# PCORI Funding Announcements: Cycle II Awardees

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**PCORI Funding Announcements (PFA) Cycle II awards were approved by PCORI's Board of Governors on May 6, 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.**

# PCORI Funding Announcements: Cycle II Awardees

## I. List of Awardees by Priority Area

### *Addressing Disparities*



### *Assessment of Prevention, Diagnosis, and Treatment Options*

## *Communication and Dissemination*

## *Improving Healthcare Systems*

## II. List of Awardees by State

# List of Awardees by Priority Area/State

## Addressing Disparities

### California

**Tung Nguyen, MD**
UNIVERSITY OF CALIFORNIA SAN FRANCISCO
*A Patient-Centered Intervention to Increase Screening of Hepatitis B and C among Asian-Americans*

Liver cancer and hepatitis B are major health disparities for Asian-Americans, while hepatitis C is a rising problem. Little is known about how to improve the quality of health care Asian-Americans receive in general and for viral hepatitis in particular. Technology, specifically mobile applications, potentially can provide a flexible and efficient way to address these challenges. This proposed project seeks to develop, implement, and test an intervention to increase hepatitis B and C screening for Asian-Americans in two healthcare systems in the San Francisco Bay Area.

The research team will develop, implement, and evaluate the efficacy of an interactive, patient-centered mobile application for use on a tablet computer to increase the rate of hepatitis B and C screening among unscreened Asian-Americans age 18 and older. The team members will use their experience from a successful track record in health promotion to develop the intervention by working with patients, community leaders and advocates, clinical staff, healthcare providers, and healthcare system administrators from a county safety net system and an academic primary care practice in the San Francisco Bay Area. The mobile application will include video clips with a physician (Video Doctor) addressing patient concerns regarding hepatitis B and C screening in the patient's preferred language: English, Chinese, or Vietnamese. A patient who has not been screened for hepatitis B will answer questions about his or her characteristics and preferences using the mobile application. The mobile application will then show video clips lasting 30 to 60 seconds with messages that address the patient's responses related to hepatitis B screening and that are delivered by an actor playing a physician. Those who are born between 1945 and 1965 also receive messages about hepatitis C screening. At the end, the tablet computer will generate a provider alert to let the treating provider know what the patient's preferences are regarding testing for viral hepatitis.

Once developed, the intervention will then be used in combination with a physician panel notification and tested against physician panel notification only in a randomized controlled trial to see which approach is better in increasing the rate of hepatitis B and C screening. The team will also work with the two healthcare systems to ensure that the interventions will be practical and easily adopted after the study is over. The findings of this project will greatly expand understanding about how to use technology-based interventions to improve quality of health care in diverse patient populations.

### District of Columbia

**Kristi Graves, PhD**

GEORGETOWN UNIVERSITY
*Nueva Vida Intervention: Improving QOL in Latina Breast Cancer Survivors and Their Caregivers*

Latina cancer survivors often lack health insurance or access to uninterrupted cancer care. Many Latinas experience language/health literacy barriers, feelings of isolation, and beliefs that cancer leads to death. For these reasons, Latina breast cancer survivors often have lower quality of life (QOL) than non-Latina survivors do.

Less is known about ways to improve Latinas' QOL. Family members/friends who serve as caregivers to Latina survivors are also impacted by the diagnosis. Many caregivers feel they do not have the coping skills to support the survivor or care for themselves. They also experience family stress. We seek to conduct a randomized controlled trial with 200 people (100 survivor-caregiver pairs) to improve QOL for survivors and caregivers. Latinas diagnosed at any stage of disease or any amount of time since diagnosis can participate. Our team includes four community-based organizations (CBOs in Washington, DC; NY; CA), researchers, clinicians, patients, caregivers, and advocates. The intervention was developed by Latina survivors and has been used successfully at a CBO for more than two years.

Survivor caregiver pairs will be assigned by chance to the intervention or usual care. Latina breast cancer survivors and caregivers assigned to the intervention will attend eight group sessions, held twice a month. Each session will cover a different topic such as communication, stress management, treatment side effects, or impact of cancer on family. Topics will be chosen based on expressed survivor/caregiver needs and provider input, including medical oncologists.

Survivors and caregivers in the intervention will meet at the same time, but in separate rooms, letting each express concerns without hurting their loved one's feelings. Each survivor will identify one caregiver for study purposes, although more than one can attend. A trained facilitator will lead each group. Session topics and format will be the same for survivors and caregivers. After each session, everyone comes together to discuss the topic. No other research has tested this program. We will do so while considering the cultural/linguistic aspects important to Latinos.

We will compare the intervention to usual care, in which Latina survivors and caregivers can receive the usual services, including patient navigation (case management) or regular support groups. These services are also offered with respect to cultural values and linguistic needs.

Participants will complete surveys prior to the intervention, immediately after, and again six months later. We will measure QOL, communication, satisfaction with care, and adherence to recommended follow-up.

If successful, our intervention will improve outcomes for Latina survivors and caregivers. The potential impact of our intervention is large: we can quickly share results through outreach to 150+ local and national groups that provide care and support to tens of thousands of Latino families facing cancer.

## Georgia

**Michael Goodman, MD, MPH**
EMORY UNIVERSITY
*Comparative Risks and Benefits of Gender Reassignment Therapies*

The goal of this study is to understand the short- and long-term health issues among transgender persons who had or are planning to have a sex change treatment. Members of the transgender community and their doctors express concerns about mental and physical health problems in this group of people; however, large studies of transgender persons in the United States have not been conducted. This project is an electronic medical record based study evaluating a group of 6,500 transgender individuals, whose care is covered by the Veterans Administration (nationally) or by Kaiser Permanente (in Georgia and in Northern and Southern California). In this study, we will compare frequencies of various diseases and deaths from various causes in transgender persons and separately in those who request female-to-male and male-to-female sex change to similar measures in a sample of men and women who are not transgender and are of the same age and race. We will also compare health problems by treatment categories (e.g., no medical treatment, versus treatment with hormones only, versus hormones plus surgery). The proposed project will be carried out by a team that includes experts in chronic and infectious diseases, mental disorders, and sexual minority health issues. All of the project activities will be implemented in consultation with the study advisors who will serve as advocates for the transgender community. This will likely be the largest study of transgender persons available to date, and the first study of its kind conducted in the United States.

## Maryland

**Earl Dorsey, MD, MBA**
JOHNS HOPKINS UNIVERSITY
*Using Technology to Deliver Multi-Disciplinary Care to Individuals with Parkinson Disease in Their Homes*

**Background:** Parkinson disease is a chronic condition that affects ~500,000 Americans. Individuals diagnosed with Parkinson disease require specialized care for their condition from a neurologist. However, 40% of current Medicare beneficiaries with Parkinson disease either do not have access to or do not utilize a neurologist. Those who do not see a neurologist are ~20% more likely to fracture a hip, to be placed in a skilled nursing home facility, and to die.

Simple, inexpensive web-based video conferencing software, akin to Skype, can connect patients in their homes to neurologists at centers of excellence, which are medical institutions supported by the National Parkinson Foundation. In two previous research studies, we demonstrated that providing remote medical care (telemedicine) is feasible, comparable to in-person care, and saves patients and caregivers time and travel. However, the feasibility and value of telemedicine has not yet been demonstrated on a national level.

**Objectives:** We are conducting a national, randomized study aimed at comparing the effectiveness of using telemedicine to deliver multidisciplinary specialty care to that of a patient's usual care enhanced with educational materials. In this study, we aim to do the following:
1. To demonstrate the feasibility of using telemedicine to deliver care into the homes of individuals with Parkinson disease who have limited access to care;
2. To show that such an approach can improve quality of life;
3. To establish that the telemedicine can enhance the quality of care; and
4. To demonstrate that this remote approach to care saves time, reduces travel, and decreases caregiver burden.

**Methods:** The study will be a 12-month, 200-person randomized research study of individuals with Parkinson disease and limited access to care. Individuals will be randomized to receive care in their

homes from specialists, nurses, and other professionals at centers of excellence via web-based video conferencing or to receive their usual care, supplemented by patient-centered educational resources.

**Patient Outcomes:** Feasibility of conducting remote assessments will be determined by the percentage of patients who complete at least one telemedicine visit. Quality of life for the patient will be measured by the Parkinson Disease Questionnaire 39, and quality of care for the patient will be measured by the Patient Assessment of Care for Chronic Conditions. Time and travel will be assessed using a patient survey, and caregiver burden will be assessed using the Zarit Burden Interview. We aim to provide evidence that will help change the current model of care to one that allows anyone anywhere with a chronic condition to receive the care that he or she needs.

## Montana

**Tom Seekins, PhD**
UNIVERSITY OF MONTANA
*Rural Options at Discharge Model of Active Planning (ROADMAP)*

Our market-based medical care delivery system does not serve rural residents very (sic). For rural residents with multiple chronic conditions, getting to a hospital and then getting back home to recover exposes the gaps in service, as well as the poor treatment they get. It exposes the current urban bias. Indeed, discharge planning when one leaves the hospital to go home has been described as a "black hole," fragmented and uncoordinated. The specific aim of this research is to involve patients and rural providers in designing rural options at discharge model of active planning (ROADMAP) that improves patient outcomes and reduces disparities.

We propose to work in four counties of the Missoula Hospital Referral Region. The total population of the area is 53,116 people living on 12,342 square miles (4.3 persons per square mile). We will recruit patients seeking treatment from St. Patrick Hospital. Patients and patient advocates will help design the ROADMAP. Researchers will evaluate its effectiveness compared to standard treatment.

Incorporating patient and provider input increases the likelihood it will be used. We expect that ROADMAP will reduce re-hospitalization by 30% and improve patient recovery and return to an active life. Assuming that half of the discharges to rural communities benefit from this process, we estimate that a comprehensive rural ROADMAP could save as much as $ 2 billion annually.

## New Mexico

**Vallabh Shah, PhD**
UNIVERSITY OF NEW MEXICO HEALTH SCIS CTR
*Reducing Health Disparity in Chronic Kidney Disease in Zuni Indians*

People reach end-stage renal disease (ESRD) due to progressive chronic kidney disease (CKD). CKD is associated with increased risks for heart disease and death. The burden of CKD is increased among minority populations compared to Caucasians. The Zuni Indians are experiencing an epidemic of CKD due primarily to the high rates of obesity and diabetes. The present study, titled Home-Based Kidney Care, is designed to delay/reduce rates of ESRD and cost associated with dialysis by early interventions in CKD. We propose to assess the safety and efficacy of conducting a full-scale study to determine if

home-based care delivered by a collaborative team composed of community health workers and University of New Mexico faculty will decrease the risk for the development and the progression of CKD.

## New York

**Ellen Poleshuck, PhD**
UNIVERSITY OF ROCHESTER
*Patient Priorities and Community Context: Navigation for Disadvantaged Women with Depression*

**Background:** Socioeconomically disadvantaged (SD) women are at elevated risk for depression and poor treatment engagement and outcomes. Many use obstetric/gynecology (OB/GYN) practices as their primary resource for physical and mental health care. Yet their depression most often goes unrecognized and unaddressed within OB/GYN, and, when addressed, engagement and outcomes are poor. Patients at the greatest risk include those with multiple biomedical and psychosocial problems, trauma exposure, healthcare barriers, and experiencing a lack of empowerment over one's own health. Through our preliminary research and work with our community advisory board (CAB) consisting of patient and provider partners, we concluded many SD patients do not feel conventional depression treatments meet their needs. SD patients require interventions with outreach and support that address the problems of most concern to them.

**Objectives:** This comparative effectiveness study responds to the PCORI Addressing Disparities Funding by comparing Personalized Support for Progress (PSP) to Enhanced Screening and Referral (ESR), both recommended by our CAB. Specifically we will:
Aim 1. Determine satisfaction among patients receiving PSP and ESR.
Aim 2. Compare outcomes of PSP to ESR for depression and quality of life (QOL).
Aim 3. Identify which patients are particularly likely to benefit from PSP compared to ESR.

**Methods:** We will target 200 OB/GYN patients in a practice consisting primarily of SD patients. To be included, patients must: have current depression, be an active OB/GYN patient at the identified practice, be 18 years of age or older, and not currently receiving navigation or case management.

Clinic patients will be screened for behavioral health and social needs while waiting for their appointments. Patients who are eligible and agree will be assigned to ESR or PSP. In ESR, patients will receive a list of the concerns they identified and offered referrals as needed. In PSP, patients will meet with a navigator to prioritize their concerns, develop a personalized care plan based on these concerns, and execute the plan over four months. PSP navigators are lay people trained in outreach, care planning, advocacy, and support from the same neighborhoods as the patients.

Patients will be evaluated for change before starting the trial, immediately following the intervention, and at three and six months follow-up. Statistical analyses will determine if there are significant differences in satisfaction and in how much patients change between the two intervention groups. Interviews will also be used to assess patient satisfaction.

**Patient Outcomes (Projected):** Depression and QOL are the outcomes identified as critical by patient partners. Our long-term objective is to establish patient-centered, effective interventions that can be used in multiple contexts to improve QOL and depression for SD patients.

## North Carolina

**Kathleen Thomas, MPH, PhD**
UNIVERSITY OF NORTH CAROLINA CHAPEL HILL
*Padres Efectivos (Parent Activation): Skills Latina Mothers Use to Get Healthcare for Their Children*

**Background:** Latinos are the largest and fastest growing minority population in the United States; by 2050, two in five children will be Latino. Latino children are disproportionately affected by poverty and other factors associated with increased risk of psychiatric disorder. However, Latino children with mental health needs are half as likely to use services as children in white non-Latino families. Latino families are more likely to report problems getting services, lack of a usual source of care and a medical home, and dissatisfaction with the care they receive. Unmet mental health needs, in turn, are associated with poor outcomes over the lifespan, both economic and social. Assessing the comparative effectiveness of interventions to overcome these disparities is a major national health priority central to PCORI's mission and mandate. Activation is a promising focus of research to eliminate disparities because it reflects a set of attitudes and skills that people can use to reduce disparities. Our work provides evidence that activation in Latino adults is associated with better quality health care and outcomes and, in African-American parents, with greater child mental health service use. There is need for further research on parent-focused interventions founded on culturally meaningful concepts to address these needs and disparities.

