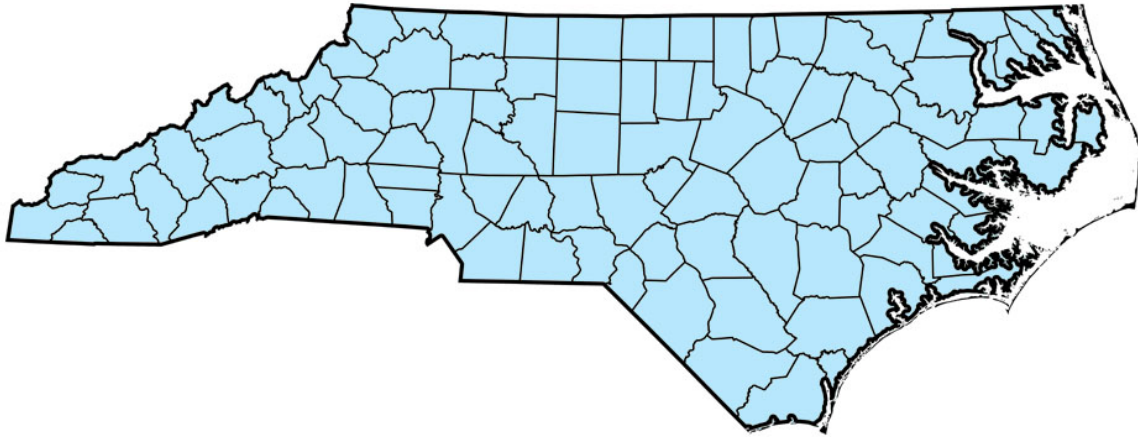




UNC
THE CECIL G. SHEPS CENTER
FOR HEALTH SERVICES RESEARCH

ANNUAL REPORT

July 1, 2013 - June 30, 2014



**The Cecil G. Sheps Center for Health Services Research
University of North Carolina at Chapel Hill**

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**The Cecil G. Sheps Center for Health Services Research
University of North Carolina at Chapel Hill
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As in the past, this year's annual report is organized into several sections. Initially, the mission of the Center is discussed, followed by a narrative review of its research, technical assistance, and training activities. The research and technical assistance activities are described by program area, followed by a description of the Center's graduate and postgraduate education activities and the library and informational services available. The Appendices summarize the Center's organizational structure with the organizational chart and Policy Board members, the contract and grant proposal success and sources of funds supporting Center activities, the seminars sponsored by the Center during the year, and, a list of publications produced by Center investigators during the fiscal year.

MISSION STATEMENT AND ORGANIZATION

The Cecil G. Sheps Center for Health Services Research, one of the nation's oldest and largest health services research centers opened its doors forty-five years ago. It seeks to improve the health of individuals, families, and populations by understanding the problems, issues, and alternatives in the design and delivery of health care services. This is accomplished through an interdisciplinary program of research, consultation, technical assistance, and training that focuses on timely and policy-relevant questions concerning the accessibility, adequacy, organization, cost, and effectiveness of health care services, and the dissemination of this information to policymakers and the general public.

The Center is a separate organizational unit under the Vice Chancellor for Research at UNC Chapel Hill. Oversight responsibility for the Center is vested in a Policy Board whose members include senior faculty and administrators from the five health science schools, as well as representatives of the health services community at large. The director receives assistance in planning and leading the Center's activities from the four deputy directors, one associate director, and from the program directors responsible for areas of health related research/policy analysis. A copy of the organizational chart for the Center can be found in Appendix A and a listing of the Policy Board members in Appendix B. Center principal investigators have faculty appointments in the following UNC-Chapel Hill schools and departments:

- School of Medicine (Departments of Family Medicine, Medicine, Pediatrics, Obstetrics and Gynecology,

- Radiation Oncology, Psychiatry, Social Medicine, and Surgery),
- School of Pharmacy,
- School of Dentistry,
- School of Public Health (Departments of Epidemiology, Health Policy and Management, Health Behavior, Nutrition, and Maternal and Child Health),
- School of Nursing, and
- School of Social Work.

NARRATIVE REVIEW OF SHEPS CENTER RESEARCH, TECHNICAL ASSISTANCE, AND TRAINING ACTIVITIES

The Sheps Center currently focuses the majority of its research, technical assistance, information dissemination, and educational activities in 11 areas (*Aging, Disability, and Long-term Care; Child and Adolescent Health Services; Health Care Economics and Finance; Health Care Organization; Health Disparities; Primary Care; Medical Practice and Prevention; Mental Health and Substance Abuse Services and Systems; Rural Health; Health Workforce; and Women's Health Services*), however the Center remains responsive to new issues.

The value of conducting studies in each of these areas is assessed continuously, and other areas of potential concentration are explored periodically to ensure that the Center applies its resources as productively as possible to questions of particular importance. In addition, since 1994 the *North Carolina Institute of Medicine* (NC•IOM) has been administratively linked with the Sheps Center. In 2014, Dr. Adam Zolotor became the Interim President of NCIOM, as Dr. Pam Silberman stepped down as President.

In mid-2013, the *Sheps Center* established a dynamic new program, **Health Workforce**, directed by Dr. Erin Fraher. The Program has already received funding from the Health Resources and Services Administration (HRSA) as a center of excellence. Also in 2013, Dr. Dan Jonas assumed leadership of the **Program on Medical Practice and Prevention**, taking over from Dr. Pignone and Dr. Harris, who directed the program for a decade. In 2014, Dr. Betsy Sleath became Director of the Program on Child and Adolescent Health, as Dr. Eliana Perrin assumed more University responsibility as an Associate Vice Chancellor for Research. This program has recently been renamed the **Program on Child and Adolescent Health** to better reflect the scope of research interests. Dr. Marisa Domino recently became the leader of the **Mental Health and Substance Abuse Services**

Program, as Dr. Morrissey stepped down after many years of service. Dr. Domino also was welcomed as the new Training Program Director for the **UNC-Duke Training Program in Mental Health Systems & Services**. For the purposes of this report, we discuss the organization and leadership that was present for most of the 2013-14 year.

Two key changes in the Center are noteworthy at this time. In the fluctuating landscape of health care research, expanding resources for the Sheps Center are the Patient Centered Outcomes Research Institute (PCORI) and the Centers for Medicare and Medicaid Services (CMS) Master Task Order Contracts. These federal contracts are competitive and have increased our partnerships with other agencies such as *RTI International* and *American Institutes for Research (AIR)*. Over the past few years, we have had early success with both organizations, adding to the portfolio of funders of health services research at UNC. Center affiliated faculty are also continuing their relationships with NIH, HRSA, AHRQ and other traditional funders of health services research.

The expiration of American Recovery and Reinvestment Act (ARRA) grants and contracts has posed challenges to the Sheps Center, with decreases in funding in some areas. Sheps Center leadership is working with the program directors and investigators to strategically focus on care quality improvement, workforce, implementation research and other areas of rapid development in health services research. The deputy and associate directors meet weekly with the director to discuss Center administration, upcoming grant proposals, and center external relations. Seminar series are open to all staff and University collaborators. A *Staff Liaison Committee* includes staff from each of the programs and support areas. This committee meets monthly and plans activities to improve Center cohesion and mission. A newly designed external website and internal-only "intranet" has features that promote Center **services**, events, idea sharing, and security awareness. Each of these forums has greatly facilitated the sharing of knowledge and expertise among projects and with campus and research partners. --- The Center's IT infrastructure available to the 11 research program areas and to research partners include: primary and secondary data management and analysis (primarily using SAS); web and database systems design and development; and, technical support and systems administration for our secure computing environment. Noteworthy items from the year include an expansion of our health care utilization secondary data services, enhanced data reporting techniques using SAS, supporting more than 30 research projects with customized web/database systems in production for project management and primary data collection, groundbreaking data visualization techniques via the web, migration to a next generation flexible server infrastructure for all computing services, SANS GSEC security training certification for our lead systems



Dr. Tim Carey announced on May 22nd that he had decided to step down as director of *The Cecil G. Sheps Center for Health Services Research* after 15 years.

He will continue to be on faculty at the UNC School of Medicine and will continue to conduct health services research at the Sheps Center. Barbara Entwisle, UNC-CH Vice Chancellor for Research, attended the announcement and thanked Carey for his service to the Center and the University. She said that while she was sad to see him step down, she was hopeful that the new director will be an equally accomplished researcher and leader. Dr. Entwisle formed a search committee for a national search to fill the Director position.

administrator, and security awareness training for *all* users of the Center's systems.

Each Sheps Center program is briefly described below, with component projects listed. Some of the completion dates occurred during the duration of this report, however, some of the projects may be in a no-cost extension. Additional detailed materials for Fiscal Year 13-14 at the Sheps Center may be found in the Appendices of this Report ([link here](#)).

Program on Aging, Disability, and Long-term Care

Phillip D. Sloane, M.D., M.P.H. and Sheryl Zimmerman, Ph.D., Co-Directors

The rapid growth of the nation's older population has increased awareness of the health service needs of older adults, and also made clear the significant demands on families and professionals who deliver health services to this population. Consequently, the primary aim of the **Program on Aging, Disability, and Long-term Care** is to improve the well being of older persons with chronic and acute illness, as well as that of their caregivers. The program emphasizes factors that affect functional status and promote self-care, independent living, and quality of

life among older adults. In addition, the program embraces a concern for the extent, quality, and availability of long-term care services for persons of any age, and for programs that address the special needs of people who have impairments. Dementia care, end-of-life care and hospice, person-centered care and practices, medication administration, caregiver training and education, falls prevention, mouth care, lighting, health care screening, nursing services, and a host of other topics are special areas of research focus.

