low-income) schools. School staff will deliver treatments. Study staff will observe and train school staff to make sure that treatments are properly administered. We will measure change in problem solving, EF, behavior, self-control, and use of medical care by getting parent report, classroom observations, and child assessments. We will use statistical methods to make sure that we are measuring meaningful amounts of change.

Outcomes: We predict that UOT will be better than CBM for children with ASD and ADHD at improving cognitive problem solving, EF, self-control, and use of medical care, but equal to CBM at improving behavior and coping. We predict UOT’s effects will be lasting. If successful in low-income children with ASD or ADHD, UOT will be the first evidence- and community-based EF treatment for this group of school-age children that targets skills that can make them more successful in their everyday lives and communities, which is what parents have told us they care about the most.

Massachusetts

Tracy A. Battaglia, MD, MPH
BOSTON MEDICAL CENTER
Eliminating Patient-Identified Socio-Legal Barriers to Cancer Care

Differences and delays in the delivery of cancer care lead to more advanced cancer at the time of diagnosis and ultimately to more deaths for low-income and minority communities. Our group helped develop a patient-navigation model using lay health workers to address patient barriers and coordinate cancer-care services, leading to more timely care. Despite the fact that patient navigation is now a standard required by the Commission on Cancer, our research shows that delays in care persist for our low-income patients with socio-legal barriers. Socio-legal barriers are defined as social problems related to meeting life’s most basic needs that are supported by public policy or programming and thus potentially remedied through legal advocacy/action (e.g., unsafe/unstable housing, unlawful utility shutoffs, or job termination). Direct feedback from cancer patients suggests a critical need to address socio-legal barriers in order to achieve quality care for all. To expand the current impact of patient
navigation on quality care for low-income patients, we will partner with patients, key community stakeholders, and the Medical-Legal Partnership (MLP) | Boston, the founding site of a nationwide program assisting healthcare teams in addressing socio-legal barriers to health. Under direction from a Patient Advisory Group and a Community Advisory Board, we will conduct a study to compare standard navigation with an MLP navigation intervention enhanced by legal support for low-income cancer patients. Our specific aims are to measure the impact of an MLP patient navigation intervention on: 1) patient-reported outcomes: distress, needs, and satisfaction; 2) clinically relevant outcomes: receipt of timely and quality cancer care; and 3) intermediate outcomes: socio-legal barriers to cancer care. We will enroll 260 low-income, racially diverse, newly diagnosed cancer patients. Half will receive standard navigation, i.e., a lay navigator integrated into the healthcare team who provides one-on-one patient contact to address traditional system barriers to care. The other half will receive MLP navigation, i.e., standard navigation enhanced by legal support including: 1) a full socio-legal needs assessment and care plan in consultation with MLP; and 2) legal assistance for eligible urgent legal needs. We will compare each group on all outcomes. Compared to standard navigation, we expect that addressing socio-legal barriers to care with MLP navigation will improve patient-reported outcomes and lead to more timely care delivery. Because of widespread national availability of patient navigation and MLP programs at hospitals serving vulnerable patients, this intervention can be quickly replicated to improve patient experience and survival.

Paula Gardiner MPH, MD
BOSTON MEDICAL CENTER

Integrative Medicine Group Visits: A Patient-Centered Approach to Reducing Chronic Pain and Depression in a Disparate Urban Population

Background: Chronic pain affects 116 million American adults and costs up to $635 billion per year. For low-income and minority patients, treatment for chronic pain is limited and often temporary. Lack of access to health care for pain and conditions caused by pain negatively affect self-motivation, and physical and emotional well-being. Many studies now report that non-medication-based treatments work well as an addition to traditional medical care for chronic pain and related conditions. What we call a “group medical visit” is one of these methods. The integrative medicine group visit (IMGV) model uses non-medication-based ways that focus on the individual patient to reduce pain and depression, enhance a patient’s ability to communicate with his/her doctor, and improve self-motivation and social support. To reduce gaps in chronic pain management, doctors and health insurance companies need to know if IMGV is safe and works well for patients. If we show that IMGV is safe and effective, then it has great potential as a new, patient-centered, group visit model for managing chronic diseases.

Objectives: Specific Aim 1: Compare the effect of the IMGV with a primary care provider (PCP) visit for chronic pain management in reducing how much pain patients report. Question 1: Will patients with chronic pain and associated conditions report less pain compared to control (those who do not participate in the IMGV) participants? Specific Aim 2: Compare the IMGV to a PCP’s visit in its ability to reduce depression. Question 2: Will patients with chronic pain and related conditions feel less depressed than those who are not in the IMGV? Specific Aim 3: Compare the effect of the IMGV to the PCP’s visit for self-management of pain. Question 3: Will patients in the IMGV have more self-motivation to reduce pain compared to those who are not in the IMGV?

Methods: We propose a comparative effectiveness randomized controlled trial for participants (N=124) mostly from low-income, minority backgrounds with chronic pain and conditions caused by pain. We will compare two treatments: (1) an 8-week group medical visit (n=62), and (2) primary care visits that
include medications and advice (n=62). We will compare each group’s results at the start of the study, at 8 weeks, and 12 weeks later.

Projected Patient Outcomes: Based on results of earlier IMGV participants, main outcomes will be self-reported pain and depression scores (Patient Health Questionnaire-8 Depression Scale). Other results include pain self-motivation, pain medication use, lifestyle changes, and quality of life surveys.

Sonya Shin, MD, MPH
BRIGHAM AND WOMEN’S HOSPITAL

Evaluating the Navajo Community Outreach and Patient Empowerment (COPE) Program

Chronic health problems such as high blood pressure, high cholesterol, and diabetes are much more common among American Indian/Alaska Native (AI/AN) individuals, compared to all other racial/ethnic groups. Since 2009, Brigham and Women’s Hospital (BWH), the Navajo Nation Community Health Representative Program (NNCHR), and Navajo Area Indian Health Service (NAIHS) have worked together to create a program that focuses on helping people with these health problems who reside on the Navajo reservation in rural Arizona and New Mexico. COPE (Community Outreach and Patient Empowerment) promotes increased health knowledge and healthy lifestyles among individuals and families, while concurrently facilitating access to good health care services. COPE works in four areas, including (1) improving coordination between Community Health Representatives and clinic providers; (2) improving CHR teaching skills through standardized training; (3) home-based, culturally-sensitive teaching materials for patients and families; and (4) strong Community Health Representative supervision. COPE started in two of the hospitals in Navajo Nation, and will expand to six more hospitals by 2016 in a stepwise fashion. This planned expansion provides an opportunity to understand if COPE is having a positive impact on people’s lives. The goal of our research is to answer these questions: (1) Does the COPE project improve the health of patients who participate? (2) Does the COPE project empower patients, providing an increased sense of control over their lives and their health-related decisions? (3) What are the key ingredients to the success of the COPE Project? (4) How do other stakeholders (providers, community health representatives, and policy makers of health care systems) view COPE? Our proposal responds to PCORI’s “Addressing Disparities” funding announcement by promoting a culturally appropriate, systems-level approach to an extremely vulnerable population of rural American Indians, who collectively suffer from high rates of chronic disease and poor health outcomes. Our existing team includes researchers, clinical providers, and community members, and uses community-based participatory methods to ensure that our research is driven by the community’s own priorities.