**Objectives:** The long-term goal of this research is to improve the mental health care and outcomes of Latino children with mental health needs. The proposed study will examine the comparative effectiveness of an activation intervention for Latino families raising children with mental health needs by means of three aims:
Aim 1. To identify parent-reported facilitators of Latino child mental health service use amenable to change through parental activation.
Aim 2. To test the comparative effectiveness of an adapted psycho-educational intervention to teach activation skills adapted for Latino mothers of children with mental health needs compared to a parent support group control.
Aim 3. To enhance the intervention, based on parent input and lessons learned from the first trial, and test its comparative effectiveness with a parent support group control.

**Methods:** Qualitative and quantitative data from Latino mothers who have a child with mental health needs (N=294) will be used in a modeling approach to address these aims.

**Projected Patient Outcomes:** The proposed study will provide evidence of the comparative effectiveness of an enhanced, culturally sensitive, advocacy skills intervention to build activation among Latino families and improve service use of their children with mental health needs compared to a preliminary adaptation of an existing intervention and to a usual care discussion group. Activation skills are a promising strategy to improve child mental health service use and to bridge cultural differences.

## Pennsylvania

**Rachel Berger, MD, MPH**
UNIVERSITY OF PITTSBURGH AT PITTSBURGH
*Using the Electronic Medical Record to Improve Outcomes and Decrease Disparities in Screening for Child Physical Abuse*

**Background:** Child physical abuse is the leading cause of trauma-related death in children younger than 4 years of age in the United States. Many of the children who are injured or die as the result of physical abuse had been previously evaluated by a physician, and the diagnosis of abuse was not recognized. Failure to recognize abuse in its less severe forms can result in repeated abuse and increased morbidity and mortality.

Numerous studies demonstrate that physicians fail to consistently screen for abuse in even high-risk situations. Studies have also shown persistent and pervasive disparities in screening practices related to both patient and hospital characteristics. Recent literature demonstrates that the electronic medical record (EMR) can be used to improve screening rates in a wide variety of diseases, thereby allowing for early intervention and improved outcomes.

**Objectives:**
1. To compare compliance rates with evidence-based screening protocols for child physical abuse before and after implementation of a trigger system within the Cerner EMR using a parallel group randomized controlled trial.
2. To compare the accuracy of screening by patient race (white vs. non-white), insurance status (private vs. public insurance), and hospital-type (community vs. academic) when physicians do and do not receive screening prompts that are embedded within the EMR.

**Methods:** A five-step process will be used to meet the objectives.
1. Integrating of triggers into the EMR that allow physicians to screen for physical abuse.
2. Testing of the "trigger system" to assess the sensitivity and specificity of the trigger system and calculation baseline screening rates.
3. Performing usability evaluation to design prompts that fit into the workflow.
4. Training physicians/physician-extenders, nurses, and social workers to use the system.
5. "Go-Live"—Randomizing of patients to activate or not activate a prompt to complete evidence-based testing.

**Patient Outcome:** The primary outcome is completion of the relevant quality metric(s) for patients in each group (control vs. experimental). The secondary outcome is lack of disparity of screening by patient race, insurance type, or hospital-type. Successful completion of these objectives will demonstrate the ability to use the EMR to improve evidence-based screening for child physical abuse and decrease disparities in screening.

**Margaret Stineman, MD** UNIVERSITY OF PENNSYLVANIA
*Mrs. A and Mr. B (People with Disabilities, Primary Care Provider Quality, and Disparities)*

Who are Mrs. A and Mr. B?
Mrs. A and Mr. B are people with disabilities who cannot get good health care. Our project is by and for people with disabilities like them.

How does this project work?
Many people working on our project have disabilities. All the leaders of the project are people with disabilities. People with disabilities will work with people without disabilities as equals.

The project asks many people about their health care. Some of them will have disabilities and others will not. Some of the people are healthcare workers. What do they all think helps people with disabilities stay healthy?

Some people in our project live in city apartments. They will have meetings to talk with each other about health care. Other people use computers. They will type in the computer about health care. They will be able to see what everyone types. It will be like a meeting.

We will ask about their illnesses and disabilities. We will learn about their doctors and other caregivers. We will ask if they can get to the doctor's office. We will ask if all their caregivers talk to each other. We will ask if people can understand their doctors. We will also ask if the doctors give good information. Our project also studies information from thousands of patients who use Medicare and Medicaid. We will look to see if patients who use Medicare and Medicaid are getting the care they need. We want to know if people with disabilities get good health care or not. We will look at types of health conditions, disabilities, and beliefs about health care. We will learn about what people using Medicare or Medicaid think about their health care. We want to find out if people who get good health care stay better able to care for themselves.

We will show people with disabilities what we learn about health care. They will help us understand how well health care is working. We will ask for ideas on making health care better.

What will this project find out?
We want to know why it is hard for people with disabilities to get good health care. We want to know if people get worse care as they become more disabled. We want to find out if people with disabilities who get better health care stay healthier and are able to take care of themselves longer.

What will happen because of this project?
We want everyone to know what this project finds out. If people with disabilities make better decisions about getting health care, they will be healthier. Also, we hope to discover ways that health care can be improved for people in the United States.

# Assessment of Prevention, Diagnosis, and Treatment Options

## California

**Clete Kushida, MD, MS, PhD**
STANFORD UNIVERSITY SCHOOL OF MEDICINE
*Sustainable Methods, Algorithms, and Research Tools for Delivering Optimal Care Study (SMART DOCS)*

Sustainable Methods, Algorithms, and Research Tools for Delivering Optimal Care Study (SMART DOCS) is a project that is defined by two main goals:

1. To develop a new approach (patient-centered outcomes and coordinated-care management [PCCM]) for diagnosing and treating patients with sleep disorders by setting up access to specific and relevant information and resources for patients and healthcare providers; this information and these resources will place patients in a better position to make informed healthcare decisions and providers to assist patients in achieving what they feel are the most important goals regarding their care.

2. To conduct a research study, in which half of the patients are selected at random to test this PCCM approach for sleep medicine and the other half are selected to follow a conventional approach of diagnosis and treatment of patients, with assessment of how satisfied the patients are with these two approaches and their perception of the quality of the care they receive.

This PCCM approach for sleep medicine uses several new and refined methods, algorithms, and tools, including an Internet-based questionnaire that screens patients for sleep disorders and produces a report for the physician that predicts potential diagnoses; use of diagnostic tests that the patient can use at home rather than in the clinic or lab; utilization of nurses and technologists to assist primary care physicians (PCPs) in the screening of their patients for sleep disorders in the PCP offices; enabling nurses, technologists, PCPs, and sleep center physicians to co-manage their patients by communicating diagnosis and treatment plans, diagnostic results, objective treatment adherence, and relevant outcomes through a secure, password-protected web portal. These elements of the PCCM approach will be tested against the standard approach for managing patients with sleep disorders in a study comparing these approaches. A stakeholder team consisting of representatives from patients, patient advocacy/support groups, healthcare providers from diverse practice settings, professional organizations, and medical device and pharmaceutical manufacturers/suppliers will be used to review and provide feedback on the PCCM approach during the study, to determine the best structure and communication pathways to ensure the success and continuation of this approach and to establish plans to expand and export the model to other medical disciplines and practice settings.

**Erika Van Buren, PhD**
FAMILY SERVICE AGENCY OF SAN FRANCISCO
*Researching the Effectiveness of a Decision-Support Tool for Adult Consumers with Mental Health Needs and Their Care Managers*

The primary goal of the proposed study is to investigate the implementation and effectiveness of the M-POWR (Managing Patient-centered Outcomes through Wellness and Recovery) system in diverse urban and rural community mental health settings. The study will compare patient participation and outcomes using the M-POWR system to a usual care control condition. Four community mental health agencies will participate in the research: two in San Francisco (urban) and two in rural New Mexico. One site in each setting will serve as the M-POWR implementation site, and the other will serve as the control site. A cluster randomized trial design will be used; service sites will be randomly assigned to intervention or usual care conditions. The study design will employ repeated quantitative measures to assess change in outcomes within and across conditions over time. Qualitative methods in the form of focus group interviews will also be used to round out the information obtained about patient and provider expectations and experiences. Outcomes of interest include: patient engagement in mental health services and shared decision making; quality of life; community living skills; access to community/social services; patient understanding and use of services options; satisfaction with the provider-patient relationship; personal progress in goal attainment; and patient functionality.

The specific aims of this study are: (1) to improve patient and provider participation in shared decision making and engagement in mental health treatment, to improve [patient] personal quality of life and to improve [patient] access to community/social services; (2) to increase patient understanding of their treatment and of treatment options; to increase their personal treatment progress; and (3) to increase patient functionality and sense of perceived support for their therapeutic outcomes. It is hypothesized that use of the M-POWR will yield significant increases in the outcomes identified within each of the above research questions, and the null hypothesis of no difference between groups receiving intervention and groups receiving usual care will be tested. A generalized estimating equation (GEE) analytic approach will be employed to test comparisons across groups. The results stand to validate the use of consumer feedback and shared decision making with care managers of mental health services, thereby extending the reach and benefit of these evidence-based strategies to a much broader, more diverse patient population with chronic needs. The results also stand to validate and reinforce the use of assessment instruments that identify life domains that are meaningful for consumers, including quality of life and community living skills, in improving patient engagement and goal attainment. Finally, the results hold potential to demonstrate the savings from employing a relatively low-cost system that is expected to help consumers and providers identify and achieve service goals in less time.

**Lari Wenzel, PhD**
UNIVERSITY OF CALIFORNIA IRVINE
*Ovarian Cancer Patient-Centered Decision Aid*

**Background:** Ovarian cancer is typically diagnosed at an advanced stage and carries the highest fatality-to-case ratio of all gynecologic malignancies diagnosed in the United States. Arguably, the most effective treatment regimen to date is provided through intraperitoneal (IP) chemotherapy delivery, together with intravenous (IV) chemotherapy, which in the most recent phase III randomized trial conferred the longest median survival (65.6 months) ever reported in advanced ovarian cancer, compared to 49.7 months in the IV-only treatment arm. However, during active treatment, patients randomized to the IP

therapy group reported significantly worse quality of life (QOL) and more treatment-related toxicities.

In short, women are less likely to die if they receive an IP component to their chemotherapy, a finding that was underscored by an NCI Clinical Alert. However, there may be greater toxicity with IP treatment. The trade-off between short-term reduced QOL and longer survival is difficult for patients to understand and then incorporate meaningfully into their decision-making process. In fact, for reasons that are not entirely clear, many patients are not offered IP therapy. Patient-centered care requires that they be given the opportunity to participate in treatment decision making.

**Objectives:** The objective of this study is to develop and test a new decision aid—named Patient Centered Outcome Aid (PCOA)—that will allow patients to assimilate information and identify trade-offs about the impact of IP/IV therapy versus IV-only therapy on their QOL and survival, based on their own preferences and personal clinical characteristics, described in terms that are meaningful to them. To accomplish this, we will (1) develop the PCOA, a patient- and provider-friendly decision aid, and (2) test the effectiveness of PCOA through a randomized controlled trial (RCT).

**Methods:** We will determine, using data from completed prospective clinical trials of IP/IV chemotherapy, the pre-treatment clinical factors associated with adverse events and successful completion of IP/IV chemotherapy (Year 1). In parallel, together with stakeholders, we will develop PCOA, pilot test it, and build the web application that will integrate and interact with the medical and health status data guided by users' response to queries. We will conduct the RCT, testing the efficacy of PCOA compared to usual care (Years 2–3). Stage III ovarian cancer patients (N=130) will be randomized to either PCOA or the control arm. They will be surveyed prior to randomization, prior to chemotherapy cycle 4, and one and 12 months post treatment. Multivariable analyses of data comparing patient-reported outcomes will be conducted, and usage statistics and process measures will be analyzed (Year 3).

**Patient Outcomes:** Compared to usual care, women in the intervention arm will be more satisfied with their decision process, their treatment choice, and their relationship with the treatment team, and they will have better QOL.

## Colorado

**Jeffrey Swigris, DO, MS**
NATIONAL JEWISH HEALTH
*Patient Participation Program for Pulmonary Fibrosis (P4f): Assessing the Effects of Supplemental Oxygen*

Pulmonary fibrosis (PF) is a rare condition that causes severe shortness of breath, a nagging dry cough, profound fatigue, and early death. Although nearly every PF patient will be prescribed supplemental oxygen (O2), we actually know very little about whether or how O2 might help patients with this horrible disease. For example, we do not know what patients and prescribers expect (or can expect) PF patients to gain by using O2; whether O2 use creates durable, meaningful improvements in PF patients' daily lives; or if such putative improvements outweigh patients' perceptions of being "tied to [their] hoses [oxygen cannulas]." In summary, thousands of PF patients are prescribed O2 despite a globally insufficient understanding of whether or how it affects them. Our overall objective is to enhance understanding of O2—its utility in and adoption by PF patients—by examining how PF patients perceive it and by determining how those perceptions and several things important to patients (such as symptoms, quality of life, activity levels) change from before to after O2 is prescribed. To conduct our

research, we will create the P4f (Patient Participation Program for Pulmonary Fibrosis) to identify patients with PF who are willing to participate in research. From the P4f, and via other mechanisms (such as Internet advertisements and through patient advocacy groups such as the Pulmonary Fibrosis Foundation), we will recruit patients with PF to participate in interviews and/or a one-year study of O2. In the one-year study, we will collect data before and for one year after PF patients are prescribed daily-use supplemental oxygen and compare outcomes, including shortness of breath, quality of life, fatigue, cough, and day-to-day functioning before and after O2. Without this study, O2 prescribers and patients will linger uninformed about the effects on patients of this universally prescribed therapy, and when PF patients and their practitioners set out to make critical decisions together about O2, they will remain hamstrung by the absence of pertinent data to inform their choices. This research program embraces PCORI's mission to involve key stakeholders even in the earliest planning phases, targets PCORI's interest in addressing care for patients with rare conditions, and directly aligns with its emphasis on studies conducted in "typical clinical populations" and "considering the full range of patient-centered outcomes."