Program Highlight: The Toolkit for Person-Centeredness in Assisted Living

The [Toolkit for Person-Centeredness in Assisted Living](#) was developed through a close partnership between the University of North Carolina at Chapel Hill and the national Center for Excellence in Assisted Living (CEAL), along with assisted living providers, residents, family members, and organizational representatives. Available for free download, the Toolkit includes questionnaires to be completed by assisted living residents and staff, and simple, easy-to-follow instructions for scoring and interpreting the results. The questionnaires measure Person-Centered Practices in Assisted Living, and are called the PC-PAL. Unlike other questionnaires that often are used, the PC-PAL questionnaires are based on research evidence and have been rigorously tested for ease of use and statistical validity.

The following research projects were active during the year:

Accelerating Change and Transformation in Organizations and Networks (ACTION II) – Note: This is a Master Task submission; there are no specific tasks for this master contract proposal. The goal of ACTION II is to promote and accelerate the development, implementation, dissemination and sustainability of evidence-based innovation in health care delivery and organization to measurably improve health care in the U.S. In support of this goal, ACTION II will focus on practice-based research to achieve the following four objectives: (1) implementation of a proof of concept, through which a previously untested innovation is tested on a small scale to demonstrate its feasibility for addressing an identified problem; (2) implementation of an innovation or improvement approach to provide information for decision-makers about structural, contextual and process factors that play a critical role in increasing (or reducing) the chances that a proven, evidence-based innovation will actually work in a given setting; (3) spread, or the taking to scale, of one or more proven innovations or delivery system improvements, including the active, wide dissemination of information about what works, accompanied by concrete guidance on

how to maximize the likelihood of successful implementation and sustainability; and (4) sustainability, to increase knowledge about the factors that contribute to, or impede, the long term sustainability of innovation. *Principal Investigator: Sheryl Zimmerman, PhD*
Funding Source: AHRQ via Abt Associates, Inc
Project Period: 07/01/10 – 06/30/15
Total Funding: \$0

A University-AAA-State Partnership to Understand the Link Between Primary Care Physicians and Aging Service Providers in the Support of Persons with Alzheimer's Disease and Related Disorders (ADRD) – Engaging physicians with ADRD service providers is a challenge. Under a 2008-2010 Innovation Grant, a partnership between the university-based Carolina Alzheimer's Network (CAN), two Area Agencies on Aging, and the NC Division of Aging and Adult Services, recruited and trained 16 primary care physicians, engaged them with ADRD services providers, and generated 75 new ADRD patient and family referrals. To determine whether this project should be continued and replicated, however, more information is needed about this program and its outcomes. In this project, related information will be obtained from 30 primary care physicians and a sample of the family caregivers who provide support to their patients with dementia. *Principal Investigator: Philip Sloane, MD, MPH*
Funding Source: United States Administration on Aging
Project Period: 09/01/10 – 08/31/12
(extended through 08/31/13)
Total Funding: \$444,916

Improving Oral Hygiene Care in Nursing Homes: The Daily Mouth Care (Tooth Brushing) Program – This project will: 1) develop an evidence-based protocol, toolkit, and training materials for improving the mouth care of nursing home residents, with a focus on persons with dementia and physical impairments whose care is difficult to provide; 2) conduct a pre-post trial of the mouth care program in three nursing homes in North Carolina, evaluating the impact of the intervention on gingivitis, plaque index, completeness of oral hygiene care, and resident agitation during care; and 3) disseminate to all North Carolina nursing homes and selected other stakeholders a training DVD on mouth care in nursing homes that provides CEU credit for nurses and nursing assistants. *Principal Investigators: Phillip Sloane, MD, MPH, Sheryl Zimmerman, PhD*
Funding Source: NC Dept of Health and Human Services via FutureCare of North Carolina
Project Period: 10/01/10 - 12/31/13
Total Funding: \$221,709

Evaluation of the Use of iN2L Technology in North Carolina Nursing Homes - Through an application to The Duke Endowment (Charlotte, NC), FutureCare of North Carolina, Inc., the non-profit educational and research foundation of the North Carolina nursing home industry (the North Carolina Health Care Facilities

Association), is proposing to conduct an 18-month evaluation of the implementation and use of a touch-screen computer-based technology for use in nursing homes that has the intention of enriching the lives of long-term care facility residents through recreational/activities enabled through the use of this technology, and to extend the impact of specific therapies offered to residents of these facilities in occupational, physical and speech therapy. Under a special subcontract to FutureCare of North Carolina, Inc., the Sheps Center will provide essential services in evaluation study design, in resident, staff and family survey methodology, in primary and secondary data analysis, report preparation and presentation to relevant audiences in the long-term care field.

Principal Investigator: Kristie Thompson, PhD

Funding Source: Duke Endowment via FutureCare of North Carolina

Project Period: 01/01/14 - 06/30/15

Total Funding: \$196,454

Goals of Care: A Nursing Home Trial of Decision Support for Advanced Dementia

Dementia is a progressive syndrome of decline in cognitive function. For 5 million Americans with dementia, therapies slow progression but do not reverse or cure the disease. Nursing home care is common; 67% of people dying from dementia die in this setting and families act as surrogates in major health care decisions. Shared decision-making about goals of care is the ethical standard for serious illness, yet families report poor quality communication, decision-making and palliative care. Compared with decisions about using or withholding a treatment, the goals of care approach encourages discussion and agreement on the primary goals of medical care, followed by treatment decisions designed to meet agreed upon goals. The study is a cluster randomized, controlled trial to test a decision support intervention for surrogates considering goals of care in advanced dementia. The intervention has two components: an audiovisual decision aid followed by a structured interdisciplinary care plan meeting. Study subjects are 300 nursing home residents with advanced dementia and their surrogates, recruited from 20 sites, to meet these Aims: Aim 1. To test the effect of the Goals of Care intervention compared to usual care, on the quality of communication and decision-making, defined as: a) quality of communication; b) family - health care provider concordance on goals of care; and c) family report of treatment consistent with wishes. Aim 2. To test the effect of the Goals of Care intervention on quality of palliative care, defined as: a) number of palliative care domains addressed in the care plan; b) symptom management; and c) family satisfaction with care for advanced dementia. Aim 3. To test the effect of the Goals of Care intervention on quality of dying, measured as: a) family - health care provider concordance on goals of care, and b) comfort in dying. This research will provide the first empiric test of decision support for the goals of care framework in dementia care. It extends decision support research to surrogates, who make most

decisions on behalf of patients with serious and incurable illness. To permit future dissemination, the intervention design is pragmatic and well integrated with nursing home interdisciplinary care.

Principal Investigator: Laura Hanson, MD, MPH

Funding Source: National Institute on Aging

Project Period: 04/15/11 - 03/31/16

Total Funding: \$2,452,398

Outcomes of Green House Homes Compared to Other Nursing Homes: What Structures and Processes are Associated with Better Outcomes?

The primary aim of this study is to identify the essential components (structures and processes) of care that relate to resident outcomes in various skilled nursing settings, with a special focus on those structures and processes that are reflected in Green House (GH) homes. In addition to examining how outcomes differ by site (i.e., GH homes compared to traditional or high-end culture change nursing homes), we will explore what specific structures (e.g., staff roles, self-managed teams, physical environment features), processes (e.g., time spent in various activities such as assistance with activities of daily living, meals, communications, care planning, socializing with elder), and various combinations of structures and processes, are associated with better outcomes (i.e., avoidable transfers to hospital or emergency department; injurious falls; and pressure ulcer development). Data collection will be in four areas: resident and site characteristics, core processes, and outcomes. Main sources of data include a profile survey, resident Minimum Data Set (M.D.S) 3.0 data, observation of core processes, staff surveys and standardized interviews, and data worksheets completed during on-site visits.

Principal Investigator: Sheryl Zimmerman, PhD

Funding Source: Robert Wood Johnson Foundation

Project Period: 07/01/11 - 06/30/14

Total Funding: \$196,409

Assessing and Expanding the Knowledge Base on Culture Change in Nursing Homes

Through literature review/environmental scan, case studies, and consultations with the project Technical Advisory Group, this project will assess and expand the knowledge base on culture change in nursing homes (NHs) and explore the potential for NH culture change as a strategy to drive improvement in quality of care and life for individuals living in NHs and in the quality of jobs of those employed by NHs.

Principal Investigator: Sheryl Zimmerman, PhD

Funding Source: US DHHS

Project Period: 09/15/11 – 01/29/11

(extended through 08/31/13)

Total Funding: \$79,335

Developing a Toolkit of Person-Centered Care Quality for Assisted Living –The goal of this research project is to develop a toolkit of valid and reliable measures of person-centered care and outcomes for use by assisted

living administrators, staff, residents, their families, and others to improve care and outcomes. The project will use a community-based participatory research approach to achieve the following aims: (1) determine the structures, processes, and outcomes of person-centered care, both conceptually and operationally; (2) conduct cognitive testing of the items with AL staff and residents and modify the items as indicated; and (3) test the toolkit of revised items to determine feasibility, conduct exploratory factor analysis, assess reliability and validity, obtain estimates, and determine agreement among stakeholders.