New York

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ST. LUKE’S-ROOSEVELT HOSPITAL CENTER

Impact of Patient Navigators on Health Education and Quality of Life in Formerly Incarcerated Patients

Background: In January of 2008, nearly 2.3 million people were either currently or formerly incarcerated, representing an estimated 1 in every 100 adults in the United States. As of January 2011, an estimated 56,000 individuals in New York City were in custody: the majority were male (96%), on average 37 years old, black (51%), and first felony offenders (65%). Chronic medical conditions such as hypertension, cardiovascular disease, and diabetes have been reported in nearly a quarter of the prison
population with high risk of mortality during the transition period of re-entry into the community. Recognizing the need for successful re-entry and linkage into care, St. Luke’s-Roosevelt Hospital’s Center for Comprehensive Care (SLRH CCC) established the Coming Home Program (CHP) in 2006. CHP has since served more than 1400 patients with many linked to care within 1 month of release.

Objectives: The primary specific aim of the study is to examine the effectiveness of using patient navigators to improve health education impact (heiQ) and quality of life (HRQOL-14) in formerly incarcerated individuals. Secondary aims are to examine the effectiveness of using patient navigators in improving health care utilization and medical outcomes.

Methods: This is a 3-year prospective randomized comparative study of the efficacy of patient navigation on health education, health-related quality of life, health care utilization, and medical outcomes in formerly incarcerated individuals. CHP patients at SLRH CCC will be recruited and screened for the study. Individuals will be randomized to the patient-navigator intervention or to a care-as-usual control condition (automated appointment reminder phone calls). Primary outcomes will be measures of heiQ and HRQOL-14. Secondary outcomes will be measures of health care utilization and chronic medical disease management (blood pressure control, trends in HgbA1c, and CD4 and HIV RNA in HIV-infected [patients] (sic)). A total of 300 recently incarcerated individuals will be enrolled, with 150 subjects each in the intervention and usual care group.

Patient Outcomes (Projected): This proposal responds to the PCORI call for “Addressing Disparities” as it will provide evidence for strategies to link and engage formerly incarcerated individuals into care, including: (1) Do patient navigators improve the health education impact and quality of life of the individual? and (2) Do patient navigators improve patient health care utilization and self-management of chronic diseases? We hypothesize that the intervention will improve health education, health-related quality of life, adherence to clinical appointments, glycemic/blood pressure control, and virologic suppression in HIV-infected [patients] (sic). The results of this study will demonstrate interventions to eliminate health disparities in a highly marginalized group going through the transitional phase of re-entry into the community.

Renee Pekmezaris, PhD
FEINSTEIN INSTITUTE FOR MEDICAL RESEARCH
Telehealth Self-Management Program in Older Adults Living with Heart Failure in Health Disparity Communities

In the United States, racial and ethnic disparities persist, even when income, health insurance, and care access are addressed. For example, there is a greater prevalence of chronic heart failure (CHF), higher rates of hospital use, and higher death rates in blacks as compared to whites. This is due to many factors, including: reduced health care access, higher prevalence of hypertension, coronary artery disease, systolic dysfunction, myocardial infarction, and obesity. Given the magnitude of this chronic health issue, the growth of the elderly population, and increases in ethnic diversity, providers need to develop new ways of caring for those with chronic conditions living in health disparity communities. The proposed research team is presently implementing a chronic care management study (Verizon-sponsored) using telehealth self-management (TSM) that effectively combines weekly provider video-visits with daily patient self-monitoring to improve patient health. This allows for quick responses to clinical changes, keeping patients out of hospital with improved quality of life. To date, patients not receiving the intervention (controls) visit the emergency room at more than four times the rate of TSM patients. Similarly, control subjects are hospitalized at twice the rate of TSM subjects. We propose to
implement a similar randomized study with health disparity community-dwelling patients. A bilingual clinician will follow patients for 3 months after hospitalization for CHF to test this approach for the proposed health disparity population. We will obtain patient/caregiver input at multiple points during the research to make necessary adjustments to the intervention to ensure that disparity patients accept/use the system, and are satisfied. To ensure that proposed outcomes have relevance for patients, a community advisory board (CAB) of stakeholders will advise the study team throughout the study process, and will include: patients, caregivers, patient advocates, clinicians with varying expertise (a geriatrician, as well as a heart failure specialist; and a community-based telehealth nurse), a well-known payer representative, a health policy expert, and a health disparities expert. We believe that studying patient use of TSM over a 3-month period will: (1) identify cost-effective care approaches for patients living with chronic disease; (2) involve the patient in identifying and testing approaches that work for them; (3) enhance provider–patient communication; (4) teach the patient how to self-monitor and explore his/her role in self-care; (5) improve patient education about treatment options; and (6) determine how “usable” the patients feel the program is. If our goals are achieved, these strategies will result in patient-led improvements in health, satisfaction, and quality of life. Knowledge gained will further understanding of the use of telehealth programs as effective self-management tools, and can lay the groundwork for the management of other chronic conditions.

Accelerating Patient-Centered Outcomes Research and Methodological Research

California

Manisha Desai, PhD
STANFORD UNIVERSITY
The Handling of Missing Data Induced by Time-Varying Covariates in Comparative Effectiveness Research Involving HIV Patients

Advances in antiretroviral therapy (ART) have dramatically reduced mortality from HIV, enabling reclassification of HIV as a chronic condition. Numerous studies suggest that some drugs increase the risk of cardiovascular disease, although findings are inconsistent. Studies differ largely due to methodological choices, including study design, definition of exposure, and approaches to handling missing data. It is crucial to incorporate information on drug exposure and other confounders over time; patients vary their regimens over time and for reasons that may be related to their condition. Thus, in order to not implicate the wrong drug, information on changes in regimen and other factors must be considered. Including information over time complicates the analysis, however. One such complication is the introduction of missing data.