## Florida

**Susan McMillan, NP, PhD**
UNIVERSITY OF SOUTH FLORIDA
*Patient Outcomes of a Self-care Management Approach to Cancer Symptoms: A Clinical Trial*

Regardless of the treatments they undergo, cancer patients endure a variety of difficult symptoms throughout their disease experience with averages ranging from seven to 14 symptoms per patient. Cancer-related symptoms, especially when symptoms are very intense, distressing, frequent, or interfere with daily activities, can lead to depression, anxiety, and diminished quality of life. Improving cancer patients' ability to self-manage difficult symptoms has the potential to diminish patient suffering, improve quality of life, and decrease emergency room visits and associated healthcare costs. We propose to test a brief and effective intervention with patients seen in a cancer center, with the goal of teaching patients symptom management skills for self-identified symptoms of highest priority to patients. The proposed randomized clinical trial will test the efficacy of the COPE intervention with patients with symptoms of moderate to high intensity, distress, frequency, or interference with their lives as a result of their cancer.

We will include 300 patients from a large comprehensive cancer center with large numbers of outpatients with breast, colorectal, lung, and prostate cancers. After consenting, patients will be randomly assigned to one of three groups. Group III will receive the COPE intervention plus usual care. This group will receive three individual intervention sessions. During the first intervention visit at the cancer center, this group will be taught the COPE intervention in a session focusing on the patient's self-identified most bothersome symptom. Role modeling and additional instruction will be provided via video, and patients will receive the *Home Care Guide for Cancer* and a copy of the video to take home. Two subsequent visits with the patient during regularly scheduled clinic visits will reinforce the principles of COPE and the use of the home care guide, and will help patients apply this approach to managing other symptoms. In addition, they will get two phone calls encouraging them to apply COPE principles. Group II will receive three supportive visits from the research team at the cancer center and subsequent meetings during clinic visits, plus two subsequent supportive telephone calls, matched for time with the COPE group. Group I, the control group receiving usual care, will receive no additional attention from our interventionists. Data will be collected weekly for nine weeks about symptoms (intensity, frequency, interference, appraisal of distress), beliefs in their ability to self-manage

symptoms, and barriers to self-management. Quality of life, anxiety, and depression will be assessed at baseline and weeks 4, 8, and 12. We predict that the COPE group will show significant improvement in depression, anxiety, quality of life, symptom intensity, distress, frequency and interference, self-management, and perceived barriers to care, as well as decreased use of healthcare resources, such as the emergency room, compared with the two control groups.

**Brian Rivers, BS, MPH, PhD**
H. LEE MOFFITT CANCER CTR & RES INST
*Navigator Guided e-Psychoeducational Intervention for Prostate Cancer Patients and Their Caregivers*

For many patients and caregivers diagnosed with prostate cancer, there is a feeling of lack of control over what is happening. In order to feel some level of control, many patients go into information gathering mode. It is very important for many patients and their caregivers to review as much information as possible, particularly given the many different treatment options for prostate cancer. Likewise, engaging in conversations with the healthcare provider is also very important for many patients and their caregivers to obtain information prior to deciding on a treatment option. However, in spite of the importance of information, many research studies have found patients and caregivers commonly report unmet educational and psychosocial needs. In response, we developed Personalized Health Information Navigator (PHIN). The goal of PHIN is to provide personalized, patient-centered treatment and outcomes information to patients and their caregivers. PHIN is an application delivered through an Apple iPad and allows the user to interact with multiple evidenced-based information sources, such as physicians, websites, and research articles. The proposed study will assess if PHIN, delivered by a patient navigator, works better than Information Booklets (IB) from the National Cancer Institute, delivered by a patient navigator. The research questions guiding our study include:

1. What is the impact of PHIN or IB, both delivered by patient navigators, on patient and caregiver outcomes (satisfaction with decision, quality of life, and prostate knowledge) and shared decision-making practices (decision-making involvement)?
2. How does PHIN improve patient and caregiver outcomes and shared decision making?
3. Who are most and least likely to benefit from PHIN? Eligible patients and their caregivers willing to participate in this community-based study will be placed either in the PHIN group or the IB group until each group has 300 participants. Each participant will be required to complete surveys at different times in the study to determine if either the PHIN or IB impacts patient outcomes and shared decision-making practices. To evaluate the impact, we will compare survey responses between the two groups at different time points. The survey responses will also be used to determine how, why, and for whom the PHIN or IB did or did not have (sic).

## Maryland

**Elliott Haut, MD**
JOHNS HOPKINS UNIVERSITY
*Preventing Venous Thromboembolism: Empowering Patients and Enabling Patient-Centered Care via Health Information Technology*

**Background:** Venous thromboembolism (VTE), comprised of deep vein thrombosis (DVT) and/or pulmonary embolism (PE), affects as many as 600,000 patients in the United States each year. More

than 100,000 deaths annually due to PE—more than from motor vehicle accidents, breast cancer, and AIDS combined—despite the wide availability of effective preventive strategies, according to the Surgeon General.

Numerous studies have demonstrated that VTE prophylaxis is under-prescribed. However, ordering of VTE prophylaxis does not ensure its administration. A retrospective review of electronic medication administration records (eMAR) for hospitalized patients at the Johns Hopkins Hospital suggests that non-administered doses of prescribed prophylaxis may be a significant issue. Of 103,160 VTE prophylaxis doses prescribed during seven months, 12% were not administered and nearly 60% of non-administered doses were documented as patient refusal. Data have suggested that documented refusal is a predictor for future non-administration, with or without patient engagement. Approximately 20% of patients missed at least two doses of VTE prophylaxis, representing more than 80% of all missed doses. Non-administered and refused doses of prescribed pharmacologic VTE prophylaxis are important, potentially modifiable reasons for suboptimal VTE prophylaxis. These data highlight the need to develop patient-centered strategies to address these deficiencies in the delivery of care.

**Objectives:** To (1) enable patients to make informed decisions about their preventive care by improving the quality of patient-nurse communication about the harms of VTE and benefits of VTE prophylaxis; (2) empower patients to take an active role in their VTE preventive care; and (3) identify and facilitate active engagement of patients who are not administered doses of VTE prophylaxis using a real-time escalating alert.

**Methods:** A multi-tiered, multidisciplinary approach will be taken to improve VTE administration rates for hospitalized patients. Patient-led, health educator–moderated training sessions for nurses will promote improved communication about VTE with patients. Informational materials developed with partnering patient stakeholders, including self-monitoring tools, will be provided to all hospitalized patients as a part of the admission package, empowering patients to take an active role in VTE prevention. When a patient initially refuses one dose of VTE prophylaxis, an eMAR-generated electronic alert (e.g., e-mail, pager, smartphone) will notify the health educator to determine how VTE prevention was communicated to the patient and, if appropriate, engage the patient in patient-centered education regarding the importance of VTE prophylaxis. Finally, if the patient continues to refuse prophylaxis, the physician will present alternatives to guideline-recommended prophylaxis to the patient to facilitate shared decision making that will better account for individual patient preferences.

## Massachusetts

**Richard Gliklich, MD**
OUTCOME
*Comparing Patient-Centered Outcomes after Treatment for Uterine Fibroids*

**Background:** Uterine fibroids are common, benign tumors that can cause severe symptoms in women of childbearing age. They affect African-American women more than women of other races. More than $4 billion is spent each year treating fibroids in the United States. Even though fibroids are common and can cause severe symptoms, there is little scientific evidence about which treatment options are better than others are. Treatment options include hysterectomy, which is the surgical removal of the uterus; other types of surgical procedures that do not involve removing the uterus; and medications. In 2010, we asked many different types of stakeholders to prioritize research questions related to the treatment of fibroids. These questions provide the basis for our proposed study.

**Objectives:** Through a process that incorporates the perspectives of many stakeholders, we will focus on three objectives:
1. We will estimate how long treatment effects (that is, relief from symptoms) last for treatments other than hysterectomy. We will estimate this by measuring how many subsequent procedures women have after the first treatment and examining whether this is affected by the types of symptoms a woman is experiencing, her demographic characteristics, or the severity of her disease.
2. We will estimate how long treatment effects last for all treatments (including hysterectomy), as measured by the return of symptoms after the initial treatment. Again, we will look at whether this is affected by symptom type, patient characteristics, and severity of disease.
3. We will examine how having stakeholders involved in the research process affects the study results and interpretation.

**Methods:** We will use two existing data sets for this study. First, we will analyze a database of electronic medical records that are linked to insurance data. More than 13,000 patients in this database have a diagnosis of uterine fibroids. For these patients, we will be able to analyze patient demographics, diagnoses and symptoms, treatments, and laboratory results. Second, we analyze electronic medical records from a network of health systems. More than 20,000 women in this database have a diagnosis of uterine fibroids. For these patients, we will be able to examine records from hospitals as well as other settings, such as clinics or physician offices. We will use appropriate biostatistical methods for these analyses. To examine the impact of stakeholder participation, we will analyze the data using the researchers' original plans, analyze the data again using a plan modified with stakeholder suggestions, and compare the results. We will engage stakeholders throughout the study to help us refine the research plan and decide how to communicate the results.

**Projected Patient Outcomes:** The main outcome will be length of treatment effect after various treatments for fibroids. We selected this outcome based on a prioritization process that incorporated the perspectives of multiple stakeholders.

**Rinaa Punglia, MD, MPH**
DANA-FARBER CANCER INSTITUTE
*Impact of Radiation Therapy on Breast Conservation in DCIS*

With greater use of screening mammography, the incidence of pre-invasive breast carcinoma or ductal carcinoma in situ (DCIS) has increased by 560% over the past 35 years. By the year 2020, more than one million women will be living with a DCIS diagnosis. Despite the large number of women affected, the optimal treatment strategy for DCIS is not known. DCIS does not spread to the lymph nodes or other sites in the body, but if left untreated, it can progress to invasive breast cancer. Mastectomy, or removal of the breast, had been the standard of care for treatment of DCIS and is curative in almost all patients; however, it is an extreme surgery for a diagnosis that may not progress to invasive breast cancer.

Currently, over 70% of women with DCIS receive breast-conserving surgery, but they then have a risk of being diagnosed with a second cancer in the same breast. Some women with DCIS undergo radiation therapy delivered to the breast after breast-conserving surgery to decrease the risk of another diagnosis in the affected breast. But, if a woman undergoes radiation for DCIS and then has a second diagnosis in the same breast, she will need a mastectomy because radiation can only be given once due to limits of normal tissue tolerance. Therefore, radiation therapy may also reduce the long-term likelihood of breast conservation. The important outcome of lifetime breast conservation with or without radiation has not been studied, resulting in patients and physicians choosing treatment without complete information

about expected treatment outcomes. Across the United States, the use of radiation therapy for DCIS varies by region of the country. Instead, the choice to add radiation should vary according to the values and preferences of each DCIS patient. To enable informed decision making by DCIS patients, we seek to provide individualized data about outcomes following breast-conserving surgery with and without radiation therapy—in terms of recurrence, disease-free and overall survival, and likelihood of long-term breast conservation. To do this, we will study patient-specific risk factors for having a new breast cancer after DCIS and the likelihood of breast-conserving surgery versus mastectomy if a woman has a second cancer diagnosis after DCIS and has not received radiation upfront, using four large data sets. The results of these analyses will then be combined into a model that will generate individually tailored predictions of the long-term likelihood of breast conservation with and without radiation therapy for DCIS. So that patients and physicians can access the results of the model, we will then design a web-based decision aid to present the trade-offs and compare expected treatment outcomes with and without radiation therapy. This decision aid will enable patients and their physicians to choose the treatment most consonant with patient preferences, and it will improve both the quality of decision making and quality of life for patients diagnosed with DCIS.

## Minnesota

**Erik Hess, MD, MS**
MAYO CLINIC
*Shared Decision Making in Parents of Children with Head Trauma: Head CT Choice*

**Background:** In the United States, more than 650,000 children visit emergency departments (EDs) annually with "minor head trauma" (Glasgow Coma Scale scores of 14–15). Among these, up to 50% undergo head computed tomography (CT), though fewer than 10% have traumatic brain injury (TBI) on CT and only 0.1% requires surgical intervention.

Over the past decade, use of CT for minor head trauma has more than tripled. Radiation from CT increases cancer risk, especially in children who are more radiosensitive than adults are. We derived and validated two clinical prediction rules (one for children under 2 years of age and one for those 2–18) for TBI in more than 42,000 children from 25 EDs in the Pediatric Emergency Care Applied Research Network (PECARN). The rules accurately quantify the risk of TBI in children with minor head trauma.

We integrated these risk estimates into a decision aid, Head CT Choice, to assist parents of children with minor head trauma in making risk-informed decisions about whether to obtain a head CT or to actively observe their child after ED discharge. Head CT Choice communicates the risk of TBI and the future risk of cancer associated with radiation exposure, informs parents of the advantages and disadvantages of management options, and aligns parents' choice with values and preferences, thus promoting shared decision making and enhancing the quality of care.

**Objectives:** Our long-term goal is to promote evidence-based, patient-centered evaluation in the acute setting to tailor testing more closely to disease risk. To, as PCORI specifies, "compare the use of risk stratification tools with usual clinical approaches to treatment selection or administration," we propose the following aims:
1. Give parents a voice and incorporate the perspectives of multiple stakeholders by refining the Head CT Choice decision aid.
Hypothesis: Engaging stakeholders in an evidence-based, iterative participatory action research process will produce a refined decision aid that is ready for testing.

2. Test if the decision aid improves validated patient-centered outcome measures and safely decreases healthcare utilization.
Hypothesis: The intervention will significantly increase parents' knowledge, engagement, and satisfaction; decrease the rate of head CT; and decrease 30-day total healthcare utilization with no increase in adverse events.

**Methods:** Patients and other PCOR stakeholders have been and will be engaged throughout the entire research process. We will refine the decision aid and test it in a pragmatic patient-level parallel randomized trial. Parents randomized to intervention will engage with their clinician in shared decision making, and parents randomized to control will receive usual care.