Principal Investigator: Sheryl Zimmerman, PhD

Funding Source: National Institute on Aging

Project Period: 09/01/11 – 08/31/13

Total Funding: \$313,383

Individually Tailored Lighting System to Improve Sleep in Older Adults

- Exposure of the retina to light in the short-wavelength (blue) portion of the spectrum is the primary stimulus causing the human brain to synchronize circadian rhythms to the 24-hour light/dark cycle, resulting in daytime wakefulness and night-time sleep. Depending on its timing, spectrum, and intensity, a light stimulus can phase advance, phase delay, or have little effect on underlying circadian rhythms. Mediators and measures of this system include serum melatonin levels and the core body temperature (CBT), as well as activity/sleep. This proposed study will help translate recent research findings related to this physiological system to practical application in the treatment of persons with primary insomnia and other sleep disorders. In collaboration with scientists at the Lighting Research Center of Rensselaer Polytechnic Institute (Troy, NY), we will develop and evaluate a low-cost, minimally obtrusive device that delivers individualized light therapy to adults with early-awakening insomnia – the most common type of insomnia in older adults, and a significant problem because of its relationship to daytime sleepiness, use of potentially hazardous sleep medication, and reduced quality of life.

Principal Investigator: Philip Sloane, MD, MPH

Funding Source: NIH via Rensselaer Polytechnic Institute

Project Period: 07/01/12 – 06/30/17

Total Funding: \$1,440,330

Public Reporting on Housing with Support Services for Aged and Disabled Consumers

– Housing with supportive services (HSS) is non-institutional housing with essential services (e.g., assistance with activities of daily living, assistance with medication administration) to enable elderly and non-elderly adults with functional and/or cognitive impairments to live as independently as possible in a non-institutional setting. It is known by a variety of names, including residential care/assisted living (RC/AL), small group homes, and Section 8/202 housing; HSS is a type of care in the family of long-term services and supports. All told, 22% of the population aged 85 years and older lives in a setting with supportive services, 7% in community housing with supports, and 15% in long-term care settings. Lack of data in general and lack

of standardized and comparable data on HSS providers make it challenging for policy makers and funders to assess the quality of care and for consumers to make an informed choice among HSS options. Public reporting of information related to the quality of care is one option to compile and disseminate information to promote decision-making and potentially improve the quality of care. Public reporting has become commonplace for various health services and sectors, but in terms of HSS it is not uniformly available and some of what is available is misleading and may not be achieving its intended purpose. Consequently, the purpose of this conference is for key stakeholders in public reporting on HSS to advance the science of public reporting on HSS.

Specifically, the conference will assess: (a) how far the field has advanced (e.g., what information is available on key issues such as services provided, costs, accessibility, staffing); (b) what has yet to occur to promote successful public reporting (e.g., the optimal strategy with which to obtain information from providers and the use of best practices to assure the information is used by consumers and consumer intermediaries); and (c) how to prioritize next steps related to public reporting. The conference proceedings will disseminate findings related to the content of the available information; its quality (e.g., data quality, computer usability, use by consumers and consumer intermediaries); its source, comprehensiveness, and geographic reach; and recommended next steps. They will be suitable for posting on the websites of AHRQ, CMS, and others. A second product will be a peer-reviewed manuscript for academic audiences, and a third will be an article suitable for HSS providers.

It is expected that this conference will make great strides in promoting the science, availability, and use of public reporting for housing with supportive services for aged and disabled consumers.

Principal Investigator: Sheryl Zimmerman, PhD

Funding Source: Agency for Healthcare Research and Quality (AHRQ)

Project Period: 08/01/12 – 09/29/13

Total Funding: \$49,636

Alzheimer's Medical Advisor A Symptom and Sign Management Toolkit for Caregivers

- Most persons with Alzheimer's disease (AD) live at home with informal (usually family) caregivers who must evaluate, manage, and communicate with health care providers about medical symptoms (e.g., pain and shortness of breath) and signs (e.g., fever and agitation). As dementia progresses, susceptibility to comorbid illness increases, communication and decision-making capacity are reduced, and transport to medical facilities becomes increasingly difficult. As a result, informal caregivers need tools that will help them evaluate, make decisions about, and manage symptoms and signs that could represent new or evolving medical illness. The proposed project will develop, field test, refine, evaluate, finalize, and disseminate the Alzheimer's Medical Advisor (AlzMA), a multi-component website that will assist informal caregivers of persons with AD to identify, evaluate, and manage new or increasing symptoms and

signs of illness and then, if necessary, clearly and effectively communicate the information to health care providers. This project represents a collaboration of teams from the University of North Carolina at Chapel Hill; the Duke Family Support Program; and Horizon Productions. *Principal Investigator: Philip Sloane, MD, MPH*
Funding Source: National Institute of Nursing Research
Project Period: 09/01/12 – 06/30/15
Total Funding: \$2,541,922

An RCT of an Educational Video to Improve Nursing Home Care in End/Stage Dementia – Alzheimer’s disease afflicts over 5 million Americans and is the 6th leading cause of death in the U.S. To date, advanced dementia research has largely focused on describing the end-of-life experience of patients with this disease. Designing and testing interventions targeting those opportunities is the current research priority for this field. Advance care planning (ACP) is the most consistent modifiable factor associated with better palliative care outcomes in advanced dementia. The opportunity for ACP is exceptional in advanced dementia but often inadequate. Thus, advanced dementia patients often get aggressive interventions that may be inconsistent with preferences and of little clinical benefit. Recent work has particularly underscored the need to avoid unwanted and unnecessary hospitalizations among these patients. Traditional ACP primarily relies on ad hoc verbal descriptions of hypothetical health states and treatments. This approach is limited because complex scenarios are difficult to envision, information from providers is inconsistent, and verbal explanations are hindered by literacy and language barriers. To address these shortcomings, the co-PIs have developed video decision support tools for ACP and shown their efficacy in several randomized controlled trials (RCTs) in out-patient settings. The over-riding goal of the EVINCE (Educational Video to Improve Nursing home Care in End-stage dementia) study is to conduct a cluster RCT of an ACP intervention vs. control among 360 nursing home (NH) residents with advanced dementia (N=180/arm) in 20 matched NHs (10 intervention/10 control). At baseline, proxies in the intervention NHs will view a video ACP decision support tool. Their preferred level of care (comfort care, limited care, life prolonging care, or uncertain) ascertained ~ 10 minutes after the video will be communicated to the primary care team. Proxies in the control NHs will experience usual ACP practices. The Aims are: Aim 1: To compare proxies’ preferences for the residents’ level of care in the intervention vs. control NHs at baseline (10-minutes post video in intervention NHs), 3, 6, 9 and 12 months. Aim 2: To compare the % of residents with ACP in the intervention vs. control NHs at 3, 6, 9, and 12 months as measured by documented: 1. Decisions to forego hospitalization; 2. Decisions to forego other treatments (tube-feeding, parenteral therapy), and 3. Goal of care discussions; and Aim 3: To compare the % of residents with hospital transfers and other burdensome treatments over 12 months in intervention vs. control NHs. A documented decision to forego hospital transfers by 6

months will be the primary outcome of this RCT. Impact: Better ACP is a key opportunity to improve advance dementia care. Video decision support is a practical, evidence-based, and innovative approach to ACP. If this RCT is successful, this will be one of the first rigorously tested interventions shown to improve outcomes for NH residents with advanced dementia. This work could have significant clinical and policy implications for the millions of Americans dying with this disease by promoting care that is more consistent with their preferences and that is less burdensome and costly. *Principal Investigator: Laura Hanson, PhD*
Funding Source: Hebrew Rehabilitation Center
Project Period: 9/30/12 - 8/31/17
Total Funding: \$150,048

Daily Mouth Care to Prevent Pneumonia in Nursing Homes: A Systems-Level Approach - Every year, almost two million episodes of pneumonia are suffered by nursing home (NH) residents across the United States, resulting in more deaths than from any other infection. Further, NH residents acquire pneumonia at a rate 6-10 times higher than older adults in the community, indicating that characteristics of these individuals and/or the NH setting put them at increased pneumonia risk. Pneumonia is an inflammatory condition usually initiated by the introduction of bacteria into the lung, such as through aspiration. In aspiration, contents from the mouth, throat, or stomach that are colonized with pathogenic bacteria are inhaled into the lungs. Poor oral hygiene is therefore a critical risk factor for pneumonia because it increases the volume and infectious nature of secretions from the mouth and throat. The objective of this project is to determine whether and to what extent pneumonia incidence in NH residents can be reduced by training nursing assistants and supervisory nursing staff to provide a pragmatic, system-level, comprehensive mouth care program to all NH residents, including use of a dedicated oral care aide. *Principal Investigator: Sheryl Zimmerman, MSW, PhD*
Funding Source: AHRQ
Project Period: 09/01/13 - 06/30/18
Total Funding: \$2,475,546