Common methods for handling missing data yield misleading descriptions of relationships. Appropriate methods for handling missing data are computationally burdensome; software does not exist for many situations, and the analyst must rely on his/her own programming skills to implement specialized techniques. Multiple imputation (MI) is a reasonably accessible and theoretically sound method for handling missing data. Available in mainstream software, its special application is required, due to the unique issues posed by time-varying covariates and outcomes that are only partially observed for those individuals who do not experience a cardiovascular event during the observation period.
We propose an extensive simulation study to evaluate commonly applied methods to this setting, to investigate the performance of standard MI in this context, and to adapt and evaluate MI methods utilized in a longitudinal setting where the outcome is fully observed to this particular setting. Based on our findings, we will develop concrete guidelines on how to use MI in the context of partially observed outcomes and time-varying covariates. We will develop user-friendly open-source software in order to optimize the use of recommended methods and to eliminate lack of software as a barrier to employing missing data methods. Finally, we will illustrate methods considered on data from the US veteran population of HIV-infected individuals using the Veterans Health Administration’s rich longitudinal Clinical Case Registry (CCR), the analysis of which motivated this proposal.

This work has the potential to greatly impact patients living with HIV. Currently, there is no consensus on which ART agents increase cardiovascular risk. Our proposal will address the implications of methodological choices for handling missing data when conducting comparative effectiveness research in the longitudinal setting. Importantly, the development of guidelines will unify analyses, enabling combination of evidence across studies in the form of meta-analyses, and accessibility to software will eliminate barriers to incorporating missing data methods into analyses.

David B. Reuben, MD
UNIVERSITY OF CALIFORNIA LOS ANGELES

Developing Patient-Centered Outcomes for Dementia: Goal Setting and Attainment

Background: Health outcomes for chronic diseases have, to date, failed to incorporate patient-centeredness. They have focused on outcomes for specific conditions (e.g., disease control), as well as mortality and general measures of quality of life, rather than reflecting individual patient goals or preferences. Dementia is a disorder where existing outcome measures have little meaning, and new measures are needed to capture the success or failure in meeting patient-centered goals. Goal attainment scaling (GAS) focuses on a patient’s individual health goals within or across a variety of dimensions (e.g., symptoms, social and role functions) and determines how well these goals are being met. However, GAS has been inadequately developed and validated.

Objectives: The proposed research will: (1) further develop GAS for dementia by partnering with patients and their families to develop a standardized set of goals, assign patient/family-determined importance to these goals, and compare this approach to other clinical outcome measures and (2) develop a methodology to re-examine and revise goals when the clinical or social situation changes, thus permitting a more precise measurement of evolving goals.

Colorado

Michael G. Kahn, MD, PhD
UNIVERSITY OF COLORADO DENVER

Building PCOR Value and Integrity with Data Quality and Transparency Standards

A growing array of patient information in electronic format is expanding the view of patient-centered outcomes research. Electronic health records, personal health records, Internet blog postings, social media sites, and wearable electronic sensors are examples of new data sources that provide a more intimate and complete view of individuals’ personal experiences with their health and the healthcare
system. However, these data sources have not been created to support clinical research. Legitimate concerns about data quality (DQ) and its impact on study validity need to be addressed. Yet, there are no guidelines for how data quality should be measured or reported. This project will develop recommendations for reporting data-quality results in a standard format that can be easily understood by both clinical investigators and nontechnical consumers, such as patients and policy makers.

We will develop an initial set of recommendations for measuring and reporting data-quality results by combining existing publications, guidelines, and practices. We will use the Internet and two face-to-face meetings to reach as many investigators, patients, and policy makers as possible for input into our recommendations.

To test if our recommendations can be implemented, we will create data-quality measures from a number of existing databases and store these data in a common format, called the Data Quality Common Data Model (DQ CDM). Using this common format, we will develop prototype data-quality reports and graphical figures that present complex data-quality results in an intuitive manner. Using a common data format will enable the tools, reports, and visualizations created in this project to be used by any other project that adopts the DQ CDM format for data-quality measures.

To validate our work, we will once again reach out to investigators, patients, and policy makers using the Internet and two face-to-face meetings. We will adjust our recommendations based on our experiences developing data-quality measures and reports and on the input we receive from our outreach efforts. We will also investigate nontechnical barriers to creating and reporting data-quality results. Possible nontechnical barriers include concerns about violating patient confidentiality, intellectual property with proprietary data, or workflow burdens.

The underlying motivation for this work is our belief that improved transparency in describing the quality of the data used to determine a research result is an important component in building trust in findings derived from these new sources of patient data.

John M. Westfall, MD, MPH
UNIVERSITY OF COLORADO DENVER
Creating Locally Relevant Health Solutions with the Appreciative Inquiry and Boot Camp Translation Method

BACKGROUND: Scientific medical discoveries often take many years to become everyday practice in healthcare facilities and communities. The resulting health recommendations often use terminology and concepts that are not easily understood by patients and community members. The University of Colorado Department of Family Medicine and our Community Advisory Councils have successfully tested two processes that may improve the translation of scientific medical discovery into language, concepts, and ultimately care that is more accessible to patients. Appreciative Inquiry (AI) engages patients to identify successful solutions to their local health concerns. Boot Camp Translation (BCT) can change patients’ views, and even beliefs, around certain medical conditions. We aim to further test and refine a combined AI/BCT method so others throughout the United States can more quickly translate health recommendations and guidelines into relevant and sustainable messages and care for diverse patients and community members.

OBJECTIVES: (1) Conduct six AI/BCT projects with rural and urban underserved Colorado communities to select priority health topics, identify factors that facilitate successful health outcomes related to the
topic, and translate evidence-based recommendations into local solutions. (2) Identify and describe the components of the AI/BCT model essential to engaging patients and community members in patient-centered research. (3) Produce a training program for patients, healthcare professionals, and academic researchers to disseminate the AI/BCT to improve patient engagement for patient-centered outcomes.

METHODS: Aim 1: Community and academic partners will recruit and convene participants for six AI/BCTs in rural and urban areas. Aim 2: We will use a specialized method (qualitative comparative analysis) to analyze data about the content and processes from each AI/BCT. With our community partners, we identify a refined and focused set of essential AI/BCT components that lead to successful translation of evidence-based recommendations. Aim 3: We will create an educational curriculum and conduct two AI/BCT trainings for community members, researchers, and health professionals. We will collect qualitative and quantitative data from participants and the training team to assess the effectiveness of the AI/BCT Training.