**Expected Impact:** If the effectiveness of Head CT Choice is demonstrated in multiple centers, it will dramatically improve the experience of care for millions of parents and children and safely decrease resource use.

## Nebraska

**KM Islam, MBBS, PhD**
UNIVERSITY OF NEBRASKA MEDICAL CENTER
*Patient-Defined Treatment Success and Preferences in Stage IV Lung Cancer Patients*

Lung cancer most often affects older persons. Patients usually present with an advanced stage of the disease when a cure is unlikely, and chemotherapy is the mainstay of treatment. Many drugs are available for treatment of late-stage lung cancer; these drugs have similar effectiveness but have a different frequency of side effects. Thus, side effects are important when choosing the best treatment for these patients. However, patients receive little guidance on how to communicate drug/side effect preferences to their physicians during treatment planning. The College of Public Health of the University of Nebraska Medical Center is collaborating with four cancer centers and the Nebraska Cancer Coalition to apply for a PCORI grant aimed at facilitating treatment choices for patients with advanced lung cancer and their physicians.

We will compare treatment preferences among different patient groups when available drugs offer the same survival but different side effects. We will then communicate patients' preferences to physicians to assess changes in clinical practice. Participants will be patients diagnosed with late-stage lung cancer and living in rural or urban communities served by the Callahan Cancer Center in North Platte, NE; Saint Francis Cancer Center in Grand Island, NE; the Nebraska Cancer Center, University of Nebraska Medical Center, in Omaha, NE; and Avera McKennan and University Health System in Sioux Falls, SD.

The research will last three years and will provide valuable treatment guidance for lung cancer patients and their treating physicians; results and recommendations will be published and also presented at state and national cancer meetings. Stakeholders, including patients, physicians, and the cancer coalition, will be involved in the planning and execution of each step of the study. In the future, a similar approach could then be tested and applied to patients affected by other diseases and facing a similar need to integrate their preferences in treatment decisions.

## New Mexico

**Annette Crisanti, PhD**
UNIVERSITY OF NEW MEXICO HEALTH SCIS CTR
*Patient-Centered Trauma Treatment for PTSD and Substance Abuse: Is It an Effective Treatment Option?*

Patient-Centered Trauma Treatment (i.e., treatment delivered by peers with lived-experience) has the potential to increase access to trauma treatment in underserved communities. This could positively impact the lives of millions of people, as 70% of adults in the United States have experienced a traumatic event.

The consequences of trauma can be devastating and far-reaching, including chronic and comorbid physical and mental health problems, for example, post-traumatic stress disorder (PTSD) and substance use disorders (SUDs). Seeking Safety (SS) is the most effective evidence-based treatment for co-occurring trauma, PTSD, and SUDs. While no specific degree or experience level is required to conduct SS, all of the evidence comes from studies that have used trained clinicians to implement the treatment, including social workers, psychologists, and psychiatrists. However, these research findings do not generalize to underserved communities that lack mental health professionals. Innovative approaches to treatment, such as peer-delivered services, are required to meet the demand for care in underserved areas. While the benefits of peer-delivered services have been well documented in many areas, the value of peers in the provision of trauma treatment is unknown. There are many reasons why peer-delivered trauma treatment would be effective, including the strong therapist-patient bond (i.e., therapeutic alliance; TA), which is an important predictor of treatment outcome and a typical result of peer-patient relationships.

The long-term objective of our study is to increase access to trauma treatment in underserved communities by providing new knowledge for patients, caregivers, or clinicians regarding effective trauma treatment options. We plan to do three things: (1) determine the effectiveness of peer-led SS (PL-SS) groups compared to clinician-led SS (CL-SS) groups in decreasing substance use and PTSD symptoms and improving coping skills, overall mental health and physical health; (2) compare levels of TA among PL-SS and CL-SS groups and examine the impact of TA on outcomes; and (3) determine if the standard Seeking Safety Instructor Training (SS-IT) is adequate for peers.

We will recruit 288 participants from a peer-run wellness center in Espanola, New Mexico. Participants will be racially/ethnically diverse and will include both males and females with trauma, PTSD, and SUDs. Patients will be randomly assigned to PL-SS groups or CL-SS groups. A research assistant will meet with study participants three times to collect outcome data. We will also meet with patients in groups to talk about overall satisfaction with treatment. Personal interviews will be conducted with SS Peer Group Leaders who complete the PL-SS-IT. Data will be analyzed and summarized.

Peer-led SS will allow patients in communities with few or no mental health care workers the option to access effective treatment for trauma that will reduce their substance use and improve their mental and physical health.

## North Carolina

**Katrina Donahue, MD, MPH**
UNIVERSITY OF NORTH CAROLINA CHAPEL HILL
*Effect of Glucose Monitoring on Patient and Provider Outcomes in Non-Insulin Treated Diabetes*

For the nearly 75% of patients living with type 2 diabetes (T2DM) who do not use insulin, decisions regarding self-monitoring of blood glucose (SMBG) is unclear. SMBG testing is a resource-intensive activity without firmly established patient benefits. While SMBG holds great promise for sparking favorable behavioral change, the potential for no benefit or even patient harm must be acknowledged.

Possible negative effects on patient quality of life must be more closely examined along with the speculative benefits of SMBG in non-insulin–treated T2DM. Among studies examining this issue, a general consensus is evolving; while SMBG may or may not be clinically useful, its value can only be fully appreciated when the SMBG results are provided to patients in a useful manner. The overarching goal of this proposal is to assess the impact of three different SMBG testing approaches on patient-centered outcomes in patients with non-insulin–treated T2DM within the real-world, clinic setting. In this pragmatic trial, 450 patients will be randomized to one of the following three SMBG testing regimens: (1) no SMBG testing; (2) once daily SMBG testing with standard patient feedback consisting of glucose values being immediately reported to the patient through the glucose meter; and (3) once daily SMBG testing with enhanced patient feedback consisting of glucose values being immediately reported to the patient, plus automated, tailored feedback messaging following each SMBG testing event delivered to the patient through the glucose meter. The first two arms represent common SMBG testing approaches currently being used. The third arm is an enhanced, patient-centered approach to SMBG testing. SMBG values will be evaluated at routine clinic visits over 52 weeks.

The following primary outcomes will be assessed: quality of life and glycemic control. We will assess differences across the following pre-specified subgroups: (1) prior experience using SMBG; (2) duration of T2DM; (3) baseline degree of glycemic control; (4) anti-hyperglycemic treatment; (5) age; (6) race/ethnicity; and (7) health literacy.

Secondary outcomes will include diabetes-related treatment satisfaction, diabetes self-efficacy, diabetes distress, self-care, hypoglycemia frequency, and patient-provider communication. Using qualitative methods, we will assess healthcare providers' attitudes and experiences with using the automated system to deliver SMBG results within the real-world, busy clinic setting. Given the time- and resource-intensive nature of SMBG and the rapidly growing prevalence of T2DM, the practice of medicine is overdue for a pragmatic assessment of the utility of SMBG in everyday, routine clinical practice that evaluates outcomes of central importance to patients living with the disease.

## Ohio

**Katherine Deans, MD**
RESEARCH INST NATIONWIDE CHILDREN'S HOSP
*Randomized Controlled Trial of a Patient Activation Tool in Pediatric Appendicitis*

**Background:** Patient activation tools (PAT) may improve patient-centered outcomes in emergency care. Emergency surgical procedures present stressful and difficult decisions. This is especially true in children, for whom caregivers must make difficult decisions quickly about the care of their child. Methods that

can provide information about treatment choices and empower families to be involved in decision making may allow them to be more confident in their decision making (decision self-efficacy) and be happier with their care (satisfaction). We believe that the PAT described in this proposal can improve decision self-efficacy and satisfaction and may improve medical outcomes in children with appendicitis and their caregivers (patient-caregiver dyads).

**Objective:** To test if adding an interactive PAT to the routine surgical consultation process will improve outcomes related to decision making and satisfaction with care.

**Methods:** Both the PAT and our proposed study were created in collaboration with a panel of stakeholders including patients, parents, doctors, nurses, and insurers. The computer-based interactive PAT informs patients and caregivers about appendicitis, helps them be more active in guiding their care, and helps them make a treatment decision that is best for them. Study subjects include caregivers and their children age 7–17 years diagnosed with early appendicitis. Each patient-caregiver dyad will be assigned to either standard surgical consultation or consultation plus the PAT. Each patient-caregiver dyad will then choose to treat the appendicitis with either surgery or antibiotics alone. The key outcomes we will measure include decision self-efficacy and satisfaction with care. We will measure other outcomes related to the decision-making process, including their understanding about the risks and benefits of each treatment option (knowledge), if they are comfortable with their decision (decisional conflict), or regret their decision (decision regret). We will also measure the number of days that the patient and caregiver spend away from normal activities (disability days: days in the hospital, days away from school or work, and days away from sports or other activities); quality of life; and medical complications such as infections, recurrence of appendicitis, and readmissions to the hospital. We will include 200 patients in this study (100 patients in each group).

**Projected Patient Outcomes:** The outcomes in this study represent important parts of the healthcare process that affect the lives of patients and their caregivers. Compared to patient-caregiver dyads receiving standard surgical consultation, we believe that those receiving the PAT will have:
• Improved decision self-efficacy, knowledge, satisfaction with care, and quality of life and have decreased decisional conflict and decision regret.
• Similar disability days, length of stay, readmissions, and medical complications.

## Pennsylvania

**Ravishankar Jayadevappa, PhD**
UNIVERSITY OF PENNSYLVANIA
*Treatment Preference and Patient Centered Prostate Cancer*

Prostate cancer is a slow progressing and debilitating disorder that substantially limits the quality and quantity of life for millions of Americans. Due to uncertainties in outcomes, it is important that patients engage in informed decision making to choose the “optimal treatment.” Patient-centered care that encompasses informed decision making can improve treatment choice and quality of care. Thus, assessing patient treatment preferences is critical for developing an effective decision support system.

**Objectives:** To test the comparative effectiveness of a conjoint analysis intervention compared to usual care and identify preferred attributes of alternative prostate cancer treatments (including active surveillance) that will aid in designing ways to help patients weigh treatment attributes. We employ values markers, to represent clusters of values for particular aspects of treatments that are valued most

by individual patients. We will test if the concordance between values markers and treatment received is predictive of objective outcomes (cancer recurrence and complications) and subjective outcomes (health-related quality of life, psychological well-being, satisfaction with decision, and satisfaction with care). Study hypothesis is that a conjoint task may have an effect on treatment choice, and prostate cancer patients whose treatment is more concordant with their values markers will have improved outcomes.

**Study Design:** We propose a two-phase study design. In Phase 1, to identify the attributes, we will conduct six focus groups of prostate cancer patients and two focus groups with physicians who treat prostate cancer. Next, we will develop a conjoint task instrument using the attributes identified in focus groups and pilot test it. This task requires the patients to trade off various treatments by assessing relative importance of particular treatment attributes. Results of Phase 1 will yield a conjoint analysis instrument to identify profiles of treatment values markers and will be used in Phase 2 to determine common values markers, or profiles of treatment attributes prostate cancer patients value most.

Phase 2 consists of a stratified (UPHS, Fox Chase, and PVAMC) randomized controlled trial study of 720 men with localized prostate cancer, aged =45 and randomized to either the conjoint task intervention group or usual care control group, and followed for up to 24 months for objective and subjective outcomes. We will analyze the effect of conjoint task intervention, association between preferences (developed using the values markers obtained at baseline, pretreatment), treatment, and objective and subjective outcomes. The conjoint task we develop and test here can lead to a values-based patient-centered decision aid and help tailor treatment decision making to the values of prostate cancer patients. This will ultimately improve clinical decision making, improve clinical policy process, enhance patient-centered care, and improve prostate cancer outcomes.

**Lakshmanan Krishnamurti, MD**
UNIVERSITY OF PITTSBURGH AT PITTSBURGH
*Comparative Effectiveness of a Decision Aid for Therapeutic Options in Sickle Cell Disease*

**Background:** Sickle cell disease (SCD) is an inherited disorder with chronic multisystem manifestations affecting 100,000 individuals in the United States, largely of minority origin, and associated with substantial morbidity, premature mortality, individual suffering, healthcare costs, and loss of productivity. Disease modifying therapies such as hydroxyurea, blood transfusion, and bone marrow transplantation, while known to be efficacious in reducing complications such as pain crisis and acute chest syndrome and improving survival, are vastly underutilized and poorly adhered to.

**Hypothesis:** We hypothesize that a web-based decision aid individualized to patient characteristics can improve knowledge and achieve more accurate perception of risks and benefits of treatment options and is associated with lower decisional conflict than standard care. To test our hypothesis, we propose the following specific aims:

Aim 1: Develop a health literacy–sensitive, web-based, decision aid to help patients with sickle cell disease make informed choices about treatment options such as hydroxyurea, chronic blood transfusion, bone marrow transplantation, and standard comprehensive care.
Aim 2: To estimate in a randomized clinical trial the effectiveness of the decision aid tailored to individual patient characteristics on patient knowledge, patient involvement in decision making, and decision-making quality, when compared with usual care.

**Methods:** In active engagement with stakeholder groups in every stage of the study, we will develop, field test, and validate a web-based decision aid that will provide accurate information on treatment options and their risks and benefits, tailored to the individual characteristics and in congruence with their values and preferences. The development team will include a physician, behavioral scientist, and parent of a child with sickle cell disease. A consumer advisory committee will review development of the instrument on a regular basis. Patients will be recruited for qualitative studies for determining the decisional needs and for doing alpha and beta testing to determine comprehensibility, usability, and acceptability. Physicians will be asked to participate in studies on usability of the instrument. The finalized instrument will then be used in a randomized controlled trial of patients making a decision about therapies for sickle cell disease; they will be randomized to receive the decision aid or standard of usual care. The impact of the decisional aid on patient knowledge, involvement in the decision process and the decisional conflict and quality will be evaluated using validated instruments. The instruments will be administered prior to the use of the decision aid, soon after the conversation with their physician and at three months following the consultation. At that point, we will also determine their uptake and adherence with treatments discussed.