2013 ASPIRE US Vaccines_Streptococcus Pneumonia in Older Adults in Retirement Community (SOAR) - We propose to work with one of the nation’s most experienced long-term care research groups to study S. pneumoniae carriage, serotypes, and antibiotic susceptibility among the growing population of older adults living in retirement communities and extended care. 1.To measure the prevalence of pneumococcal carriage, circulating pneumococcal serotypes, and antibiotic susceptibility of pneumococcal isolates from older adults living in retirement communities and extended care. 2.To examine the above endpoints among individuals with increased risk of pneumococcal infection, such as diabetes mellitus, chronic pulmonary disorders, or other immunocompromising conditions. 3.To identify potential target populations for PCV-13

immunization, by finding independent risk factors for pneumococcal carriage. Setting. 3 retirement communities in central North Carolina, and the extended care facility of the Durham Veterans Affairs Medical Center. Participants. 400 adults > 65 years of age, recruited with equal distributions from skilled nursing facilities (SNF), assisted living (AL), and independent retirement community settings. Exclusion criteria include: moderate or severe dementia, receiving hospice care, and non-English speaker. Design. After obtaining consent and HIPAA waiver, a nasopharyngeal swab will be collected from each participant. Specimens will be cultured for *S. pneumoniae*, and analyzed for serotype and antibiotic susceptibility using methods developed by the CDC. In addition, a survey will be administered to all participants to assess chronic diseases, potential risk factors for pneumococcal carriage, and prior pneumococcal and influenza immunization status. A chart review will be performed to confirm immunization history, and record chronic conditions difficult to capture by self-report (e.g., chronic renal failure). Statistical Analysis. Prevalence of carriage will be estimated by dividing numbers of positive cultures by numbers of participants. Similarly, prevalence will be estimated by group, such as living location (SNF, AL, community), specific chronic illnesses, and three levels of co-morbidity burden based on the Charlson Comorbidity Index (Katz, 1996). Proportions of adults with carriage will be compared between groups using the Z statistic for comparison of binomial proportions. Distributions of serotypes and antibiotic susceptibility patterns of the isolates will be described, and the proportion of identified serotypes which are included in PCV-13. Finally, we will examine independent risk factors for carriage using multivariate logistic regression. Implications. Our study will: 1) Measure circulating serotypes and antibiotic resistance of *S. pneumoniae* in this population, and the potential benefit of PCV-13; 2) Generate information on the possibility for herd protection in this population; and 3) Identify individuals at higher risk of carriage, which would enable prioritization of immunization to protect the community.

Principal Investigator: Sylvia Becker-Dreps, MD, MPH

Funding Source: Pfizer, Inc.

Project Period: 10/01/13 – 10/01/14

Total Funding: \$99,999

Infection Management and Antibiotic Stewardship in Nursing Homes

– Antibiotic stewardship (i.e., promotion of appropriate antibiotics to improve outcomes, reduce antibiotic resistance, and decrease the spread of multidrug-resistant organisms) is an innovation increasingly viewed as urgent for the care of nursing home (NH) residents. Reasons underlying the call for antibiotic stewardship in NHs include an increasing prevalence of healthcare-associated infections with multidrug resistant organisms, high rates of use, and estimates suggesting that some prescriptions may not be needed. Challenges to reducing “potentially inappropriate” antibiotic use are many, however, and relate to the NH structure, prescribing processes, and patient characteristics. The proposed implementation and

dissemination project, conducted by a multidisciplinary team with extensive experience in the field, seeks to identify and field test the best methods for promoting antibiotic stewardship in nursing homes. Approximately 33 nursing homes in North Carolina will be involved in the study.

Principal Investigator: Phillip Sloane, MD

Funding Source: AHRQ

Project Period: 05/01/14 - 04/30/17

Total Funding: \$498,698

Program on Child and Adolescent Health Services Research

Betsy Sleath, Ph.D., R.P.H., Director

Barriers to quality health care services for children and adolescents, as well as racial and regional disparities in child and adolescent health status, persist throughout the United States. To address the challenges these realities present, the **Program on Child and Adolescent Health Services** focuses on ways to ensure the development, implementation, and evaluation of high quality, evidence-based services for children and adolescents. Researchers strive to find innovative ways to empower children, adolescents, and their families to become more active participants in their care, and conduct research to evaluate interventions and programs that address health status and disparities. The program also provides technical assistance to policymakers, advocates, and health care providers. Investigators work with national, regional, state, and local organizations and agencies to improve child and adolescent health through research that assures that health care services will be accessible, affordable, comprehensive, coordinated, community-based, child and family-centered, and culturally competent. Current areas of investigation include: mental health and well-being, obesity, asthma, children with complex health care needs, Latino health, provider-patient communication, community-based participatory research, immunization, quality-of-life in children with cancer, and interventions to promote positive parenting skills.

The following research projects were active during the year:

Padres Efectivos (Parent Activation)- Skills Latina Mothers use to get Healthcare for Their Children - Latinos are the largest and fastest growing minority population in the US; by 2050, 2 in 5 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.

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. The 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 and disparities with wide-ranging impacts consistent with PCORI's research agenda.

Principal Investigator: Kathleen Thomas, PhD

Funding Source: Patient Centered Outcomes Research Institute(PCORI)

Project Period: 08/01/13 - 07/31/16

Total Funding: \$1,249,005

Evaluation of the NC Healthy Start Baby Love Plus Program to Address Racial Disparities in the Eastern, Northeastern, and Triad Regions of North Carolina –

This project is a partnership between the Sheps Center's Program on Child Health Services and the NC DHHS Division of Public Health. Since 1996, the Sheps Center team has worked closely with colleagues at the Division of Public Health in the continued development of the enhanced maternity care coordination and outreach program, as well as identifying special areas of concern to improve perinatal health outcomes in some of the poorest counties of our State. The goal of the program is to reduce disparities in infant mortality through strengthening community capacity and enhanced individual perinatal services in Bertie, Edgecombe, Greene, Martin, Pitt, Tyrrell, and Washington counties (East); Gates, Halifax, Hertford, Nash, and Northampton counties (Northeast); and Forsyth and Guilford counties (Triad). We provide information on birth outcomes, use of perinatal health services, associated costs, and consumer satisfaction using primary and secondary data, including vital records, Medicaid claim data, Health Department administrative records, and a series of community surveys. The combined effort of the Sheps Center and NC Division of Public Health's *Baby Love Plus* Program has resulted in over \$14 million in federal awards from the Maternal and Child Bureau, HRSA, DHHS.

Principal Investigators: Milton Kotelchuck, PhD (97-01) and Julia L. DeClerque, DrPH (since 2001)

Funding Source: Maternal and Child Health Bureau, U.S. Department of Health and Human Services via subcontract with N.C. Department of Health and Human Services

Project Period #1: 12/97 – 06/01 Funding: \$1,021,031

Project Period #2: 07/01 – 06/05 Funding: \$947,324

Project Period #3: 07/05 – 05/13 Funding: \$610,050

Project Period #4: 07/13 – 05/14 Funding: \$123,777

Project Period #4: 08/01/14 - 08/31/14

Total Funding: \$11,669

Secondary Program Area: Women's Health Services Research

Evaluation of the NC Healthy Start Baby Love Plus

(all 3 Regions: East, Northeast, Triad) – The purpose of this research is to continue the ongoing evaluation of the North Carolina Healthy Start Initiative, currently in seven rural Eastern counties, two urban counties (Triad), and five rural Northeastern counties of the State. This infant mortality reduction initiative of the North Carolina Department of Health and Human Services Division of Women's and Children's Health, funded since 1997 by the federal Division of Healthy Start of the Health Resources and Services Administration, US Department of Health and Human Services, enhances the current North Carolina Baby Love Program offered in geographic areas of high minority infant mortality. This initiative was designed to reduce disparities in infant mortality through enhanced community capacity, outreach, and individual case management perinatal services.

Principal Investigator: Julia L. DeClerque, DrPH

Funding Source: (NCDHHS)

Project Period: 06/01/10 – 05/31/11 Funding: \$177,675

Project Period: 06/01/11 – 05/31/12, extended through 09/09/12 Funding: \$165,213

Project Period: 06/01/13 – 05/31/14

Total Funding: \$123,377

Since its inception, the Child and Adolescent Health Services Program has included projects which were primarily technical assistance in nature, several aimed at improving the planning and evaluation skills of maternal and child health (MCH) leaders at the state and local levels primarily in the Southeast. The following technical assistance project was active this year:

Time to Conceive Pregnancy Cohort-Ovulation Add-On Study-

This contract was to design and implement modifications and enhancements to the existing Time To Conceive online data system study in order to allow additional data collection instruments and event tracking. The Sheps Center's programming team modified the web-based data collection and participant tracking system used in Dr. Anne Steiner's Time To Conceive study to provide a new protocol, implement two additional data collection forms, and prepare for data extractions and analysis.

Principal Investigator: Roger Akers

Funding Source: SSI/NIEHS

Project Period: 10/01/13 - 6/30/14
Total Funding: \$16,097
Secondary Program Area: Women's Health Services Research

A Comprehensive Review of State title V Performance Indicators and Needs Assessments – The federal Title V program is an important legislative provision that acknowledges the needs of the nation's mothers and children and provides the financial mechanism to support the states and other agencies in their efforts to improve maternal and child health. Many problems faced by mothers and children throughout the country are the same across the country, but states also face unique problems and state MCH programs are in the best position to assess the needs of the population they serve, design programs to address these needs, and evaluate success. The Maternal and Children Health Bureau (MCHB) operating within the Health Resources and Services Administration (HRSA) administers the Title V program and works with the states in a partnership that acknowledges the unique abilities and concerns brought to MCH issues by each State. Title V support has evolved over time in terms of both how funds are provided to the states and how the states must account for how they use them to further the cause of women and children they serve. Change from categorical programs to block grants recognizes the needs of individual states to address their own problems. With increased flexibility in use of federal funding for program implementation comes the obligation to account for how those dollars are spent and what impact they have on the lives of the target population. The evolution of accountability has occurred over the past 25 years. A needs assessment, required every five years, was the first accountability measure to be required and mandated performance measures were second, instituted in 1997. Both the states and MCHB have worked well in partnership to implement these accountability measures and to ensure that information reported by the states is of the most value possible and not submitted in a vacuum. To this end, MCHB makes state plans and performance data available to the public via the Title V Information System. In addition, MCHB uses information submitted by the states to examine trends in needs and performance and to inform change within the Bureau to meet their overall goal to assist mothers and children by responding to state MCH needs. This project uses the wealth of information provided by states as part of the needs to examine trends in the priorities states set for addressing maternal and child health needs. Among the information that has been examined are aggregate changes in states' priority needs, those areas where states will focus their efforts in the next 5 years, which are realigned as appropriate during each needs assessment process. Also examined are state performance measures, i.e., those unique measures developed by states in response to their identified priority needs, as well as other performance measures and indicators that are part of MCHB's exemplary performance reporting system. Focus on needs assessment and evaluation of performance has multiple benefits. Understanding the shifting health and health care

landscape for mothers and children allows states and the Bureau to plan and use their limited resources wisely. Analysis of trends and individual state performance also can provide valuable information for others as promising practices in individual states are identified.