PATIENT OUTCOMES (PROJECTED): The patient outcome is six AI/BCTs of evidence-based guidelines into concepts and language that resonates with patients and community members in diverse urban and rural underserved communities. The primary outcome is the refined AI/BCT methodology to successfully translate health guidelines identified by patients into language that helps patients have meaningful conversations with their healthcare providers. A complete understanding of this process will allow development and dissemination of the AI/BCT methodology.

Georgia

Qi Long, PhD
EMORY UNIVERSITY
*Statistical Methods for Missing Data in Large Observational Studies*

Missing data are frequently encountered in observational studies including registries. They are particularly prevalent and often inevitable in large observational studies, such as national registries. This study is motivated by the Paul Coverdell Acute Stroke Registry, which is aimed to measure, track, and improve the quality of care and access to care for stroke patients and contains a large amount of missing data. Naive analysis without adequate handling of missing data is known to lead to biased and less robust results. While statistical methods have been developed for missing data in low-dimensional settings, methods for high-dimensional settings (e.g., large observational studies) remain underdeveloped. In particular, imputation in the presence of a large number of variables has not been systematically investigated. Furthermore, identifying important variables that are associated with patient outcomes (a procedure also known as variable selection in statistics) is of great interest in many large observational studies, which, however, is often complicated by missing data. For variable selection for imputed data, there has been limited research, and principled approaches are especially lacking for both small-scale and large-scale data.

In this study, we will develop novel multiple imputation methods for missing data in large observational studies, develop novel variable selection methods in the presence of missing data in large observational studies, develop and disseminate software packages in R that implement the proposed methods, and perform numerical studies to assess the proposed methods. The proposed methods will be applied to the Coverdell stroke registry data to assess the impact of missing data on estimation of nationally accepted quality indicators and identify patient and hospital characteristics that are associated with quality of care. Progress on the development of statistical methods will be guided by and evaluated
through the analysis of the Coverdell registry data and extensive Monte Carlo simulation studies. The proposed methods will allow investigators to obtain robust, valid results on patient outcomes that are less sensitive to missing data in analysis of large observational studies. We will also educate and train stakeholders and graduate students on statistical methods for missing data.

The proposed methods, applied to the Coverdell registry data, will allow for identification of important factors, steps, or gaps in patient care that are associated with patient outcomes and that would otherwise be missed using existing methods. The results will help improve patient care and stroke-related outcomes, including recurrence, death, and disability, and ensure that patients receive the highest quality of care currently available. The proposed methods are general and can be applied and promise similar benefits to any large observational studies with missing data, leading to more robust results and help improve patient outcomes.

Iowa

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UNIVERSITY OF IOWA

Understanding Treatment Effect Estimates When Treatment Effects Are Heterogeneous for More Than One Outcome

Helping patients make patient-centered treatment decisions requires treatment effect evidence that is aligned to the circumstances of individual patients. Because real-world treatment choices often affect several outcomes, this evidence must include relationships between treatment choice and the array of consequences that can result from this choice. Randomized, controlled trials (RCTs) are usually insufficient to supply this evidence, as RCTs describe the treatment effects for a single outcome and may not reflect the circumstances of many patients in real world. In addition, if treatment effects vary across patients, it is impractical and probably impossible to generate sufficient RCT evidence for all patients in all circumstances.

Analysis of observational data has been suggested as an alternative to find estimates of treatment effects across patient circumstances and across outcomes. Observational databases often afford large sample sizes, providing power to estimate treatment effects across patient subsets for alternative outcomes. Treatment variation in observation databases stems from patients and providers making treatment choices instead of randomized treatment assignment. If the benefits and risks associated with a treatment vary across patients, and treatment choice is based on this variation, this has real implications on the treatment effect evidence that can be ascertained from analyzing observational data. Failure to interpret evidence of treatment effects from observational data properly could lead to treatment and policy mistakes.

We propose investigating the properties of statistical estimators for use with observational data when treatment effects vary across patients for more than one outcome. First, we will use simulation modeling to assess the properties of these estimators under various relationships between treatment benefit and risk. Second, we will assess the effects of renin-angiotensin system antagonists (ACE/ARBs) on benefits and risks for patients post-stroke who also have a history of chronic kidney disease (CKD) using Medicare claims data from the Chronic Condition Warehouse. Third, we will perform chart abstraction for a sample of patients post-stroke to assess estimator assumptions, and we will interpret our estimates in light of the estimator properties we uncovered via simulation and assumption validity.
Patient-centered outcomes research (PCOR) helps patients and stakeholders “make informed healthcare decisions, allowing their voices to be heard in assessing the value of healthcare options,” but information on what patients and stakeholders value is often lacking. The values of patients and stakeholders can be identified by actively engaging them through consultation or by applying “stated-preference methods” to measure their priorities and preferences. Although both approaches are important, stated-preference methods have several advantages. They can incorporate both qualitative and quantitative methods, and they can be used with large, diverse populations, including hard-to-reach patients and stakeholders. The validity, reliability, and generalizability of the findings of stated preference studies can be assessed. Finally, the preferences of different sub-groups can be compared, and groups of individuals with similar preferences can be identified and described.

Our proposal focuses on advancing and disseminating methods for patient and community engagement in PCOR and has three objectives. First, we will demonstrate good practices for patient and community involvement in PCOR projects by applying principles of community-based participatory research (CBPR). Second, we will address several key methodological questions pertaining to the use of stated-preference methods. As outlined in the specific aims, these include identifying the best methods for identifying patient priorities (Aim 1), the best method for designing preference studies (Aim 2), and strategies for analyzing variation in preferences (Aim 3). We also seek to assess the relevance of stated-preference methods to patients and stakeholders (Aim 4). Third, we will demonstrate good practices for applying stated-preference methods by studying the priorities and preferences of patients with type 2 diabetes. Type 2 diabetes was chosen because it is a chronic disease that requires meaningful patient involvement to improve outcomes. Type 2 diabetes affects 25.8 million people (8.3%) in the United States and disproportionately affects African American and Latino populations. While type 2 diabetes provides an important case study, our research will advance approaches and methods that will be broadly generalizable to other diseases and to diverse patient and stakeholder groups.