**James Lewis, MD, MS**
UNIVERSITY OF PENNSYLVANIA
*Patient Valued Comparative Effectiveness of Corticosteroids versus Anti-TNF alpha Therapy for Inflammatory Bowel Disease*

There is no cure for the inflammatory bowel diseases (IBD)—Crohn's disease (CD) and ulcerative colitis (UC). Intermittent use of corticosteroids (CS) was the main treatment strategy for acute exacerbations of IBD until the introduction of biologic therapies targeting tumor necrosis factor alpha (anti-TNF). There are very limited data directly comparing the safety and effectiveness of CS and anti-TNF therapy, particularly among elderly and disabled patients. A single, small clinical trial in a predominantly younger population demonstrated a therapeutic advantage of anti-TNF therapy plus azathioprine versus CS in the first year. However, fear of complications of chronic immunosuppression often deters patients from pursuing anti-TNF therapies.

In this study, we will test the hypothesis that the greater efficacy of anti-TNF therapy results in reduced need for bowel resection surgery, fewer serious infections, and reduced short-term mortality risks and, therefore, has a more favorable benefit-to-harm profile than CS for IBD. In Aim 1, we will quantify patients' preferences for relevant treatment outcomes by implementing a discrete choice experiment. Participants will choose between two medical treatment options with various attributes (e.g., the risk of serious infection, treatment failure requiring surgery, death, etc.). Using the methods of conjoint analysis, we will compute mean preference weights for each of these attributes.

In Aim 2, we will conduct a comparative effectiveness study among Medicare Parts A, B, and D beneficiaries with IBD. We will compare the incidence of severe infection, bowel resection surgery, and death among new users of anti-TNF therapies and CS. We will compute propensity scores (PS) to describe the propensity for treatment with anti-TNF compared to CS, and we will match CS- and anti-TNF–treated patients on the PS. Cox regression will be employed to assess the hazard ratio for each of the outcomes.

In Aim 3, we will combine the results from Aims 1 and 2 to compute the relative net benefit of the two treatment strategies after accounting for patient preferences for each outcome. For each patient, we will compute a preference-weighted value for each month of follow-up using an initial treatment carried forward model that allows patients to switch therapies if the first is not effective. We will retain the matching on PS from Aim 2, and the sum of these values will be compared between the groups. As a complementary approach, we will also develop a discrete event simulation model that compares the two treatment strategies in terms of benefits and harms, using patient preference data from Aim 1 and drawing transition probabilities from Aim 2.

This study will use novel methodology to provide a critically needed assessment of the overall risks and benefits of these two treatment strategies, informed by quantitative patient assessments of therapeutic trade-offs. The results should lead to improved outcomes for patients with IBD.

## Tennessee

**David Penson, MD, MPH**
VANDERBILT UNIVERSITY
*Generating Critical Patient-Centered Information for Decision Making in Localized Prostate Cancer*

Prostate cancer (PCa) is the most common solid tumor and the second leading cause of cancer death among American men. While surgery, radiation, and observation have all been deemed appropriate therapies for localized PCa, many questions remain unanswered. In fact, AHRQ's 2008 evidence report on the comparative effectiveness of therapies for localized PCa concluded that "no one therapy can be considered the preferred treatment for localized PCa." The report called for high-quality, prospective cohort studies that identify men at the time of diagnosis and collect comprehensive patient, tumor, and treatment selection characteristics in an effort to generate critical patient-centered information to aid in decision making in localized disease.

The proposed study will generate the critical information that patients need to make decisions about PCa treatment that reflect their personal preferences and values. Using an existing population-based study of 3,691 men diagnosed with PCa in 2011, we will collect patient-reported outcomes three years after their diagnosis. The study participants underwent a variety of treatments, including open and robotic surgery, modern radiation techniques, and active surveillance. We have already collected patient-reported outcomes and medical record information at baseline, six, and 12 months after diagnosis. By collecting three-year outcomes, the study will determine which PCa treatments "work best; in which patients; and in whose hands."

We will specifically compare the effectiveness of contemporary surgical and radiation techniques for localized PCa in terms of the six-, 12-, and 36-month patient-reported outcomes and quality of life, side effects, cancer control, and treatment complications. Prior studies have identified these outcomes as the ones patients consider when choosing therapy. We will also identify subgroups of patients who respond better to certain treatments than others, effectively tailoring the results of the study to the individual patient. Finally, we will explore how the effectiveness of therapy is influenced by the quality of care delivered, in hopes of aiding patients not only in choosing which treatment to receive, but which facility/provider they should use to deliver their care.

## Washington

**Janna Friedly, MD**
UNIVERSITY OF WASHINGTON
*Long Term Outcomes of Lumbar Epidural Steroid Injections for Spinal Stenosis*

Spinal stenosis is one of the most common causes of low back pain among older adults and can result in significant disability. Despite this, we still do not know which treatments for spinal stenosis are most effective, nor do we know what outcomes are most important to these older adults. We propose to answer a number of questions about spinal stenosis by interviewing a diverse group of older adults with spinal stenosis. We are currently conducting a clinical trial of epidural steroid injections (ESI) for spinal stenosis (LESS trial), and we propose to interview the patients who have completed the trial, as well as other older adults with spinal stenosis, to help us understand what is important to them in terms of outcomes. We have successfully recruited more than 300 subjects in 16 US sites (we expect to reach our goal of 400 by 5/13). We seek to answer the following key questions.

Aim 1: Outcomes of Importance to Patients
1a. What are the most important treatment outcomes to older adults with spinal stenosis?
1b. Do outcome measures for pain and function commonly used in back pain trials adequately reflect what is most important to older adult patients with spinal stenosis?
1c. What is the minimum improvement from ESI that older adults with spinal stenosis consider worthwhile?

Aim 2: Individualized Decision Aids
2a. Do decision aids tailored to older adults with spinal stenosis change patient decision making regarding subsequent treatments?
2b. Do patients respond differently at subsequent outcome assessment time-points after receiving tailored decision aids that contain their own individual outcome data from prior treatments?

Aim 3: Long-Term Outcomes
3a. What are the long-term risks and benefits of ESI for spinal stenosis?
3b. Which subgroups of patients are most likely to benefit long-term from ESI for spinal stenosis?

We propose to answer these important questions using several strategies. To identify and prioritize outcomes important to patients, we will conduct focus groups with a diverse group of older adults with spinal stenosis. We will provide LESS patients with an individualized report of their outcomes and treatment(s) they received. We will randomly give half of the patients these reports before the interview and half after the study ends. We will interview participants to see how decision aids influence decision making about future treatments and change outcomes. In Aim 3, we will determine what patient and disease characteristics predict long-term outcomes identified and confirmed in Aims 1 and 2 to be most important to patients.

Given the diverse patient population in LESS and the extensive data that we will have on baseline characteristics, as well as long-term outcomes of importance to patients, we will be able to provide concrete information back to patients and providers to help them make decisions based on a patient's unique combination of disease and patient characteristics, as well as their desired outcome and values.

**Sarah Westcott McCoy, PhD**

UNIVERSITY OF WASHINGTON

*Developmental Trajectories of Impairments, Health, and Participation of Children with Cerebral Palsy*

**Background:** Families of children with cerebral palsy (CP) identify that maximizing motor abilities; preventing problems due to muscle weakness, tight joints, and lower fitness; and assisting their children to be able to participate in daily life should be key goals of rehabilitation services. Children with CP vary in their motor abilities, and rehabilitation services that are offered vary, which makes choices difficult. There are no clear guidelines about what services are the most effective and when they should be used for achieving these key goals. Families want sound information on how to consider and select the best services for their children.

**Objectives:** The long-term goal of this research team is to provide families of children with CP and service providers sound information, based on study of many children with CP, to assist in making decisions about rehabilitation services. In partnership with parents of children with CP and service providers, our specific aims are to: (1) create and compare graphs that reflect the change in balance, muscle strength, joint flexibility, associated health conditions, physical activity, and participation in daily life across age 1.5 to 12.5 years, for children with CP who are grouped by functional motor ability levels and (2) identify and compare the characteristics of rehabilitation services of children whose developmental change in balance, muscle strength, joint flexibility, physical activity, and participation in daily life are higher and lower than average, according to the growth graphs, which are grouped by functional ability levels.

**Methods:** We will recruit 600 children with CP and their parents from North America who are 1.5 to 10.5 years old at the start of the study to participate. We will collect information five times, every six months across two years, using appropriate tests of the children's balance, range of motion, muscle strength, and physical activity. Parents will complete questionnaires that include information on the family, the child's endurance for activity, health conditions, participation activities, and rehabilitation services. After classifying children by functional ability, we will use modeling statistics to create graphs of developmental growth curves of the children's change in the abilities measured. We will then examine what aspects of services predict the best developmental growth in the children.

**Patient Outcomes (Projected):** The developmental curves will assist families, in collaboration with service providers, to determine growth in their children on the abilities measured in comparison to children with CP who have similar functional abilities. This will help families to address the question: "What will happen to my child?" Knowing which type of services predict the best growth in children with CP will provide direction for service provision choices.

# Communication and Dissemination Research

## Illinois

**Allen Heinemann, PhD**
REHABILITATION INSTITUTE OF CHICAGO
*Developing Quality Metrics from Patient-Reported Outcomes for Medical Rehabilitation*

Healthcare quality in the United States varies widely; this variation has created calls for performance improvement and provider accountability to improve care quality. The only way to know if healthcare quality is improving is to document performance using standard quality measures. Quality measures permit comparisons of how well hospitals deliver care. Quality measures are used for public reporting, quality improvement, and hospital payments.

Patient-reported outcome measures (PROMs) provide a valuable information source in describing health changes during rehabilitation hospitalization. However, inpatient rehabilitation facilities rely primarily on clinician-rated outcomes, such as functional status and goal attainment; the patient's voice is not a part of hospital evaluations. However, there are major challenges to using PROMs for accountability and performance improvement, including limited use in clinical practice and uncertainty about how to aggregate PROMs for performance improvement.

This proposal addresses this lack of information by identifying issues that are important to the quality of care for rehabilitation patients that could be collected as patient-reported outcomes. We will evaluate the feasibility of collecting PROMs and specify the questions that are required for quality measure development.

An advisory committee of stakeholders will help guide the project; it consists of consumer advocacy organizations, patients, clinicians, and policy makers. They will provide input on valued outcomes of medical rehabilitation and patient-reported outcomes that reflect these values. The project's design includes focus groups of patients with stroke, spinal cord injury, traumatic brain injury, Parkinson's disease, multiple sclerosis, and other neurological disorders. We will administer advisory committee–selected PROMs to 300 rehabilitation inpatients and evaluate the feasibility of PROM administration, considering patient and organizational issues.

This proposal fulfills PCORI's patient and stakeholder involvement, transparency, and inclusiveness goals. The project engages clinicians, patients, and caregivers; we will be prepared to disseminate results to rehabilitation stakeholders including clinicians, patients and caregivers, payers, and policy makers so as to maximize opportunities for implementation.

## Maryland

**Rebecca Aslakson, MD**
JOHNS HOPKINS UNIVERSITY

*Utilizing Advance Care Planning Videos to Empower Perioperative Cancer Patients and Families*

Many cancer patients pursue aggressive surgery in the hope of cancer cure or life prolongation. However, in doing so, patients and families often avoid advance care planning; they do not discuss specific goals and wishes should disease progress despite surgery. Moreover, a subset of patients become critically ill following surgery, and family members must make life-and-death decisions without knowing patient wishes. Preoperative advance care planning—facilitating patient and family discussions concerning perioperative goals, hopes, and fears—would empower patients and families to better choose which therapies and procedures they want outside of the initial surgery and for the months following surgery.

Advance care planning aids exist, but none were developed for or evaluated in a surgical patient population. Furthermore, video-based advance care planning tools are an innovative way to better empower patients and families. Previous research shows that, with the aid of an advance care planning video, patients and families are more knowledgeable about treatment options and more comfortable with making decisions. Moreover, when better educated, these patients and families frequently choose less aggressive therapies. However, video-based advance care planning tools have not been developed or tested in a surgical patient population.

We propose to develop and evaluate a video-based decision aid for pancreatic cancer patients and families pursing aggressive surgical cancer treatment. We hypothesize that, in patients and family members, the video-based decision aid will facilitate better clarification of goals-of-care, increase comfort with decision making regarding future therapies, and decrease anxiety and depression after surgery.

Based on previous studies in nonsurgical populations, we also hypothesize that video-based decision aids will decrease future healthcare utilization by patients.

The video content will be based on previously existing decision aids and what cancer surgery patients and families tell us about those aids and about their own perioperative experiences. For example, the video could include what the spouse of a cancer surgery patient wished she had known prior to her husband's surgery or things a patient wished he had done or talked to his family about prior to surgery. We also evaluate the video's impact on patient and family: postoperative anxiety and depression levels, comfort with decision making, and healthcare utilization.

Throughout all stages of this study, intervention content is determined, reviewed, and evaluated by cancer surgery patients and their families. The research team itself is comprised of five researcher-clinicians, two family members, and one cancer patient. The intervention will be developed in a pancreatic cancer surgery population but is designed to apply to all patients pursuing major surgery, regardless of diagnosis or type of surgery planned.

**Albert Wu, MD, MPH**
JOHNS HOPKINS UNIVERSITY
*Reverse Innovation and Community Engagement to Improve Quality of Care and Patient Outcomes*

The residents of urban centers suffer from many health and social problems. In East Baltimore (EB), many barriers frustrate residents' aspirations to achieve health and well-being. Community-based organizations (CBO) can help but reach only a fraction of potential clients. Hospitals, providers, and community members often are unaware of available medical and community-based services.