Principal Investigator: Victoria Freeman
Funding Source: Maternal and Child Health Bureau, HRSA, USDHHS

Project Period: 09/28/11 – 09/27/13

Total Funding: \$150,973

Young Parents Connect 13-14 - The purpose of this research is to evaluate of the North Carolina Support for Expectant and Parenting Teens, Women, Fathers and Their Families project (Young Parents Connect), serving five counties – Bladen Nash, Onslow, Rockingham and Wayne. This adolescent health initiative of the North Carolina Department of Health and Human Services Division of Public Health / Women's and Children's Health Section, funded by the federal Office of Adolescent Health, Office of the Assistant Secretary for Health, US Department of Health and Human Services, enhances the previous North Carolina Young Mothers Connect offered in counties with demonstrated need for (1) self-sufficiency (high drop-out rates in grades 7 – 12, high poverty rates); (2) parenting skills (high rates of substantiated child abuse and neglect case), utilization for preventive care services for children, late entry into prenatal care, unmet need for family planning services, maternal tobacco use and poor pregnancy and birth outcomes (short birth interval, repeat teen pregnancy.. This initiative was initially designed to reduce infant mortality through enhanced community capacity, responsibility, and ownership of infant mortality reduction efforts and enhanced individual perinatal services. Since 1997, federal funding for this project has centered on reducing racial disparities in infant mortality and most recently includes components for screening and treatment of perinatal depression as well as targeted case management for high-risk families in the interconceptional period who are enrolled in the Medicaid program. Using primary and secondary data (including: vital records, Medicaid files, health department administrative records, and community surveys), information on birth outcomes, use of perinatal health services, associated costs, and consumer satisfaction is being provided to program staff to use for on-going evaluation and program planning. The community surveys are conducted using a combination of in-person interviews, telephone interviews, public "intercept" interviews, and group interviews. This Initiative involves four component intervention models, which are purposefully overlapping and integrative: 1) Community-based Consortium, 2) Care Coordination/Case Management, 3) Outreach and Client Recruitment, and 4) Education and Training Services. Community-based Consortia have been formed as joint efforts between the project counties in each Region, and serve in an advisory capacity for the program. They assist with program planning, operations, monitoring, and evaluation. The Care Coordination and Case Management portion of the

program enhances the current Pregnancy Medical Home, Care Coordination services provided by the State. The Outreach and Client Recruitment effort involves Community Health Advocates who function as case-finders in the community and provide population-based education and assist families with accessing and using local perinatal health services. And the Education and Training efforts are intended to improve knowledge and skills of consumers, public health service workers, and community leaders with respect to infant mortality issues and risk factors. The North Carolina Healthy Start Initiative is in its fifth cycle of federal funding. The upcoming contract year will be the fifth of a five-year cycle for the Triad Region, the fourth of a five-year cycle for the East Region and the final year of a two-year cycle for the Northeastern Region.

Principal Investigator: Julie DeClerque, DrPH

Funding Source: NCDHHS Division of Public Health

Project Period: 01/17/14 - 07/31/14

Total Funding: \$259,922

Program on Health Care Economics and Finance

Sandra B. Greene, Dr.P.H. and George “Mark” Holmes, Ph.D., Co-Program Directors

A central concern in the health care system is the rising cost of services and the growing realization that resources are limited. The Sheps Center’s **Program on Health Care Economics and Finance** continues to focus on both the general economics of personal health services as well as the specifics of program and organizational finance. In the former category, the Center’s emphasis is on issues of fair and effective distribution of resources, both public and private. In the financial sector, issues of efficiency and productivity in delivery units and targeted programs are examined.

The following research projects were active during the year:

Cardiovascular Outcomes Research Center for Atherosclerosis Risk in Communities (ARIC) – The Atherosclerosis Risk in Communities Study (ARIC), sponsored by the National Heart, Lung, and Blood Institute (NHLBI) is a prospective epidemiologic study being conducted in four U.S. communities (Forsyth County, NC, Jackson, MS, suburban Minneapolis, MN, and Washington County, MD). ARIC is designed to investigate the causes of atherosclerosis, clinical outcomes, and variation in cardiovascular risk factors, medical care, and disease by race, gender, and location over time. To date, the ARIC project has published over 800 articles in peer-reviewed journals. Starting in November 2010, NHLBI provided funding for an ARIC Cardiovascular Outcomes Research Center (CORC) based at the Sheps Center. The multi-disciplinary research team, led by Sally Stearns, is composed of health economists, cardiologists, internal medicine clinicians, epidemiologists, and faculty in cardiovascular pharmacy

practice. ARIC includes two components: a Cohort Component, which has tracked a sample of approximately 16,000 people who were age 45-65 in 1987 through five clinic visits and annual telephone follow-up; and a Community Surveillance Component. Detailed hospital record abstractions (for heart failure, stroke, and coronary heart disease) and Medicare claims data are available for both components. The CORC is currently conducting five studies using the Cohort Component: (1) an overview of the potential for outcomes research in an ongoing epidemiologic study; (2) the association of anger-proneness with increased risk of onset of heart failure; (3) the association between Medicare claims for antihypertensive medications among persons self-reporting hypertension and subsequent cardiovascular outcomes; (4) socio-demographic and health-status factors associated with self-reported medication adherence; and (5) the effects of medication adherence following hospital discharge and subsequent readmission for persons with heart failure.

Principal Investigator: Sally Stearns, PhD

Funding Source: National Heart, Lung, and Blood Institute (NHLBI)

Project Period: 11/01/10 - 10/01/14

(extended through 11/14/16)

Total Funding: \$2,929,978

Master Task Order-Advisory and Assistance Services in the Areas of Health Care Financing and Medicare –

Note: This is a Master Task submission; there are no specific tasks for this master contract proposal. This master task, MedPAC, order allows UNC and the Sheps Center to compete for an indefinite number of specific tasks for the Medicare Payment Advisory Commission.

Principal Investigator: Mark Holmes, PhD / Marisa Domino, PhD

Funding Source: Medicare Payment Advisory Commission

Project Period: 10/01/11 - 09/30/16

Total Funding: \$0

HRSA Evaluation Studies IDIQ Master Task Order . Domain 1: Assessment of Effectiveness and Efficiency of HRSA-Supported Programs-Operations, Outcomes and Performance and Analysis of Contextual/Policy Issues which may Impact HRSA-Supported Activities – This application from the Cecil G. Sheps Center for Health Services Research (the Sheps Center) at The University of North Carolina at Chapel Hill (UNC-CH) responds to RFP 13-250-SOL-0005, Domain One. We propose to provide focused, high-priority, short-term evaluation activities in support of various Bureaus and Offices within the Health Resources and Services Administration (HRSA). Specifically we will conduct assessments of the effectiveness and efficiency of HRSA supported programs and their operations, outcomes, and performance as well as analysis of contextual and/or policy issues which may impact HRSA supported activities. The core investigative team is drawn from senior research fellows at the Sheps Center who also have faculty appointments at the

Department of Health Policy and Management within the School of Public Health. Additional investigators affiliated with the Sheps Center or School of Public Health will be available according to specific project needs, including faculty from the School of Medicine.

Principal Investigator: G Mark Holmes, PhD

Funding Source: HRSA/ Office of Acquisition Management and Policy

Project Period: 09/27/13 – 09/26/18

Funding Period: 09/27/13 – 09/26/14

Total Funding: \$2,500

Program on Healthcare Engineering Research

Stephen D. Roberts, Ph.D., Program Director

The **Healthcare Engineering Research Program** is an affiliation with the North Carolina State University Edward P. Fitts Department of Industrial and Systems Engineering and with the Personalized Medicine Faculty Cluster (consisting also of faculty from Statistics and Mathematics) at NC State through the Chancellor's Faculty Excellence Program. The purpose of Healthcare Engineering is to develop "analytics" that support the optimal allocation of scarce health resources in the delivery of health care and the optimal treatment decisions for individual patients based on diverse information.

Quantitative methods provide a complement to experimental methods for the evaluation and design of new health e delivery programs and health policy. The relationship within Sheps provides a cross-university collaboration whose shared interest is in improving the access, quality, and cost of health care.

Some of the projects in this NC State/UNC collaboration include the following:

Simulating donor liver availability and quality - Maria Mayorga, Stephanie Wheeler (UNC), A. Sid Barritt (UNC) and Eric Orman (Indiana).

Model for colorectal cancer screening compliance and long-term outcomes - Maria Mayorga, Kristen Lich (UNC) and Mike Pignone (UNC).

Predicting health and economic outcomes associated with smoking cessation interventions - Maria Mayorga, Kristen Lich (UNC) and Jennifer Pearson (American Legacy Foundation).