To facilitate the dissemination of our findings, we have engaged a local community board and a national diabetes advisory panel who will be engaged via regular meetings, a quarterly newsletter, and a project website. Our dissemination plan will focus on the dissemination of lay explanations of our methods and results and document case studies of our patient/community engagement and application of stated-preference methods to type 2 diabetes.

Kay Dickersin, MA, PhD
JOHNS HOPKINS UNIVERSITY
Integrating Multiple Data Sources for Meta-analysis to Improve Patient-Centered Outcomes Research

Project Summary: Our research addresses “methods for conduct of systematic reviews of patient-centered comparative effectiveness research topics.” Systematic reviews and meta-analyses are among the most powerful comparative effectiveness research methods, because they summarize what we know from existing research to see how well a treatment works. However, the typical systematic review does not include all existing evidence, because published research tends to be “cherry-picked,” and presents a biased subset of the total sum of evidence. The PCORI Methodology Report recognizes this
problem ("reporting bias") and has called for new methods to improve the validity and efficiency of systematic reviews. An additional problem is that systematic reviews commonly focus on questions that are answerable (based on data available in published reports) but not particularly meaningful to patients.

Until recently, there has been little to remedy these problems—but new developments in the “open access” movement may be a game changer, as previously inaccessible trial data becomes available. These detailed forms of data—from individual patient data (IPD) datasets to clinical study reports (CSRs) from drug company files—are rapidly coming into the public domain for drugs and devices for all therapeutic areas, and they will be available to researchers doing comparative effectiveness research and patient-centered outcomes research.

Our objective is to explore the reliability and validity of incorporating evidence from multiple data sources (including previously inaccessible detailed trial data) for two high-impact case studies, and to produce open-access guidance about using multiple data sources, which can be added to by others, for those producing systematic reviews of patient-centered outcomes research. We also aim to examine whether detailed trial datasets for clinical trials include patient-centered outcomes (PCO) data, and, if so, discover a relatively untapped but important source of existing data for PCO research.

Anticipated Impact: Our findings will show (1) how to improve future systematic reviews by providing pragmatic and empirically grounded methodological guidance regarding the pros and cons that inevitably will exist when using multiple data sources and potentially (2) whether previously hidden trial data can provide a new, inexpensive and high-quality source of patient-centered outcomes research.

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Sensitivity Analysis Tools for Clinical Trials with Missing Data

Missing outcome data are a widespread problem in clinical trials, including trials with patient-centered outcomes. While unbiased estimates can be obtained from trials with no missing data, this is no longer true when data are missing on some patients. The essential problem is that inference about treatment effects relies on unverifiable assumptions about the nature of the mechanism that generates the missing data, leading to concerns about the validity and robustness of trial results. A recent National Research Council (NRC) Report recommends that “examining sensitivity to the assumptions about the missing data mechanism should be a mandatory component of reporting.” PCORI Methodology Standard MD-5 echoes this recommendation.

While Chapter 5 of the NRC Report outlines a general framework for conducting global sensitivity analysis (like “stress testing”), there are two major problems with existing methods that have limited their usefulness: (1) they have not been implemented in software packages, and (2) they do not adequately address non-monotone missing data patterns (i.e., patients provide data irregularly). The NRC Report recognizes “the development of software that supports coherent missing data analyses” as a “high priority” and highlights non-monotone missing data as one of the “important areas in which progress is particularly needed.”

This project aims to address these problems by (a) creating unified and coherent methods for global sensitivity analysis of clinical trials with monotone and non-monotone missing data; (b) developing free, open-source and reproducible software in SAS and R to implement the methods; (c) demonstrating the
methods and software using clinical trial data with patient-centered outcomes; and (d) disseminating the methods and software.

A website will facilitate distribution of software, documentation, datasets, case studies, videos, etc. and allow communication with our user-base. A monograph will be written and short-courses presented at major stakeholder conferences. A highly diverse and talented advisory board will help ensure that our methods and software meet the needs of stakeholders and are broadly disseminated.

With software, PCOR researchers will be able to conduct and report the results of sensitivity analyses of clinical trials with missing data. In this way, patients, their caregivers, regulators, and policy makers can more adequately judge the robustness of the inferences from these trials to assumptions about the missing data mechanism. This will lead to greater or less confidence in the study results, which may impact healthcare decisions. We expect that PCOR researchers, knowing that the results of their studies will be subjected to a “stress test,” will place greater emphasis on minimizing missing data through better trial design and conduct.

Ravi Varadhan, PhD
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Filling Two Major Gaps in the Analysis of Heterogeneity of Treatment Effects for Patient-Centered Outcomes Research

Given the same treatment, some people receive benefit, some experience harm, and others are unaffected. This project studies heterogeneity of treatment effect (HTE), which means to study how the same treatment can have different effects on different people. This issue is very important to making personal healthcare decisions, but there are major challenges to knowing when the differences in treatment effects are real. The approach used most often, subgroup analysis, can produce misleading findings.

The Bayesian approach to study HTE can reduce the chance of misleading findings by allowing the use of prior information and prior beliefs of different stakeholders about the likelihood of treatment effect varying across people. However, the Bayesian approach has been underused in HTE analysis for three main reasons: lack of understanding about the role and impact of prior information and belief, lack of guidance on how to understand the prior distribution, and lack of easy-to-use software to conduct analysis.

Another basic problem in the analysis of HTE is that it depends on the outcome scale used to study treatment effect (e.g., ratios or differences). It is not clear which outcome scale is better or whether it is useful to study HTE in terms of all scales.

The Patient-Centered Outcomes Research Institute’s (PCORI) Methodology Committee, in its recent report, identified these two issues, underutilization of Bayesian approach and choice of effect scale, as having a high priority for patient-centered outcomes research.

In this proposal, we aim to fill these two critical gaps in the analysis of HTE.
Specific Aims:
1. To encourage Bayesian analysis of HTE
   a. To develop recommendations on how to study HTE using Bayesian statistical models
   b. To develop a user-friendly, free, validated software for Bayesian methods for HTE analysis
2. To develop recommendations about the choice of treatment effect scale for the assessment of HTE in PCOR

The main products of this study will be: (i) recommendations or guidance on how to do Bayesian analysis of HTE in PCOR, (ii) software to do the Bayesian methods, (iii) recommendations or guidance on choosing appropriate treatment effect scale for HTE analysis in PCOR, and (iv) demonstration of our products using data from large comparative effectiveness trials. These products will influence current practice and lead to meaningful improvement in patient health, well-being, or quality of care.