Community engagement can improve understanding and use of healthcare services, thereby improving patient outcomes. We propose to adapt a World Health Organization community engagement approach to support the Johns Hopkins (JH) Community Health Partnership (J-CHiP), an initiative targeting high-risk adults with chronic conditions who reside in surrounding ZIP codes. The overall goals are to improve the health of EB residents by enhancing communication and "co-developing" a community engagement partnership between JH hospitals and clinics, CBOs, and community. The specific aims are to: (1) adapt a community engagement approach to five EB ZIP codes to develop an intervention to strengthen the partnership and bidirectional flow of information about health and human services between JH hospitals and clinics, 10 selected CBOs, and residents of surrounding neighborhoods; (2) apply the co-developed intervention to the 10 CBOs and J-CHiP staff; and (3) evaluate the effectiveness of the intervention on patient, CBO, and J-CHiP outcomes. In Aim 1, selected CBOs will co-develop resource materials, systems, and procedures to function in the enhanced referral network, including an atlas of community assets, and a system to track the services CBOs deliver. Aim 2 will deliver the intervention to selected CBOs and J-CHiP staff. For each of 1,260 J-CHiP patients, we will designate a "closest" CBO, based on prior use and geographic distance. Aim 3 will evaluate the program using a randomized design.

Patients whose closest CBO is an intervention CBO (iCBO) will be compared to controls with non-iCBOs. The primary outcome for each patient is change in number of ED visits + hospital days. Additional patient outcomes will include self-reported access to care, self-efficacy, and satisfaction with care. Additional pre- and post-analyses will compare the number of services delivered by intervention CBOs and outcomes for J-CHiP workers. We will also use case study methods to examine how iCBOs work in their new role with patient and J-CHiP stakeholders. Stakeholder input, especially from community members, has been incorporated at every step of the project, including proposal development and community-selected lead and co-investigators. The project will create a locally designed and evaluated referral and follow-up system that will extend care networks from hospitals and clinics to community partners, thereby improving community-wide care coordination that meets the medical and social needs of people with chronic conditions. If successful, it could be sustained and replicated in other communities.

## Massachusetts

**Margarita Alegria, PhD**
CAMBRIDGE HEALTH ALLIANCE
*Effectiveness of DECIDE in Patient-Provider Communication, Therapeutic Alliance, and Care Continuation*

**Background:** Serious deficiencies in quality of behavioral health care have been identified, but experts suggest these deficiencies could be addressed if providers sought patients' perspective about their illness and shared power and responsibility. Shared decision making (SDM), a form of patient-provider communication where both parties bring expertise to make treatment decisions, has the potential to improve quality of behavioral health care. However, prior work on jointly improving patient and provider SDM in behavioral health has been inconclusive. Furthermore, there has been limited information to help identify effective SDM interventions, and whether they impact quality of care, or the

underlying mechanisms leading to improvements in SDM; and there have been no prior studies of whether racial/ethnic or linguistic concordance influences SDM.

Our research team conducted a patient intervention (DECIDE-PA) that showed improvements in patient activation and self-management in behavioral health care. However, we found that some providers were unresponsive or reacted negatively to patients' increased activation, which may have led some patients to drop out of care. In response, we propose to combine DECIDE-PA with a provider coaching intervention (DECIDE-PC) to increase providers' receptivity to patient activation and improve SDM. We also respond to clinic administrators who request evidence of the interventions' impact on improving quality of care to sustain the intervention.

**Objectives:** (1) test the effectiveness of DECIDE-PA+PC compared to usual care in improving SDM and patient-perceived quality of behavioral health care; (2) test whether patient-centered communication and therapeutic alliance mediate the effect of DECIDE-PA+PC on SDM; and (3) explore whether ethnic/racial or language matching between patient and provider moderates the relationship between the effect of DECIDE-PA+PC on SDM and quality of behavioral health care.

**Methods:** For Objective 1, we implement a randomized controlled trial comparing DECIDE-PA+PC with usual care on SDM and perceived quality. We identify treatment effects that account for differences in individual mental health, provider, and clinic characteristics across the experimental groups. For Objective 2, we identify underlying mechanisms of the effect of the DECIDE-PA+PC intervention on SDM with careful consideration to mediation analysis and adjustment for the timing of the measures so that we can increase confidence in our causal claims. For Objective 3, we expand Objective 1 models to test whether DECIDE-PA+PC impacts SDM and perceived quality of care differentially by concordant/discordant patient-provider dyads.

## Minnesota

**Navneet Majhail, MD, MS**
NATIONAL MARROW DONOR PROGRAM, INC.
*Individualized Care Plans for Hematopoietic Cell Transplant Survivors*

Hematopoietic cell transplantation, also known as a blood and marrow transplant (transplant), is used to treat life-threatening diseases such as blood cancers (leukemia and lymphoma). Patients who survive months to years after transplant (survivors) and are cured of the disease still need medical care for a long time to prevent possible complications. Examples of complications are damage to organs (including heart, lung, and kidney), infections, and other cancers. These complications happen because of the chemotherapy and radiation therapy the patients may have received for their disease or transplant. Many complications can be prevented or treated if they are found early. Doctors and researchers developed guidelines for after-transplant medical care to prevent these complications, but many survivors still do not get the care they need. They can miss important checkup appointments and tests.

We believe that giving survivors a complete list of past treatments, drugs, and the tests they should get at their checkups will improve their medical care. This list is called a Survivorship Care Plan (SCP). We want to do a research study where we will give transplant survivors a personalized SCP. To create this SCP, we will use a national registry (list of health information on patients) to know what complications survivors may be more likely to develop because of health factors such as their age, sex, transplant type,

and if they received radiation. Then, we will use the guidelines to create a list of tests needed to prevent any possible complications.

There are two parts to our study. In the first part, there will be 80 participants (people who agreed to join the study). The participants will be survivors and their providers (doctors and nurses). The study will be run by trained researchers. We (the researchers) will talk to the participants over the phone and ask them what kinds of information the SCP should have and how it should look. We will also ask the participants how they would prefer to receive the SCP. We will use this feedback to develop a final version of the SCP. There will be 495 survivors in the second part of the study. We will randomly assign them (e.g., flipping a coin) to one of two groups. One group will get an SCP that was developed in the first part of our study, and the other group will not. We will follow the groups to see if the SCP helps survivors feel better about the care they need and if it improves the care they receive. This study is about creating a special resource for transplant survivors. We believe the resource will improve their after-transplant medical care and overall health. Our study especially focuses on survivor participation and the use of their feedback. The resource will help survivors have better conversations with their doctors and make more informed decisions about their health care.

## Missouri

**Tessa Madden, MD, MPH**
WASHINGTON UNIVERSITY SCHOOL OF MEDICINE
*Implementation of Patient-Centered Contraceptive Provision in Community Settings*

**Background:** More than three million pregnancies each year are unintended or unplanned—this means that the pregnancy is unwanted or the timing is wrong. Unplanned pregnancy contributes to poor health outcomes for women and children. Contraception or birth control helps to prevent unplanned pregnancy. Long-acting reversible contraceptive methods such as intrauterine devices (IUDs) and implants are the most effective birth control methods for preventing pregnancy and are more effective than other methods, such as oral contraceptive pills or condoms. However, long-acting birth control is used less commonly in the United States than pills and condoms. If more women used long-acting contraception, this would likely lead to fewer unplanned pregnancies. We are not sure how best to increase the use of these long-acting methods. Contraceptive counseling may help. The Contraceptive CHOICE Project (CHOICE) is a research study of more than 9,000 women who were provided with birth control at no cost. The study was designed to increase the use of long-acting contraception and reduce unplanned pregnancy. All women received contraceptive counseling that discussed all reversible birth control options. Seventy-five percent of women in the study chose an IUD or an implant and were much less likely to have an unplanned pregnancy.

**Objective:** Our overall goal is to reduce unintended pregnancy. In this study, we plan to apply our results from CHOICE into the real world. We suspect that contraceptive counseling alone is not enough to increase use of long-acting contraception. This is because factors such as cost and healthcare provider misconception may make it difficult for women to get IUDs and implants. We think that contraceptive counseling is important, but cost may prevent many women from obtaining the birth control methods that they want.

**Method:** The proposed project would compare two different ways of providing contraception in community healthcare clinics. In the first, patients will receive contraceptive counseling that talks about all birth control methods. They will also have a visit with their healthcare provider. In the second,

patients will receive the same contraceptive counseling. They will also have a visit with their healthcare provider, who will have had special training in long-acting contraception. They will also receive help paying for a long-acting method if they do not have health insurance or their insurance does not cover the method. Women who participate in this study will provide information by completing surveys. They will complete a survey after their visit with their healthcare provider and six weeks, six months, and 12 months later. We will then compare how many women have an unplanned pregnancy between the two groups. We will also look at what birth control method women chose, how happy they were with counseling about birth control, how happy they were with the clinic visit, and whether they keep using their birth control method.

## New York

**Supriya Mohile, MD, MS**
UNIVERSITY OF ROCHESTER
*Improving Communication for Chemotherapy: Addressing Concerns of Older Cancer Patients and Caregivers*

**Background:** With the aging of the population, the number of older patients with cancer will increase. Oncology clinical trials historically have excluded patients with health conditions (e.g., chronic diseases, disability, memory problems) other than cancer. Because the majority of older patients have other health conditions, they are not represented on clinical trials and, as a result, data on the safety and efficacy of chemotherapy in this population is lacking. In this context, where data is limited and risk from treatment is high, better communication about age-related health status issues between older patients with advanced cancer, their caregivers, and their physicians may improve decision making for chemotherapy and quality of life. Geriatric assessment (GA), surveys that capture patient-centered outcomes, is used by geriatricians to identify concerns (e.g., function, cognition) important to older persons with cancer and their caregivers. The majority of oncologists have not adopted GA, largely because of lack of knowledge on how to best utilize GA in clinical care.

**Objectives:** The primary objective of this study is to determine whether providing a web-generated GA summary to older patients with advanced cancer, their caregivers, and their physicians can improve communication about age-related concerns that could affect chemotherapy outcomes. Other objectives are to determine if the intervention improves quality of life and patient and caregiver satisfaction with the decision-making process for chemotherapy.

**Methods:** Community oncology sites within the University of Rochester Community Clinical Oncology Program (CCOP) network will be assigned to either GA intervention (Arm 1) or usual care (Arm 2). Prior to chemotherapy initiation, patients aged 70 and over (N=500) with advanced cancer (i.e., incurable) will complete a GA. The physicians, patients, and caregivers at sites assigned to Arm 1 will receive a web-generated summary of all GA results plus targeted interventions to consider for implementation. Arm 2 will reflect usual care, but information regarding clinically significant depression or cognitive issues detected by GA will be provided. The visit prior to starting chemotherapy will be audio-recorded (to measure the number of concerns brought up by patients and caregivers and whether they were addressed by their physicians), and measures of quality of life, decision-making preferences, and satisfaction will be collected.

**Patient Outcomes:** GA provides a mechanism by which older patients can report their own health status concerns. Although these issues are important to older patients and their caregivers, they are not routinely incorporated into the decision-making process for chemotherapy. This proposal will fill vital

gaps in knowledge regarding whether empowering older patients with advanced cancer and their caregivers with GA information can improve communication about age-related concerns.

## North Carolina

**Hazel Tapp, PhD, BSC**
CAROLINAS MEDICAL CENTER
*Comparing Traditional and Participatory Dissemination of a Shared Decision-Making Intervention*

**Background:** Changing the behavior of health providers can be challenging, and significant gaps exist in our knowledge of how to best spread or disseminate new medical evidence into everyday practice. This is true when the evidence involves a new patient-centered care method such as shared decision making (SDM). The most common dissemination methods used are journal publications, presentations, and educational material that often fails to produce timely or sustainable practice level changes. A unique partnership between a Medicaid network and a well-established group research network provides an ideal venue to examine the effectiveness of new effective methods of dissemination. We previously developed an asthma toolkit that was tested across a regional network of pediatric, family medicine, and internal medicine healthcare practices in Mecklenburg County, North Carolina. During this study, key principles of community-based participatory research were used to engage providers and patients to develop a Facilitator-Led participant OWned (FLOW) approach to dissemination. The FLOW approach uses practice facilitators to guide practices through the process of adapting the toolkit into the existing culture and workflow. This approach led to rapid dissemination and sustainability of the toolkit across six practices. The initial results have shown marked improvement in patient outcomes (including increased adherence to taking medications that control asthma and decreased disease complications) with increased patient involvement in the creation of the care plans.

**Objectives:** The objective is to determine what dissemination strategy most effectively increases practice level adoption of shared decision making, improves patient outcomes, and increases patient involvement in care decisions.

**Methods:** Here we will leverage a partnership between the statewide Medicaid network and NCNC, a statewide consortium of research networks, to identify best practices for dissemination of the shared decision-making toolkit. We will test the FLOW method for dissemination on a larger scale by randomizing 30 primary care practices from four practice-based research networks to one of three dissemination arms: (1) FLOW approach to dissemination; (2) traditional dissemination with facilitator exposure; and (3) passive dissemination.

**Patient Outcomes (Projected):** The primary outcome will be patient perceptions of involvement in their care, measured using a patient survey and qualitative data collection. Secondary outcome measures will be: asthma complications (defined by ED, hospital utilization, and medicine given during asthma complications) and adherence to medication that controls asthma, measured by pharmacy refill rates. This study will provide crucial data to support a novel method for dissemination of a new paradigm of care delivery into primary care practices.

# Improving Healthcare Systems

## California

**Tumaini Coker, MD, MBA**
UNIVERSITY OF CALIFORNIA LOS ANGELES
*Using Telehealth to Deliver Developmental, Behavioral, and Mental Health Services in Primary Care Settings for Children in Underserved Areas*

**Background:** Primary care clinicians should provide comprehensive, family-centered care that addresses unmet developmental, behavioral, and mental health (DB/MH) needs. However, data indicate that most children who need DB/MH services do not receive them. Access to DB/MH services is often severely limited, while a lack of communication and coordination between specialty and primary care providers often prevents optimal outcomes even for those with DB/MH access. A patient-centered model for telehealth has the potential to transform DB/MH services by integrating them into primary care. If DB/MH specialty providers are able to deliver services remotely to many sites from a central location, large numbers of children across multiple small, but conveniently located, primary care clinics can gain ready and sustainable access to DB/MH providers.