Comparing methods of modeling patient choices and behaviors - Maria Mayorga and Stephanie Wheeler (UNC).

Modeling the complex interaction between comorbidities: breast cancer and diabetes - Maria Mayorga, Julie Ivy, Jennifer Mason (UVA) and Kelly Hunt (MUSC).

Health Systems Engineering Certificate Program - Stephen Roberts.

Whole Hospital System Efficiencies - Stephen Roberts.

Optimization of Agent-Based Simulation for Health Care Systems - Stephen Roberts.

Simulating Individual Choice in Colorectal Cancer Screening - Maria Mayorga and Stephen Roberts.

Optimal Design of the Seasonal Influenza Vaccine with Manufacturing Autonomy - Osman Ozaltin.

Machine Learning Methods for Annual Influenza Vaccine Update - Osman Ozaltin and Rui Song.

Eliciting Lipid Management Guidelines' Valuation of Future Life - Osman Ozaltin, Murat Kurt and Brian Denton.

An Optimization Framework to Improve Patient Safety in Radiation Therapy Care Delivery - Julie Ivy and Lukasz Maszur (UNC).

Bedside Patient Rescue - Julie Ivy, Muge Capan (Christiana Care), and Jeanne Huddleston (Mayo Clinic).

Modeling to inform decision making regarding Mode of Delivery - Julie Ivy, Vidyadhar Kulkarni (UNC), Evan Myers (Duke), Meera Viswamanathan (RTI) and Reed Johnson (Duke).

Modeling Ductal Carcinoma in situ (DCIS) pathways within a population - Julie Ivy, Louise Henderson (UNC), and Shengfan Zhang (Arkansas).

Program Highlight: Model for colorectal cancer screening compliance and long-term outcomes

By Maria Mayorga, Kristen Lich, Mike Pignone, Stephanie Wheeler and Lich Hassmiller.

This project reflects a strong collaboration between NC State, the Sheps Center, UNC HPDP, UNC SPH/SOM, and ICISS/Lineberger researchers.

In collaboration, the UNC and NC State team built a detailed model of individuals' choice and response to public health interventions to create a model of colon cancer progression. This enables researchers to estimate the cost-effectiveness of these interventions in terms of long-term health outcomes when applied to a population of individuals.

Colorectal cancer (CRC) screening rates are sub-optimal, particularly among vulnerable populations. However, there is little guidance available for policymakers about how to prioritize investment for effective interventions. The goal of this project is to model the effectiveness and cost-effectiveness of evidence-based statewide interventions aimed at both improving CRC screening in vulnerable North Carolina adults aged 50-75 and reducing screening disparities among these groups. To this end, we develop a simulation model of colorectal cancer in a heterogeneous population of individuals.

The progression of cancer is modeled and is affected by individuals' characteristics and their receipt of screening and mode of screening. Multi-level statistical models are used to determine individual screening outcomes. We present a framework for analyzing interventions that affect final outcomes by systematically affecting a change in individual screening patterns. Moreover, recognizing that sub-populations respond differently to interventions, we present a procedure for choosing the most effective intervention.

For this cancer model, we evaluate the cost effectiveness of public health interventions that affect people's screening behavior, using both short term outcomes such as percent up-to-date with screening and downstream outcomes such as life years lost to cancer. We use a census-based comprehensive synthetic population that represents the population of the State of North Carolina to project intervention effects and screening demand at the population level.

Program on Health Care Organization Research

Bryan J. Weiner, Ph.D., Program Director

The organization of health services and practice arrangements for health care providers is changing continually. Emphasis in the **Program on Health Care Organization Research** is given to understanding the fundamental changes confronting providers and the way in which the organization of medical services at the community level influences the dissemination of prevention, treatments and early detection services.

The following research projects were active during the year:

Clinical Trials Matrix Support - The NCI Clinical Trials Advisors to the NCCCP and to the proposed National Cancer Institute Community Oncology Research Program (NCORP) and SAIC-Frederick, Inc. seek support to further develop, refine, and evaluate the NCCCP Clinical Trials Best Practice Matrix tool for broader use in NCI community cancer research program development beyond NCCCP. The NCCCP Clinical Trials Best Practice Matrix aims to improve the quality and performance of the conduct of clinical trials in the community by providing a tool to guide and benchmark NCI research sites as they strive to reach beyond compliance with the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) minimum standards toward exemplary conduct of clinical trials. The tool may also prove useful to other NCI program performance, including the Cancer Centers Program, the Center to Reduce Cancer Health Disparities' Community Networks Program, and the Division of Cancer Prevention's (DCP) Early Detection Research Network, as the tool's capacity lies in the guidance it provides as a process map for continuous quality improvement. When sites plan, implement and evaluate their processes and performance, it results in improved quality of research infrastructure systems and conduct of trials. DCP's support of this effort aligns the Division with the NCI's continued efforts to support efficient, high quality research. The purpose of this procurement is to acquire support from the University of North Carolina at Chapel Hill and Dr. Bryan Weiner to further develop, refine, and evaluate the NCCCP Clinical Trials Best Practice Matrix Tool for broader use in NCI community cancer research program development beyond NCCCP.

Principal Investigator: Bryan J. Weiner, PhD

Funding Source: SAIC-Frederick, Inc.

Project Period: 06/05/13 - 03/31/14

Total Funding: \$51,653

The Health Care Organization Research Program had the following technical assistance project active this year:

Division of Health Services Regulation Support of Databases – This project supports the Division of Health

Services Regulation in the development and use of the hospital discharge database and the ambulatory surgery database. The Sheps Center receives data from the State data processor on a quarterly basis, reviews and edits the data, and builds an annual database. These databases are used to support the Division in health planning and related activities.

Principal Investigator: Sandra B. Greene, DrPH

Funding Source: NC Department of Health and Human Services, Division of Health Services Regulation (formerly Division of Facility Services)

Project Period: 11/01/02 – 06/30/12 (extended through 06/30/15)

Total Funding: \$144,768

Program on Health Disparities Research

Giselle Corbie-Smith, M.D., M.Sc. and Paul A. Godley, M.D., Ph.D., Program Co-Directors

The **Program on Health Disparities Research** seeks to foster multidisciplinary, policy-relevant research to improve the health and healthcare of underserved communities through community and academic partnerships in research, teaching, and dissemination of knowledge. Central to its mission is the development and training of new investigators in health disparities research, strengthening and empowering communities of color to address health disparities, and enhancing the national visibility of health disparities research at the University of North Carolina at Chapel Hill. The Program brings together a diverse and multidisciplinary group of investigators with expertise in quantitative and qualitative research methods to address complex social, environmental and organizational issues affecting underserved populations.

Program Highlight: Lung Cancer Disparities Intervention Trial Interim Results

The **Lung Cancer Surgery: Decisions Against Life Saving Care – The Intervention Center** trial, has interim data that show that we are successfully recruiting and that treatment rates are well above historical trends.

The data suggest interventions of real-time, electronic tracking systems, race-specific QI, and health equity sensitive navigation have been successfully applied and appear promising.

Supplement – This grant provides supplemental funding under the American Recovery and Reinvestment Act of 2009 (ARRA) to R24M.D.001671 Project GRACE CBPR grant to support innovative scientific partnerships with community-based and faith-based health organizations. The grant enables us to enhance the evaluation plan of our HIV prevention intervention by providing a health intervention to the comparison communities, and to expand community partnerships via subcontracts to two

community-based and one faith-based health organization serving the comparison communities. This enables us to work with local health organizations who can best bridge science to practice through their direct connection to health disparity populations. These funds not only enhance Project GRACE, but also create more jobs in the communities. This grant helps those hit the hardest with the current recession, strengthens and broadens scientific partnerships with community-based and faith-based health organizations, and invests in long term improvements in the community by reducing health disparities and improving socioeconomic conditions that cause health disparities.

Principal Investigator: Giselle Corbie-Smith, MD, MSc

Funding Source: National Center for Minority Health and Health Disparities (NCMHD)

Project Period: 09/01/09 – 02/28/13 (extended through 02/28/14)

Total Funding: \$600,000

Mentoring in community influences on CVD risk –

The specific aims for the new research to be supported through this K24 Midcareer Investigator award include: 1) Determine the feasibility of training a current cohort of community health advisors as navigators to link residents with multiple cardiovascular risk factors to local healthcare systems; 2) Determine the impact of health navigators on cardiovascular risk factor control (HgbA1C, physical activity, BP control, smoking) and access to care for community members at increased risk for cardiovascular disease; 3) Identify community and social factors that influence cardiovascular risk factor control and outcomes. This two-arm trial will investigate the role of navigators on cardiovascular outcomes in community based outreach programs to improve access and utilization of medical services. Two to three navigators at each of the four sites will be utilized. Patients will be randomized to either a navigator intervention or to usual patient management practices, with measurement at baseline and six months. This study targets a disease condition and population of significant importance — CVD risk factor prevention in rural African Americans — and extends an existing effective model in several important ways. This study situates the navigator and patient within the community (rather than the healthcare system) thus increasing the cultural relevance of the intervention. Rather than a focus on one condition, navigators will support access and management of several chronic conditions, thus addressing the reality of multiple co-morbidities in underserved patients. Lastly, augmenting patient data with community variables allows a comprehensive analysis of external influence on cardiovascular disease prevention and healthcare utilization.