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Development of a Causal Inference Toolkit for Patient-Centered Outcomes Research

One problem central in using real-world data such as Medicare, Medicaid, electronic health records, and clinical registry data to prove cause and effect for treatments and patient outcomes is that confounding occurs that arises because the prior treatment affects the outcome, which, in turn, affects the future treatment, etc. Commonly used statistical methods are not well equipped to appropriately handle this phenomena and tend to produce biased estimates. In this proposal, we want to introduce researchers to two cutting-edge approaches to address this problem: Inverse-probability (IP) weighting of marginal structural models and the parametric g-formula approach. However, these important tools for patient-centered outcomes research (PCOR) are not well understood, due to lack of applications to real-world data. In particular, how to tailor the use of these advanced methods to large administrative data is largely unknown. Existing computer software facilitating the use of IP weighting and g-formula has not been developed to use on such large databases. Furthermore, such software has primarily been accessible to elite statisticians in a few universities and not to general researchers or clinicians.

The goal of this research is to develop a specialized toolkit, called the causal inference (CI-Toolkit) to provide a comprehensive, practical, and accessible guide to implementing these advanced statistical techniques so researchers can ask and answer questions about cause and effect of various treatments—answers patients are most concerned about. Patients want to understand causation, not just the association, when making complicated health-related decisions. Specifically, the CI-Toolkit has three major components:

1. Structured/tailored guidelines and recommendations for clinical researchers regarding use of IP weighting and g-formula methods in large observational data.
2. A web-based, user-friendly, open-source software package that contains a set of functions and procedures to facilitate the use of IP weighting and g-formula approach.
3. Three case studies to illustrate the process of adapting guidelines and software developed in 1 and 2 to specific contexts and to show step-by-step implementation.

The clinical utility, user-friendliness, and effectiveness of the CI-Toolkit will be evaluated among multiple stakeholders so that it can be easily shared by applied researchers in need. The successful development of CI-Toolkit represents a major step towards filling a methodological gap regarding statistics that can be used to produce cause-and-effect results in the PCORI draft Methodology Report. We hope the CI-
Toolkit will promote broader use of these advanced statistical methods in future studies and provide patients and their caregivers and families with the scientifically valid information they need to make informed decisions about their health care.

Massachusetts

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BRIGHAM AND WOMEN’S HOSPITAL

Methods for Comparative Effectiveness and Safety Analyses in a High-Dimensional Covariate Space with Few Events

Background: Studies of comparative effectiveness and safety based on existing data evaluate treatments as used in routine care by diverse patient populations. These studies add to the medical evidence by answering questions that cannot be answered in randomized trials. Most studies based on electronic healthcare data use propensity score (PS) methodology, a statistical technique that works to ensure that patient outcomes are compared only in patients who are similar. Using these methods, investigators can be sure that observed differences in patient outcomes across treatment groups are not driven by underlying differences in patients but are driven by real differences in the effects of the treatments under study. Even in large studies, these methods can fail. However, in studies where few patients had the outcome event of interest, each observed event is highly influential, and potential problems are exacerbated. Studies with few events are common and highly relevant for decision makers. They include studies of new treatments, treatments for rare diseases, and treatment effects in patient subgroups. Despite the importance of these studies and their potential methodological problems, methods for studies of few events have not been studied. Refining PS methods to make better use of outcome information is key to improving PCOR studies with few events.

Objectives: The objective of this project is to evaluate and improve existing PS methods to optimize the use of outcome information in studies with few events.

Methods: Based on input from stakeholders, we will design two realistic simulations studies that produce multiple simulated datasets with few observed outcome events. We will apply each proposed analytic strategy to these simulated datasets and compare the treatment effects estimated with each strategy to the true treatment effect that was simulated. We will also apply each proposed analytic strategy to three example studies based on healthcare claims data, including: (1) a study of the cardiovascular safety of anticonvulsant medications, (2) a study of the risk of venous thromboembolism associated with antirheumatic drugs, and (3) a study of the risk of strokes in patients taking new versus traditional anticoagulants.

Patient Outcomes: This study will improve analytic strategies in studies with few observed outcome events so that investigators can quickly and accurately answer questions on the comparative effectiveness and safety of treatments, even when the relevant patient population is small, as in studies of newly marketed treatments, treatments for rare diseases, or treatment effects in subgroups. Therefore, patients and their healthcare providers will have better information for making optimal patient-centered treatment decisions.
Causal Inference for Effectiveness Research in Using Secondary Data

Patient-centered outcomes research (PCOR) can only be successful with valid analytics.

The routine operation of the US healthcare system produces an abundance of electronically stored data that capture the care of patients as it is provided in settings outside of controlled research environments. The potential for utilizing these data to inform future treatment choices and improve patient care and outcomes of all patients in the very system that generates the data is widely acknowledged. Particularly for elderly multi-morbid patients and most other vulnerable patient groups who are often excluded from randomized trials, these data, properly analyzed, are key to improving care. Further, such secondary data reflect the health outcomes as they occur in routine care, a main goal of effectiveness research.

Given these key properties of secondary data and the abundance of electronic healthcare databases covering millions of patients, it is critical to strengthen the rigor of analyses of such data. Highly innovative analytic approaches have recently been developed that (1) are solidly grounded in the principles of science and (2) are made to best fit any electronic healthcare data source.

With the involvement of top researchers, patients, doctors, and other decision makers, we plan to evaluate how much better these new methods perform. To prove this, we use several large databases of electronic medical records and health insurance records. We will test the relationship between two newer and frequently used cardiovascular therapies. We will also use computer-generated artificial data in which we can impose a known association. In such simulation studies, we can further understand and improve the performance of these new analytic methods.

The project will yield guidance on the optimal use and advantages of these new approaches for patient-centered outcomes research. It will further improve the performance of these methods in settings important to patients and their doctors.

Improving the Use of Patient Registries for Comparative Effectiveness

A key challenge in prospective registries is that patient-reported outcomes (PROs) and physicians’ ratings of effectiveness and toxicity may be collected at structured intervals that do not coincide with the starting and/or stopping of treatment. Information on treatment starts and stops may be collected only periodically, so that the precise dates of these events may not be known. We propose the following aims to address the challenges presented by these uncertainties. First, we will examine the effect of varying methodological choices for dealing with PROs and treatment exposures under different assumptions in a prospective registry of rheumatoid arthritis (RA). Since few RA treatments have been compared in head-to-head RCTs, there is little comparative effectiveness data. The investigators have access to a prospective RA patient registry (BRASS) that includes 10 years of follow-up for over 1,100 patients. In addition to semiannual patient and physician questionnaires, the investigators have access to electronic medical records; this information can serve as a reference standard. We will conduct focus groups with RA patients to understand which PROs are most important. These results will inform simulation studies to evaluate potential strategies for dealing with the methodological challenges of
prospective registries under different assumptions on various outcomes and exposures.