**Objective:** The objective of this study is to integrate developmental, behavioral, and mental health services into pediatric primary care using a telehealth model that will be tested with children in low income, urban communities.

**Methods:** In partnership with a multisite, Los Angeles–area community clinic consortium, North East Valley Health Corporation (NEVHC), we will use telehealth to integrate DB/MH services into primary care for low-income, publicly insured children. During Project Year 1, we will conduct and analyze interviews with parents, clinicians, and staff at NEVHC to assess their perspectives on the delivery of child DB/MH services and on a potential telehealth-based system for providing DB/MH specialty care in primary care settings to children ages 5–12. These data will be used in a stakeholder-engaged process to customize a telehealth-based delivery system for child DB/MH services that can be integrated into primary care settings. During Project Years 2–3, we will compare this customized telehealth-based system to the usual in-person referral system at NEVHC in 400 children ages 5–12 who require DB/MH specialty referral. This study will examine whether a telehealth DB/MH delivery model can be an effective, efficient, and family-centered way to provide integrated DB/MH services to children in low-income communities.

**Patient Outcomes:** (1) access, (2) quality (timeliness, family-centeredness, coordination, parent experiences of care), (3) parent satisfaction, (4) child DB/MH clinical outcomes, and (5) child's quality of life.

**Mary Reed, DPH**
KAISER FOUNDATION RESEARCH INSTITUTE
*Interactive Personal Health Records: Use of a Web-Portal by Patients with Complex Chronic Conditions*

Personal health records offer patients the option to access their medical information through a secure "patient portal" website and the ability to manage their health care online at any time of day or night through interactive tools, including lab result review, visit summaries, secure e-mail messaging to

healthcare providers, medication refill ordering, and wellness programs. Portal tools offer patients the option to access some types of health care without visiting their providers and pharmacies in person or needing to call during business hours. For some patients, this may be a convenient way to avoid traveling to medical facilities and pharmacies, reduce time off from work (or other duties such as caregiving), and increase communication with healthcare providers through e-mail. For other patients, including those with limited access to the Internet or those who prefer in-person communication with physicians and pharmacists, using the patient portal may be a cumbersome or ineffective way to access health care. Still, patient web portals have great potential to change the way that health care is delivered and have been proposed as a promising way to decrease medical errors and increase high-quality health care. In 2012, 75% of US adults expressed interest in having web-based access to their medical records, but less than 40% of physicians reported having the capability to offer these online services. Far fewer healthcare delivery settings offer the types of cutting-edge patient portal tools we will examine in our study.

We will study all 800,000 patients with chronic conditions in a large integrated delivery system that has offered its patients access to a patient portal since 2006. Our research questions are: (1) Which patients use web portal tools and which do not? Why or why not? and (2) How does using web portal tools (compared with not using these tools) affect the patient healthcare experience? We will use a patient survey to collect patient-reported preferences and experiences with using (or not using) patient portal tools and to understand who uses these tools and why (or why not). We will also study how many in-person visits patients have, including doctor's office visits, emergency room visits, and hospital stays to better understand how using patient portal tools affects these types of traditional health care and look at how well patients' chronic conditions are managed to understand how using patient portal tools affects overall health.

As more healthcare providers and delivery systems consider offering their patients access to a web-based portal, more will be using these tools. We hope that our study, with findings that apply specifically to patients' own preferences and characteristics, will help patients understand how using a web-based portal might affect their healthcare experience.

## Colorado

**Daniel Bessesen, MD**
DENVER HEALTH AND HOSPITAL AUTHORITY
*A Toolbox Approach to Obesity Treatment in Primary Care*

**Background:** Obesity is common and causes many medical problems in adults, such as diabetes, high blood pressure, high cholesterol, sleep apnea, heart attack, and stroke. A range of treatments has been shown to be effective to treat obesity. These treatments include intensive lifestyle modification, meal replacements, and weight-loss medication. However, most primary care settings do not provide very much obesity treatment. This is because primary care providers (PCPs) are not well trained and because reimbursement for the treatments is not consistent.

**Hypothesis:** If PCPs have training in weight management and if most of the cost of treatment is reimbursed, we believe that a "toolbox" of treatments can produce a clinically important amount of weight loss in a large group of patients.

**Design:** We are proposing to establish a registry of patients who have obesity and at least one common medical condition related to their weight. From the registry, we will randomly select 350 people who will be offered treatments to assist with weight loss. The remainder of the patients in the registry can still receive treatment for obesity but will not have reimbursement for the treatments. We will conduct the study at Denver Health, which is a large public healthcare system that treats a low-income, ethnically diverse population. All 350 patients will be offered some self-monitoring tools for weight management and the chance to take a computer assessment to select the right treatment for weight loss. Patients who complete this and who record their food intake and physical activity for one week will be offered a "Level 2" treatment to help with weight loss. The Level 2 treatments will include: a voucher for a commercial weight-loss program; an intensive group behavioral weight-loss program; meal replacements; fitness center membership; or weight-loss medication. Patients will be able to choose which treatment they want, with the approval of their PCP. A patient navigator at Denver Health will help with the computer assessment and with accessing the treatments. Each patient who completes the self-monitoring will be offered the Level 2 treatment for one year. We are interested to see what percentage of patients lose at least 5% of their starting weight. We will also look at changes in blood sugar, blood pressure, and cholesterol. We will look at how much it costs to do this intervention and whether patients need less medication for their weight-related conditions at the end of the study.

**Impact:** If the study is successful, we plan to take the results to the leaders at Denver Health to see if they will make obesity treatment more broadly available for all patients there.

## District of Columbia

**Holly Mead, BA, PhD**
GEORGE WASHINGTON UNIVERSITY
*Evaluating Cancer Survivorship Care Models*

**Background:** With better treatments and screening, more people are surviving cancer. When treatment ends, however, many cancer survivors face ongoing challenges that require long-term follow-up. For example, cancer and its treatment can lead to physical problems (e.g., heart damage, new cancers, fatigue), emotional issues (e.g., fear of recurrence, anxiety, depression), and practical issues (e.g., employment difficulties, insurance challenges, financial issues). Many people who finish treatment feel "lost in transition"; they have difficulty managing the impacts of cancer and find little support from the healthcare system. Healthcare providers are not prepared to provide follow-up care and help manage these issues, and survivors are often unaware they may be at increased risks for these challenges.

Over the past decade, healthcare providers and researchers have begun creating survivorship clinics to address survivors' needs, but little evidence exists on what care should be provided. As a result, clinics vary tremendously in terms of what care is provided (e.g., screening for new cancers, referring to specialists, discussing healthy behaviors, conducting a physical exam). Importantly, survivors themselves have not been given the opportunity to define what services they believe are most important.

**Objectives:** This project seeks to answer the research question: what impact do different models of follow-up care have on patient-centered outcomes for cancer survivors? Our aims are to create tools to better understand what patients want and need and what care is currently being provided across the country. Then we will study the comparative effectiveness of these care models and how they impact outcomes that matter most to survivors. A key component of the project is the use of a stakeholder advisory board chaired by a survivor that will include survivors, survivor advocates, clinicians, healthcare

professionals, and a representative of an organization that accredits cancer programs.

**Methods:** We will first ask survivors, in focus groups and through a national survey, what services they believe are most important to create a survivor-prioritized framework for quality survivorship care. We will also conduct a survey of cancer programs across the country to determine what services they are providing, how, and by whom and compare this care to the survivor-prioritized framework to see if existing services are meeting survivors' defined standard of care. Understanding different survivorship practices will also help us describe care models so we can conduct research to compare the effectiveness of these models on addressing survivors' needs.

**Projected Patient Outcomes:** We will assess the differences across care models related to survivors' reported satisfaction; health-related quality of life (i.e., important aspects of a person's well-being); ability to manage their cancer post-treatment; and appropriate healthcare utilization.

**Sarah Scholle, MPH, DPH**
NATIONAL COMMITTEE FOR QUALITY ASSURANCE
*Evaluating the Impact of Patient-Centered Oncology Care*

**Background:** Advances in cancer treatment mean that a growing number of Americans are living with cancer and experiencing it as a chronic, long-term condition. National panels led by consumers have identified the need for improved cancer care in the areas of communication between providers and patients and their families, care planning, attention to nonmedical needs, care coordination, and provision of evidence-based treatment. The patient-centered medical home (PCMH) model of care is being widely adopted as a way to provide accessible, proactive, coordinated care and self-care through primary care practices. During active treatment for cancer, the oncology practice is often the primary setting supporting the patient and coordinating cancer treatment. By implementing the PCMH model, an innovative oncology practice in Pennsylvania has been able to improve access and reduce emergency department visits and hospitalizations for its patients.

**Objectives:** Building on these recommendations and experience, the National Committee for Quality Assurance has worked with the National Coalition for Cancer Survivorship, the American Society of Clinical Oncology, Oncology Management Services, Independence Blue Cross, and RAND, as well as a broader multi-stakeholder advisory group, to define the Patient-Centered Oncology Care model. We seek PCORI support to pilot and evaluate this model. Specific research questions are:
1. Does Patient-Centered Oncology Care improve patient experiences and quality of care? Does it reduce undesirable events such as emergency department visits and hospital stays?
2. How does adoption of Patient-Centered Oncology Care vary across a variety of practices, and what factors affect adoption?

**Methods:** The demonstration will take place in 10 oncology practices in southeastern Pennsylvania. Practices will receive implementation support during the 24-month demonstration period. They will be evaluated using patient surveys, quality measures, and measures of emergency department and hospital use. Results from these practices will be compared in two ways: (1) with their performance before they became oncology medical homes and (2) with other similar practices. Patients, clinicians, and health plan leaders will help design the project and disseminate results. The project uses PCORI resources efficiently by building on ongoing efforts.

**Patient Outcomes (Projected):** People with cancer are seeking high-quality, coordinated, and supportive care. The Patient-Centered Oncology Model has the potential to address current gaps in cancer care. If this model can demonstrate better care, then patients will have important information about what kind of care is possible. Our multi-stakeholder team will be poised to support widespread dissemination through training, policy, and payment initiatives.

## Georgia

**Michael Jones, PhD**
SHEPHERD CENTER
*A Patient-Centered Approach to Successful Community Transition after Catastrophic Injury*

Can a patient- and family-centered approach to education, mentoring, and support be effective in minimizing hospital readmissions for patients recovering from spinal cord injury? Shepherd Center—a specialty rehabilitation hospital—annually treats more than 500 patients with spinal cord injuries. Our patients have intensive care needs. Many will face a lifetime of risk for developing life-threatening medical problems.

Despite these challenges, Shepherd has an excellent record of patient outcomes. Our discharge-to-home rate and rate of re-hospitalizations in the first 30 days after discharge are substantially better than the national average.

Our success is due in part to the extensive support and assistance provided to patients and families after discharge. These services have been donor-funded in the past and are not sustainable. With input from patients and families, we are looking carefully at our discharge planning and post-discharge supports to identify the "must-have" components that will help our patients return home safely and without medical complications.

Several opportunities have been identified to revise our discharge planning and post-discharge supports for patients and families. Three of the most promising ideas will be developed further: (1) revising our patient and family care management training to take advantage of new, interactive learning approaches; (2) establishing one-to-one mentoring to provide guidance and support from peers with similar injuries; and (3) creating a new Internet portal for patients and families to communicate with each other, with peer mentors, and clinical staff and to access information related to their conditions. All three approaches are intended to instill greater self-confidence in our patients and families that they can effectively manage the patient's care needs.

We seek funding to determine if this patient/family-centered approach to discharge planning and support is effective and sustainable. We plan to refine and implement the proposed system changes and evaluate their effects on hospital readmissions and quality-of-life outcomes after discharge. Specific aims of the project are to: (1) design, build, and test refinements to our discharge planning and post discharge supports; (2) implement system changes that are shown to be effective; and (3) formally evaluate effectiveness of the refined program.

The experiences of patients admitted to Shepherd Center for rehabilitation services during the course of the project (about 1,400 newly injured patients with spinal cord injuries) will be used to assess the effectiveness of these patient/family-centered initiatives.

## Illinois

**Denise Hynes, MPH, PhD, RN**
UNIVERSITY OF ILLINOIS AT CHICAGO
*Bringing Care to Patients: A Patient-Centered Medical Home for Kidney Disease*

**Background:** Patients with end-stage renal disease (ESRD) receive care from several different doctors at multiple locations. They often have other chronic diseases that require complex care and are at a higher risk for emergency room visits and hospitalizations. The patient-centered medical home (PCMH) model has been proposed as a solution to patients with complex needs such as those with ESRD. We will compare a PCMH model with usual care on ESRD patients and their caregivers.

**Purpose:** The purpose of this project is to compare a PCMH model of care with the usual care of ESRD patients and their caregivers. We propose to enhance the usual care team for ESRD patients by providing a primary care doctor in the context of regularly scheduled dialysis sessions and by adding health promoters to help support patients and their caregivers. Patient and family stakeholders and care team members will assist in the design and refinement of the PCMH model.

**Method:** We plan to implement this model at the University of Illinois Hospital and Health Sciences System (UIHS) dialysis center and a local Fresenius Medical Care dialysis center. Patients receiving dialysis at participating centers will receive an initial comprehensive care visit followed by ongoing care from a multispecialty provider team during the patients' regularly scheduled dialysis visits. Each patient's care team will include a kidney doctor, a primary care doctor, an advanced practice nurse, a dialysis nurse, a dietician, a pharmacist, a social worker, and a health promoter. The primary care doctor will be available in the dialysis clinic to provide general and preventive care to the patient before or after dialysis sessions. This doctor would also coordinate care with other specialists/clinicians on the patient's care team. The trained, bilingual (English/Spanish) health promoter will assist with making and rescheduling appointments, obtaining transportation, and reinforcing education components.

**Outcomes:** We expect that this approach will increase patient access to care for other conditions and will increase care coordination and communication among members of the patient's care team. These improvements could potentially increase the likelihood of preventing complications or identifying problems earlier and allow for a more successful treatment. We expect that this will reduce emergency room visits and hospitalizations for dialysis patients. In addition, we anticipate that the addition of health promoters to the clinical team will help support and educate patients and their caregivers and, as a result, patient quality of life will improve and caregiver burden may be reduced.