Principal Investigator: Giselle Corbie-Smith, MD, MSc

Funding Source: National Heart Lung and Blood Institute

Project Period: 12/01/10 – 07/31/15

Total Funding: \$952,716

Lung Cancer Surgery: Decisions Against Life Saving Care – The Intervention Center – This American Cancer Society sponsored study is designed to use a health literacy and culturally appropriate communication intervention for patients and electronic data tools for providers to optimize surgical treatment for early stage lung cancer for all patients and to reduce the surgical gap between African-American and white lung cancer patients. Currently, more minority patients fail to undergo potentially life-saving surgery for lung cancer. The reasons appear to be largely related to poor communication between patients and health care providers. This multi-site study will attempt to determine whether a brief intervention will reduce that disparity.

Principal Investigator: Samuel Cykert, MD

Funding Source: American Cancer Society

Project Period: 07/01/11 – 06/30/16

Total Funding: \$600,000

Developing Topic Briefs for Addressing Health and Health Care Disparities Research Priority Area – The University of North Carolina developed twelve (12) briefs on issues pertaining to health disparities research. The objective of each brief was to provide advisory panelists (i.e. patients, stakeholders, and scientists) with clear, concise background information about each issue to facilitate their ability to discuss the merits of each topic as a potential PCORI funding announcement. The advisory panels, based on their discussion, help prioritize topics and rank-order the 12 issues on the basis for their recommendations. The topic briefs were used as a tool to spur discussion within PCORI advisory panels.

Principal Investigator: Mark Holmes, PhD

Funding: PCORI

Project Period: 03/01/13 - 04/30/14

Total Funding: \$96,716

Reducing Cardiovascular Disease Risk Factors in Rural Communities in NC – Cardiovascular disease (CVD) is the leading cause of death in the U.S., however African American residents of rural areas in the south and southeast regions have the highest prevalence of CVD of any group. African Americans carry a significant burden of CVD risk factors that often co-occur; this burden is amplified in rural communities. CVD disparities at the intersection of race and geography are driven by individual risk behaviors and complicated by factors such as limited access to quality healthcare, socio-economic inequities, limited health care infrastructure and environmental barriers to behavior change. Interventions to ameliorate CVD burden in rural African American communities will require placing the individual in the context of the larger community and taking advantage of new technologies to support behavior change. However, how best to integrate mobile technology into existing evidenced based interventions (EBIs) is still an emerging field and social and physical environmental factors important in rural communities are rarely considered in existing EBIs. The proposed study will address this gap in the literature by determining the feasibility and efficacy of

adapting EBIs to consider the social and physical environment in important in rural African American communities and determining the acceptability of mobile technology in these communities to support behavior change. The proposed study is built on the strong foundation of Project GRACE's 8-year history of designing and testing interventions using a community-based participatory research (CBPR) approach, and individual and collaborative expertise in community-based CVD outreach, service and research. We have developed a phased CBPR study with a long-term goal to reduce rates of CVD in Eastern NC. The overall objective of this proposal is to assess feasibility of implementing an EBI, adapted to the needs and interests of a rural community in order to plan a large scale study. To that end our specific aims are to 1) expand and sustain. Project GRACE CVD coalition of community and academic stakeholders to develop successful CVD risk prevention strategies in rural communities; 2) conduct a mixed-method community needs and assets assessment based on: a) assemble, review and assess existing sources of CVD data; b) identification of community strengths and resources using a web-based survey of community, faith based, social service and health care organizations; c) determine the acceptability of components of CVD risk reduction EBIs and community members' perceptions of possible targets for intervention using focus group interviews; d) determine specific family influences (barriers and facilitators) on acceptability of EBI acceptability; 3) adapt PREMIER, a multi-component EBI using intervention mapping; and 4) conduct a small-scale randomized control trial to assess a) efficacy; and, b) feasibility and adaption of implementing adapted PREMIER in rural settings.

Principal Investigator: Giselle Corbie-Smith, MD, MSc

Funding Source: National Heart, Lung, and Blood Institute

Project Period: 03/15/14 - 02/28/18

Total Funding: \$264,727

Program on Primary Care Research

Donald E. Pathman, M.D., M.P.H. Program Director

An ample supply of primary care services is a fundamental building block of any health care system. Historically, much of the Sheps Center's **Primary Care Research** has addressed the access, personnel, organization, quality, and cost issues that pertain to health services delivery, especially in rural areas. The focus of much of this research is on access, personnel, organization, quality, and cost issues that pertain to health services delivery, especially in rural areas. Current research efforts in this program include addressing issues of recruitment and retention of health care practitioners.

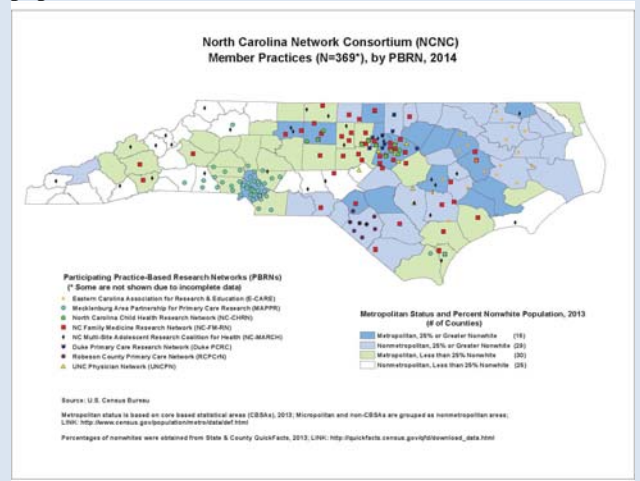
Current research efforts in this program include addressing issues of recruitment and retention of health care practitioners in rural practice, the projection of need and demand for health professional personnel and helping primary care practices in their goals to improve quality patient care and reduce costs.

The following research projects were active during the year:

Program Highlight: The North Carolina Network Consortium

NCNC is a diverse statewide consortium of providers, academic institutions, and patients whose mission is to address pressing questions related to the delivery of primary care health services and the management of primary care problems. Seven practice-based research networks (PBRN) have combined resources in forming the NCNC.

They represent over 1400 providers in over 300 practices across the state, including all three primary care specialties (family medicine, internal medicine, and pediatrics) and strong representation of minority populations. Please visit www.ncnc.unc.edu.



North Carolina Healthcare Quality Alliance Contract

– The North Carolina Healthcare Quality Alliance (NCHQA) is a collaboration of leaders in the delivery of healthcare in North Carolina. NCHQA is developing quality measures for the treatment of chronic diseases, recruiting primary care practices to adopt these measures, and providing training and support to practices for improving quality of care, including support for implementing electronic medical records systems compliant with federal guidelines. NCHQA currently relies on contracts with outside organizations, including UNC-CH, for staff to support its work. Activities under this contract will be of a statewide nature and involve collaborating and working with multiple external entities. We are responsible for providing the following services to NCHQA: 1. Management and Planning; 2. Financial; 3. Data Collection, Analysis and Presentation.

Principal Investigator: Warren Newton, MD, MPH

Funding Source: North Carolina Healthcare Quality Alliance

Project Period: 07/01/10 – 06/30/13

(extended through 08/31/13)

Total Funding: \$267,573

Transforming Primary Care Practice in North

Carolina – The Patient-Centered Medical Home (PCMH) model involves complete primary care practice redesign

with the ultimate goal to improve the quality of patient care and reduce cost. Detailed information on the best methods of practice transformation is needed to help the growing number of practices as they plan to go through this process. The overall objective of this study is to evaluate the adoption and process of transformational change in primary care practices belonging to the North Carolina Improving Performance in Practice program (NC IPIP). examine how specific components of the change relate to key health outcomes and explore environmental, organizational and financial conditions that are conducive to transformational change. The aims of this study are to 1) confirm the transformational change process that has occurred within 40 selected practices in the NC IPIP, 2) evaluate which components of change are most linked with improvement in the quality care indicators for diabetes and asthma, 3) for a subset of 12 practices that evidence varying degrees of success in implementing transformational change, utilize quantitative and qualitative methods to obtain a richer understanding of the change process, examine the effect of environmental conditions, organizational characteristics and financial resources on the change process and describe the costs involved in transformational change at the practice level, and 4) provide a set of recommendations that can be applied at the individual practice level and at the health care organization level to assist in the PCMH transformation process. The ultimate goal and the significance of this study is to describe the transformation process and arrive at a set of implementable recommendations that can be shared broadly to assist individual practices and health care organizations moving toward the PCMH model.

Principal Investigator: Katrina Donahue, MD, MPH

Funding Source: AHRQ via subcontract with the University of Michigan

Project Period: 08/01/10 - 07/31/13

Total Funding: \$599,997

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) that 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 behavior 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 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 health care 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 every day, routine clinical practice that evaluates outcomes of central importance to patients living with the disease.

Principal Investigator: Katrina Donahue, MD, MPH, and Laura Young, MD, PhD

Funding Source: PCORI

Project Period: 08/01/13 - 07/31/16

Total Funding: \$2,090,699

North Carolina IMPaCT: Advancing and Spreading Primary Care Transformation

– For the IMPaCT project, we will enhance our current efforts by conducting a regional leadership development program that will enhance the effectiveness of the regional medical and quality improvement leaders. We will also enhance our current patient-centered medical home change package to include focused attention on the role of primary care in transitions between care settings. In addition to several ongoing evaluations in the state, we will evaluate the rate of improvement in performance, utilization, and cost of care by duration in CCNC and participation in NCAHEC improvement networks. Lastly, a major aspect of this proposal is to disseminate the NC primary care practice support model so that other states can take advantage of our experience and lessons learned. We will work with the National Academy for State Health Policy to disseminate tools and experiences broadly through issue briefs, detailed descriptions of the NC programs, and national webinars and conferences. We will also work intensively with 3 states to help them implement their own multi-sector primary care support efforts.