Second, we will test the effects of the simulation results in outcomes models using the actual data from the relevant RA prospective registry. Among patients who have failed treatment with a TNF antagonist to (a) compare the effectiveness of two different biologic treatments (abatacept versus tocilizumab) and (b) compare the risk of infection associated with abatacept versus tocilizumab. About 50% of patients with RA will eventually receive a biologic agent. Almost all patients receive a TNF antagonist as first-line biologic, but 50% of patients will not respond adequately or cannot tolerate them, requiring a biologic agent with a different mechanism of action, such as abatacept and tocilizumab. There is almost no evidence-basis to choose between agents. Data from BRASS will be analyzed to study these questions using the different assumptions tested in the simulations from Aim 1. Results of the models will be compared with other available information to determine the best analytic strategies. Finally, we will survey patients and providers about the acceptability of different intervals for reporting PROs and physician-reported outcomes. With information from Aims 1 and 2 on how different assumptions on reporting PROs and physician-rated outcomes bias analyses, we will go back to patients and providers involved in the BRASS registry to understand how the burden of reporting affects their involvement.

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Integrating Causal Inference, Evidence Synthesis, and Research Prioritization Methods

This proposal seeks to advance methods for doing comparative effectiveness research (CER) by combining causal inference (how we decide if something is beneficial or not), meta-analysis (how we combine evidence), and research prioritization (how we should decide what research to do) in the evaluation of outcomes important to patients. We examine the quality and degree of relevance of evidence that is based on observational studies (OBS) and/or randomized, controlled trials (RCTs) considering varying levels of evidence detail (published summaries of a study or having de-identified individual patient data). Randomized trials provide the most unbiased estimates of therapeutic benefit but are expensive and time-consuming. Observational studies, in contrast, can be more contemporary and estimate benefit occurring in routine “real-world” practice, but may be biased because physicians (or patients) choose particular treatments (selection bias) or because of particular patient or physician characteristics affecting treatment selection and outcome (confounding). To establish the benefits and harms of therapeutic interventions based on OBS and/or RCTs with varying levels of evidence detail, we seek to inform decision making and outcomes (survival) that matter to people, highlighting comparisons (in this case, medical therapy or coronary revascularization for coronary heart disease). Our long-term objective is to evaluate and enhance current methodologies to improve CER by (1) examining the differences in patient populations and results of RCTs and OBS analyses, (2) developing and expanding ways of combining evidence to integrate OBS and RCT data, and (3) assessing the value of reducing uncertainty in the current state of knowledge as a foundation for improved and efficient CER. We aim to answer the following questions: How do patient populations in RCT and OBS studies differ; does the estimated treatment efficacy differ among RCT and OBS populations; would various OBS-based prediction models yield the results observed in different populations? Can our statistical approaches anticipate and resolve differences between RCT and OBS analyses, and can they be used to explore subgroups of patients or individuals with a unique set of conditions? We will use individual patient-level data from RCTs and from a detailed longitudinal clinical OBS dataset to extend methodologies for (1) comparing and understanding OBS and RCT results by using state-of-the-art statistical methods, (2) combining different sources of evidence at different levels of detail, and (3) assessing the “value of information” to determine when gathering more information through additional research would be an
efficient use of societal resource. We expect these analyses to result in improved methods for conducting CER that will enhance the validity and credibility of CER.

New Hampshire

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Facilitating Patient Reported Outcome Measurement for Key Conditions

Background: Researchers have built many different surveys for patients to complete to show what a person’s health status is, in general (e.g., physical abilities, mental health, social activities), and have also developed many different surveys to show how specific diseases impact their health (e.g., knee pain). But no one has shown how to efficiently combine patient’s answers to generic and disease-specific questions to give whole-person measures of health.

Objectives: Overall goal: To use a new model for expanding generic health surveys (in this case, PROMIS) to include condition-specific questions important to patients, in order to develop tailored surveys that work well for people with two important health problems: osteoarthritis of the knee and heart failure. Specific Aims: (1) Collect patient and clinician views on the importance of existing and new survey questions to develop brief PROMIS Condition-Specific Impact Assessments (PROMIS-CSIA) for people with osteoarthritis of the knee and heart failure; (2) test PROMIS-CSIA with people with these conditions to learn if the survey does a good job of measuring a person’s generic and condition-specific health; and (3) produce “crosswalks” from PROMIS-CSIA to commonly used condition-specific surveys for osteoarthritis of the knee and heart failure to make it possible to link the scores from one to the other. This is like translating a measure made in inches and feet to a measure made in centimeters and meters. This is done to make sure that the PROMIS-CSIA surveys are seen as relevant and useful by patients who have these health problems.

Methods: Study Population: Patients with osteoarthritis of knee and heart failure. Sample Sizes: Focus groups and interviews with about 96 patients and 24 providers and about 1,200 patients completing surveys for measurement testing and calibration. Methods: Focus groups and interviews will be used to identify condition-specific health impacts important to patients but not covered by existing generic PROMIS questions, and to make expanded PROMIS-CSIA surveys for people with osteoarthritis of the knee and heart failure. Established techniques will be used to test whether or not the PROMIS-CSIA surveys are accurate and useful. Crosswalks will be built to link popular condition-specific survey results to PROMIS-CSIA results.

Projected Patient Outcomes: Study Results: We will (1) demonstrate the value of using a general model to unify generic and condition-specific surveys using easy to understand scales that can be applied to many other diseases and (2) provide accurate PROMIS-CSIA surveys for osteoarthritis of the knee and heart failure to measure disease burden from the patient’s viewpoint. Importance to Patients: Accurate whole-person assessments for osteoarthritis of the knee and heart failure patients will be available to measure impact of disease, impact of treatments, and changes in health outcomes that matter to patients, over time.
North Carolina

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RTI INTERNATIONAL
*Measuring Patient-Centered Communication for Colorectal Cancer Care and Research*

Background: Patient-centered communication (PCC) is a key part of patient-centered care. For example, it helps patients to be more satisfied with their health care, and it can improve health and quality of life. But there is a need to develop ways to measure PCC. Well-tested measures of PCC are needed to help design and evaluate health programs that aim to improve patient-centered care and communication. The National Cancer Institute saw the need to develop better ways to measure PCC and funded a project to improve understanding of PCC. The project involves developing good survey questions to ask cancer patients. However, before these survey questions can be used, they need more testing.