**Jerry Krishnan, MD, PhD**
UNIVERSITY OF ILLINOIS AT CHICAGO
*PATient Navigator to rEduce Readmissions (PArTNER)*

**Background:** Being healthy, feeling in control, and staying out of the hospital are outcomes strongly valued by patients. However, hospital readmissions remain high, especially among African-Americans and patients of minority-serving institutions (MSIs). MSIs provide care for many patients with limited social support and health literacy, who contribute to high readmission rates. Patients' interests converge with those of hospitals now that, as part of quality improvement (QI) initiatives, the CMS has imposed financial penalties to hospitals with high 30-day readmission rates. Thus, MSIs may be at higher risk to be affected by CMS penalties and will benefit from improving patients' outcomes and reducing

readmissions. Classically, QI efforts focus on clinical interventions, and patients/caregivers have not played a major role in the development of QI efforts. In a novel approach to improve patients' outcomes, we started engaging patients and caregivers at an MSI. They conveyed feelings of abandonment, anxiety/fear, and inadequate self-efficacy during transition from the hospital and expressed great interest in educational and social support, provided during home visits by a community health worker (CHW), as well as the need for telephone-based social/peer support.

**Objectives:** We propose to engage stakeholder groups at an MSI, including patients/caregivers, in an iterative process to develop a CHW-based Patient Navigator (CHW-Navigator) toolkit tailored to their needs to augment the benefits of a QI program to reduce readmission. We will compare the effectiveness of an integrated CHW-Navigator on the patient experience, 30-day readmissions rates, and other outcomes.

**Methods:** Using stakeholder focus groups (patients/caregivers, clinicians, hospital administrators, representatives of SHM BOOST), we will design a program that includes: (1) a CHW patient navigator, supported by hospital-based clinicians (social worker, nurses, physicians), for in-person visits during hospitalization and a post-discharge home visit, to provide social support and literacy-appropriate self-management skills training and (2) a patient/caregiver peer-led information line for ongoing telephone-based peer support, in collaboration with a patient advocacy group. We will pilot test the program and modify the intervention based on results and on stakeholders' input. We will then conduct a randomized clinical trial (~1,100 patients) to study the effects of the CHW-Navigator program on patients' experience, self-management, and functional status and on readmission rates.

**Importance:** This timely program has the potential to greatly impact MSIs' QI efforts, by tailoring to the needs of the patients they serve. The CHW-Navigator toolkit will be integrated in the resources available to hospitals implementing SHM's BOOST, ensuring rapid diffusion and scalability.

**Lee Lindquist, MD, MPH, MBA**
NORTHWESTERN UNIVERSITY AT CHICAGO
*Advance Planning for Home Services for Seniors*

**Background:** Remaining in their own home is one of the highest priorities of most seniors. Seniors often do not have an understanding of home care services. Likewise, seniors do not understand their health trajectory or plan accurately for future needs, which leads to them not remaining safely in their homes as long as they could. Seniors rarely believe that they will be hospitalized, although people aged 65 years account for 35% of hospitalizations annually. As a result of hospitalizations, seniors experience functional decline with placement in nursing homes. Seniors are often left out of critical decision making on their long-term care. Stressed family members choose nursing facilities while the senior is hospitalized and, in many cases, make decisions to move seniors out of their homes. If seniors and their families understand home care services and plan for health events (e.g., hospitalizations, functional loss), then seniors could potentially remain safely in their homes longer. The goal of this proposal is to develop and test an advance planning tool to help seniors understand projected health needs and plan ways to remain in their own homes when these crises occur.

**Objectives:** Through partnerships with seniors, senior community groups, area agencies on aging, and homecare agencies, we plan to:

Aim 1: Develop, pilot test, and refine an Advanced Planning for Home Services (APHS) Tool to assist seniors in making informed choices about issues in their health trajectory that influence their ability to remain in their own home.
Aim 2: Conduct a randomized controlled trial of the APHS Tool intervention to determine subject understanding of home care services and health trajectory and other patient-centered outcomes.
Aim 3: Disseminate the APHS Tool nationally through senior focused organizations (Home Care Association of America, Village to Village Network).

**Methods:** The APHS Tool will be developed by seniors and tested by seniors, for use by seniors with the partnership of university-based researchers. For Aim 1, focus groups with seniors and caregivers will be conducted with results informing the content/design of the APHS Tool. The tool will be tested in electronic and paper formats with 50 seniors each to inform further refinement of the tool. In Aim 2, a randomized controlled study of the APHS Tool will be conducted with 600 community-living seniors with attention control as one arm and APHS Tool as the other arm. Patient-centered outcomes of understanding of health trajectory, understanding of home services, knowledge on access to home services, and communication with their families/health providers will be examined. In Aim 3, the APHS Tool will be actively disseminated among the senior-focused national organizations of the Village to Village Network, Home Care Association of America.

This study will produce a viable advance planning for home services tool that will enable seniors to make informed decisions about safely living at home.

## Indiana

**Bradley Doebbeling, BS, MD, MS**
INDIANA UNIV-PURDUE UNIV AT INDIANAPOLIS
*Improving Healthcare Systems for Access to Care and Efficiency by Underserved Patients*

**Background:** Research has shown that access to health care is a major problem in the United States. In 2007, one in 10 adults reported that they either delayed or did not receive needed health care due to financial or insurance reasons. People confront many other barriers to access, in addition to financial barriers. Despite recent changes to policy and efforts to improve efficiencies, there are still widespread problems with accessing health care in Indiana Community Health Clinics (CHCs). In this research project, we are focused on helping underinsured people in Indiana overcome barriers to gaining access to care at CHCs. Our Indiana Access Collaborative is comprised of Indiana CHCs; CHC patients; the Indiana Primary Healthcare Association; MDwise, Inc.; and interdisciplinary researchers who are all working together to improve the situation for underserved patients.

**Objectives:** Our primary goal is to help develop procedures to help underinsured people efficiently and effectively get the care they need for common health problems. Our study questions are:
1. What are effective, patient-centered, system strategies to reduce barriers of availability, accommodation, and affordability to care?
2. Will expert panels and simulation modeling of proposed innovative policies help identify and prioritize the most feasible and impactful approaches to improve access?
3. Will implementing patient-centered, system redesign approaches identified above improve access in intervention CHCs more than in comparison clinics?

**Methods:** We will conduct the project in seven of eight CHCs that have volunteered to participate. We will interview patients, staff, and providers at these CHCs in order to better understand the barriers, challenges, and successful strategies that are used to get needed health care. We will organize the interview findings into categories that will be formally reviewed, added to, and prioritized by a panel of patients, healthcare providers, and experts. We will then use simulation (a systems engineering method) to model the way patients are enrolled in healthcare plans and scheduled for appointments to test alternatives and identify strategies for improving these processes. Finally, we will implement the new strategies in four of our partner CHCs and compare efficiency and satisfaction. We will train, coach, and monitor our partner CHCs' efforts to develop and continually improve access to care for their patients.

**Patient Outcomes (Projected):** Many patients share the concern: "Will I be able to get the care I need if I become ill?" Because our team is a collaborative of patients and stakeholders in Indiana, we anticipate the proposed project will have an immediate impact on access. Expected patient outcomes are increased satisfaction, access, and engagement due to streamlined enrollment and appointment scheduling. Systems will be able to efficiently enroll patients in healthcare plans and prevent emergency room visits and avoid long waits at clinics.

## New York

**Jonathan Tobin, PhD**
CLINICAL DIRECTORS NETWORK, INC.
*Collaborative Care to Reduce Depression and Increase Cancer Screening among Low-Income Urban Women*

Bronx County, NY, is the poorest urban county in the United States, and its population is mostly Latino and African-American. Although many health problems face Bronx residents, cancer stands out as the leading cause of early death, and death rates due to cancer are higher in the Bronx than New York City as a whole. Detecting cancer early through screening improves an individual's chance of survival; however, many barriers to screening exist. One barrier that has received relatively little attention is depression. Studies suggest that women who are depressed are less likely to be screened. The link between mental health and cancer screening is particularly important to address in areas like the Bronx, in which women face the burden of higher rates of death due to cancer and high rates of depression.

Depression affects almost one in four minority women; although individuals often seek help for depression in primary care, primary care depression management practices need improvement. Drawing on the expertise of our partners at community health centers and community-based organizations, as well as patients, this study will find out whether an intervention that addresses depression and cancer screening needs at the same time among women aged 50–64 in the Bronx is more effective at improving cancer screening and patient-reported outcomes for women with depression than an existing, previously tested cancer screening intervention alone. To achieve this, we will recruit about 700 women aged 50–64 from three Bronx community health centers who are depressed and not up to date with at least one of the recommended cancer screenings (i.e., breast, cervical, and/or colorectal cancer screening); all three types of screening are necessary in this age group. We will then randomly assign study participants to one of the two intervention groups, and we will compare the results of each group to see which is more effective.

Our four main aims are:
1. Compare the impact of the two interventions on patient-reported outcomes, including cancer screening knowledge and attitudes, self-efficacy, depression-related stigma, provider referrals,

participation in mental health care, medication use, quality of life, satisfaction with care and treatment decisions, and depression.
2. Compare the effectiveness of the two interventions in increasing breast, cervical, and colorectal cancer screening.
3. Determine whether reducing depression increases the likelihood that participants will receive cancer screening.
4. Determine whether effectiveness of the two interventions to increase cancer screening varies according to patient characteristics, such as the duration of depression, presence of other chronic conditions, and obesity.

This study is designed to enhance our understanding of how to improve the ability of community health centers to increase cancer screening and reduce depression among low-income minority women and how to best support this population in making cancer-screening decisions.

## Utah

**Flory Nkoy, MD, MS, MPH**
UNIVERSITY OF UTAH
*Redesigning Ambulatory Care Delivery to Enhance Asthma Control in Children*

Many children with asthma have too many asthma attacks. Asthma guidelines suggest children with asthma and their parents should learn more about asthma to manage it better between doctor visits. This includes understanding the symptoms of active asthma, recognizing when they are getting worse early, and contacting their doctor right away to adjust medications early and avoid asthma attacks. Little has been done to make it easier for children with asthma and their parents to do this.

We created a tool that helps parents manage their child's asthma. The tool is called the electronic-AsthmaTracker (e-AT). With the e-AT, parents and children partner with their doctor to track asthma symptoms regularly, recognize early when they are getting worse, and act before an asthma attack happens.

Parents and their children helped us develop the e-AT. After using it for several months, they told us the tool was helpful, and they gave us suggestions to make the e-AT even better. They wanted the e-AT to capture and hold their interest without taking too much time or effort. They wanted to know how well it really works. Parents and their children with asthma have been an important part of this project from the beginning.

To continue to make the e-AT better, we want to do a research study of children with asthma, ages 2 to 12; their parents; and doctors. We will ask parents and doctors to help us in our study so it is meaningful to them and to help us make the e-AT a useful tool for all children with asthma.

Our research goals include understanding what the e-AT can do for children with asthma to make their lives better, have less asthma symptoms, and miss less school. We want to see if it keeps parents from missing work and is beneficial to them and their children. We want to see if it helps doctors and clinics keep asthma patients out of the emergency room and hospital. To do this, we will ask five clinics and parents who go with their children to these clinics to use the tool. Another five clinics will not use the tool but will continue regular care for asthma as a comparison group. This will help us understand what the e-AT can do.

With parents who use the tool, we want to study what issues in life make it easier or harder to use it. We want to understand why some people use tools like this regularly for many weeks or months and why others lose interest and stop using after only a few weeks or months. We think this study will be helpful in making the e-AT better and improve the life of children with asthma and their parents.

## Washington

**J. Randall Curtis, MD, MPH**
UNIVERSITY OF WASHINGTON
*Health System Intervention to Improve Communication about End-of-Life Care for Vulnerable Patients*

**Background:** Four decades of research on end-of-life care indicate that people who are dying often spend their final days with a significant burden of pain and other symptoms and receive care they would not choose. Patient-clinician communication about end-of-life care is an important focus for improving care for three reasons: (1) when it occurs, it is associated with improved quality of life, reduced anxiety, and fewer intensive life-sustaining therapies at the end of life; (2) physicians frequently do not have discussions about end-of-life care with their patients, even though most patients desire these discussions; and (3) our preliminary studies suggest that a simple intervention based on each patient's informational needs and preferences can increase the occurrence and quality of patient-clinician communication about end-of-life care. By tailoring patient-clinician discussions to the individual patient, patients will be able to make care decisions that are best for them, and clinicians will be able to provide patients with the care patients desire.

**Objectives/Specific Aims:** Our long-term goal is to ensure that patients receive the end-of-life care they desire through improved patient-clinician communication. If effective, this health-system intervention will improve: (1) the occurrence and quality of patient-centered communication about end-of-life care for patients with chronic life-limiting illness and their families; (2) the agreement between patients' wishes for care and care received; and (3) the burden of symptoms of anxiety and depression experienced by patients and families.

**Methods:** We propose a randomized trial of a "feedback form" provided to patients, family members, and clinicians, specifying the individual patient's communication needs and preferences concerning end-of-life care. The trial will be tested with 120 clinicians who provide care to eligible patients at clinics of a large healthcare system. Eligible patients (six per clinician for a total of 720) will include those with chronic, life-limiting illness. Up to three family members per patient and three interdisciplinary team members per clinician may participate. Clinicians will be randomized to the intervention or usual care; the intervention will be compared with usual care. Self-report questionnaires will be completed by patients and family members at the start of the study, at three months, and at six months. Analyses will include a statistical approach that takes into account the fact that there will be more than one patient for each physician and that data are collected at multiple time points.

**Patient Outcomes:** Outcomes include patient assessments of: (1) frequency and quality of patient clinician communication; (2) agreement between care patients desire and care received; and (3) symptoms of anxiety and depression. All of these patient-centered outcomes are assessed by patients using validated surveys. We will also assess family members' symptoms of anxiety and depression.