Objectives: This study aims to test and finalize PCC survey questions that can be used for several purposes. First, to evaluate programs that try to improve patient-centered care and communication. Second, to track PCC in large populations (such as a national survey of cancer patients) and set goals to improve PCC. And third, to help researchers study how PCC leads to different results for patients. The overall goal of the project is to develop PCC survey questions that can be used with all types of cancer patients. But this study only looks at patients with cancer of the colon or rectum, or colorectal cancer (CRC). Patients with this type of cancer often face complex care, see more than one doctor, and have to make important decisions about their treatment. This group of cancer patients is being studied because they are a lot like other cancer patients in many ways.

Methods: This study has three activities. First, it involves doing interviews with 18 CRC patients to test the draft questions. Second, it involves doing a survey with more than 1,000 CRC patients. The results of the survey will be used to see how well the questions work to measure PCC. And third, it involves creating two versions of the final PCC measures. One version is a short version of the PCC with fewer survey questions. The other is a long version with more survey questions. These two versions can be used for different purposes. The project also includes working with a group of advisors that includes stakeholders such CRC patients, researchers, doctors, and nurses. The people on this panel are well known and respected in their fields. They can also help spread the word about the PCC measures once they are completed.

Better Care Results for Patients: PCC can help patients handle the emotions that often come with finding out that they have cancer. It can also help them to understand and remember important information, to talk with different doctors, to cope with the unknown, to share in making decisions about their treatment, and to build trust with their care team. Good communication between patients and their care team can have a big effect on how patients feel about their cancer care and how satisfied they are with their care.
Texas

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Evaluating Methods to Engage Minority Patients and Caregivers as Stakeholders

For patient-centered outcomes research (PCOR) to help patients to make better healthcare decisions and to take advantage of proven healthcare advances, patients need to serve as advisors to help these studies meet community needs. However, patients and caregivers are often not included among advisors from the community (called stakeholders) for PCOR. In this project, we are studying the best ways for patients to serve as stakeholders, especially people from hard-to-reach groups or who are often not involved in research. Our project has two goals: (1) to study two methods to recruit minority (Hispanic) patients and caregivers to be stakeholders and (2) to develop a guide for researchers and the community about ways to best involve patients and caregivers as stakeholders to guide PCOR.

Our study is being held in two similar Texas counties (Frio and Karnes) with at least 50% Hispanic residents. We will compare two different ways to recruit Hispanic patients to be stakeholders, with the help of two community advisory boards (CABs) from each county. The CAB includes people who work in health care, business, or other groups who have strong ties to the county. In Frio, the CAB will help recruit people to sign up as stakeholders, and these people ask others to be stakeholders, and those people will ask others to join. This is called “respondent driven sampling” (RDS). In Karnes, the CAB will help us learn about the types of people who live in the county and what they do so that our research team can specifically ask people from different groups to be stakeholders. This is called “purposive sampling” (PS), and we believe that this is more representative of community opinions. Our goal is to recruit 65 people in each county to be stakeholders who are Hispanic, aged 40 to 75, and have chronic pain in their back or joints or give care to such a person (total 130). The topic that our stakeholders will discuss is improving care options and decision making by persons with chronic low back pain (CLBP) to improve daily function. Stakeholders will learn about the problems of treating CLBP from videotaped patient stories and a web-based program for a mobile app. In a series of group meetings, stakeholders will separately and as a group generate ideas for research to improve care for CLBP. We will evaluate and compare the RDS and PS methods of recruiting stakeholders based on: (1) staff resources/time, (2) whether the stakeholders are a diverse group, (3) stakeholder experiences, (4) mathematical grouping of their ideas on maps, and (5) ratings of each group’s ideas on importance and how practical they are from an Internet survey of 400 Hispanic adults from Texas. Based on this work, we will develop a guide that will help researchers evaluate and use the best methods to involve patients and caregivers to serve as stakeholders. This guide will allow patients to advise how PCOR can best meet their own and their community’s needs with a final goal of improving their health.

Washington

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FRED HUTCHINSON CANCER RESEARCH CENTER
A Structured Approach to Prioritizing Cancer Research Using Stakeholders and Value of Information

Background: As the US population ages, the number of cancer patients is expected to rise by 55% by 2030. The tremendous burden that these new cancers will represent creates a strong need to revamp the research funding process so that research investments have the greatest impact on this impending
public health crisis. Because public and private funding levels for cancer research have been declining, perhaps the greatest challenge facing the cancer research community today is finding ways to align research portfolios under increasingly constrained budgets to have the greatest impact on the future cancer burden.

Objectives: The first overall objective of this project is to develop a model to bring broader input from external stakeholders, including patients and consumers, into cancer clinical trials research. The second overall objective is to develop a way to estimate the potential value of information (VOI) of proposed research studies. VOI estimates are a new metric that will be added to the other aspects of research trials that are already included in the decision-making process, such as the results of the scientific peer review. VOI estimates may be useful to those who are responsible for allocating limited research funds across a wide number of study proposals.

Methods: This study will address these objectives within SWOG, a large US cancer clinical trials cooperative group. The stakeholder intervention places stakeholders in SWOG disease committees, at the time that research ideas are being developed into study summaries. The VOI intervention is aimed at SWOG’s Executive Committee members, as they are responsible for final selection of research projects in SWOG’s diverse research portfolio. VOI will utilize a novel minimal modeling approach to rapidly develop estimates of the value of research for each proposed study. Evaluation metrics include surveys, rankings of research studies, and time from initial research idea to selecting projects for funding. The research approach is a pre/post design with evaluators blinded to time of survey (pre/post).

Projected Patient Outcomes: The ultimate purpose of medical research is to improve the lives of patients. We hope that this study will allow research groups and funders to design and select research studies that maximize the relevance and impact of cancer research. We also hope our process will provide a model for stakeholder engagement and research prioritization, which can then be applied to other research organizations within and beyond cancer. We believe that making better choices about the clinical questions we choose to address, and the resources we bring to bear on those questions, is fundamental and vital to accelerating discovery of novel and effective ways to improve human health.