Principal Investigator: Darren Dewalt, MD

Funding Source: AHRQ

Project Period: 09/01/11 – 09/29/13

Total Funding: \$999,961

NHSC Site Self-Assessment of Recruitment and Retention Needs Project – Coordinate activities and timelines with the Bureau of Clinician Recruitment and Service (BCRS) to finalize tasks for the self-assessment study. Complete self-assessment survey for approximately 7,000 NHSC sites to determine capacity and technical assistance needs. Administer the self-assessment electronically, analyze the data, and submit the final report with recommendations for a multi-year technical assistance strategy for the NHSC. Prepare Quarterly Reports to submit to the NRHA.

Principal Investigator: Donald Pathman, MD

Funding Source: National Rural Health Association

Project Period: 04/01/12 - 08/31/13

Total Funding: \$70,000

Multi-State Retention Collaborative & Practice Sights Continuation Project

– This project is to: Incorporate North Carolina Office of Rural Health's State Loan Repayment data from the Practice Sights legacy retention module to the web-based Practice Sights Retention Management System; Incorporate North Carolina Medical Society Foundation's Community Practitioner Program data from the Practice Sights legacy retention module to the web-based Practice Sights Retention Management System; Incorporate Year 1 of the Multi-State/NHSC Retention Collaborative NHSC survey data into the Practice Sights Retention Management System; and Have data included in summary reports, available for ad hoc analyses and show in an individualized report for each clinician.

Principal Investigator: Donald Pathman, MD, MPH

Funding Source: NC Foundation for Advanced Health Programs, Inc

Project Period: 03/01/2014 - 09/30/2014

(extended through 03/31/15)

Total Funding: \$244,310

Multipayer Advanced Primary Care Practices (MAPCP)

– NC is one of eight states participating in the CMS-funded MAPCP Demonstration, which examines the use of medical homes and other novel primary care practices in a multipayer environment. The Sheps Center team is leading the NC evaluation of this expansion of the award winning Medicaid medical homes program to other payers, including Medicare and private payers in NC. The evaluation will focus on claims-based outcome measures including expenditures and quality of care

Principal Investigator: Marisa Domino, PhD

Funding Source: CMS via NCCCN

Project Period: 04/01/13 - 03/31/14

Total Funding: \$45,664

Understanding the Direct and Indirect Costs of Transformation to Medical Homes - The Patient-Centered Medical Home (PCMH) model involves

complete primary care practice redesign with the ultimate goal of improving the quality of patient care and at reduced cost. Detailed information regarding the practice level costs of performing transformative activities is needed to help the growing number of practices and practice organizations as they navigate this process. The overall objective of this study is to examine the direct and indirect practice level costs of supporting care transformation by evaluating costs within five small to medium sized primary care practices that have demonstrated improved clinical outcomes in diabetes or asthma measures within the North Carolina AHEC Practice Support Program and have also received PCMH recognition status by the National Committee for Quality Assurance. The aims of the study are to 1) analyze the overall costs of transformative activities that are supported by the NC AHEC practice support program that include the original and ongoing quality improvement activities defined by the NC IPIP program as well as the activities performed to qualify these practices as Medical homes by NCQA and 2) to disseminate our costs analysis results to stakeholders in health care and care transformation. This project will enhance understanding of the practice level costs of transformation which will be of value to policy makers, quality improvement organizations and primary care physicians. It is expected that products of this work could help practices streamline and anticipate costs when embarking on work related to practice transformation.

Principal Investigator: Jacqueline Halladay, MD, MPH
Funding Source: AHRQ
Project Period: 09/31/13 – 03/31/15
Total Funding: \$99,998

Program on Medical Practice and Prevention

Daniel Jonas, M.D., M.P.H., Program Director

Variations in the practice of medicine have received national scrutiny because of their considerable social, economic and quality of care implications. The Center’s **Program on Medical Practice and Prevention** collaborates with practicing physicians in North Carolina and across the United States to explore these variations and their implications for health care outcomes. Work with the Agency for Healthcare Research and Quality (AHRQ) has continued and expanded over the past decade, with continuing investigator initiated awards but, most prominently, rapid growth in contract work.

Initiated in October 1997, AHRQ funded the Research Triangle Institute (RTI) and the University of North Carolina at Chapel Hill to become one of 12 Evidence-Based Practice Centers (EPCs) nationally. In September 2012, AHRQ awarded the 4th AHRQ master task order contract to provide a variety of services and products to support the development of new scientific knowledge through research on the outcomes of healthcare items and services. The activities below reflect many EPC-related projects. Activities performed by the DEcIDE

(Developing Evidence to Inform Decisions about Effectiveness) Network reflect the general principle that clinicians and patients should have the best available evidence upon which to make choices in health care items and services. Hence, the network rapidly develops scientific evidence and new analytic tools to assist healthcare providers, patients, and policy makers with making informed decisions about the comparative effectiveness, appropriateness, safety, and outcomes of healthcare items and services, particularly prescription medications and medical devices.

The following research projects were active during the year:

EPC III - Comparative Analysis of Selected Frameworks

– The RTI/UNC-CH Evidence-based Practice Center will develop the project protocol, set criteria for and conduct a comparative analysis of selected frameworks and lead a group of technical experts in an effort to prioritize contextual factors.

Principal Investigator: Timothy S. Carey, MD, MPH, and Bryan Weiner, PhD

Funding Source: AHRQ via Research Triangle Institute (RTI International)

Project Period: 01/01/12 - 07/31/12

(extended through 01/31/14)

Total Funding: \$50,248

Program Highlight: Dr. Daniel Jonas, Evidence-based Practice Center Co-Director, led a team from UNC and RTI to review published studies examining the use of drugs to treat alcohol use disorders. The researchers conducted a systematic review of 122 randomized controlled trials and one cohort study. They then graded the strength of the evidence on the impact of drugs on alcohol consumption. The research was published in the Journal of the American Medical Association in May 2014.

They found that two drugs, acamprosate (brand name Campral) and oral naltrexone (brand name Revia), have the best evidence supporting their benefits. Both drugs reduced return to drinking and improved other drinking outcomes. Among medications used off-label (i.e., those not FDA approved for alcohol use disorders), moderate evidence showed improvement in some drinking outcomes for topiramate and nalmefene.

“The health implications of preventing return to drinking and reducing alcohol consumption are substantial,” Jonas said. “Modeling studies have shown that such improvements would result in significant reductions in alcohol-attributable mortality, costs from health care, arrests and motor vehicle accidents.”

The study received news coverage from national, regional and local outlets.

EPC III: Genomic Testing for Risk of Recurrent

Cancer - UNC personnel at the RTI-UNC Evidence-based Practice Center (EPC) will collaborate with investigators at RTI to: 1) conduct a systematic review of available literature for evidence that testing of molecular markers of the risk of tumor recurrence, used separately or in combination with 'standard' indicators of risk recurrence, improves predictions of tumor recurrence and leads to changes in physician decisions about patient treatment and to improved patient outcomes, and 2) produce an organized report of the findings of the systematic review, that presents available evidence for the identified key questions.

Principal Investigator: Timothy S Carey, MD, MPH, and Daniel Jonas, PhD

Funding Source: AHRQ via RTI

Project Period: 10/25/12 - 01/13/14

Total Funding: \$168,620

Developing and Assessing Contextual Frameworks for Research on Implementation of Complex System Interventions

The RTI/UNC-CH Evidence-based Practice Center will work with the Agency for Healthcare Research and Quality and a technical expert panel (TEP) to (1) assess methods used to adapt a consolidated framework for implementation research (CFIR) to patient-centered medical home (PCMH) and process redesign (PR) and (2) assess the usability of the modified frameworks for PCMH and PR implementation research. We will use Information from these efforts along with findings from a literature search and review and input from a second TEP to adapt the CFIR to a third, to be determined, complex health system intervention. The final product will be a peer-reviewed methods paper.

Principal Investigator: Timothy S Carey, MD, MPH

Funding Source: AHRQ via RTI

Project Period: 08/28/12 - 08/31/13

Total Funding: \$95,553

Evidence-based Practice Centers (EPCs) IV – Note:

This is a Master Task Order; there are no specific tasks for this master contract proposal; there will be multiple tasks undertaken. Research Triangle Institute and UNC-CH, as the RTI-UNC EPC, have been awarded a *fourth consecutive* 5-year master task order by the Agency for Healthcare Research and Quality (AHRQ). UNC-CH will be a subcontract to RTI for this Indefinite Delivery/Indefinite Quantity (IDIQ) award. The goal of EPC work is to present the 'state of the science' on a given topic in a manner that can be directly applied to decisions made by users of health care information. These users include clinicians, patients, policy-makers, and payers, and may be individuals or their related organizations. Topics cover all health care clinical and therapeutic areas of focus, from preventative services to implementation of medical devices. EPCs conduct rigorous systematic reviews, synthesize results of systematic reviews and report the findings, advance the methodology of systematic review, collaborate with partners and perform other related EPC activities.

Successful execution of each of these essential activities requires an effective and efficient team of multidisciplinary individuals with a high level of consistent functioning at both the individual and collective levels.

Principal Investigator: Daniel E. Jonas, MD, MPH

Funding Source: AHRQ via RTI

Project Period: 09/01/12 – 08/31/17

Total Funding: Varies. Master Task Order Contract with Multiple Task Order Contracts listed below.

Associate Editor Duties for the EPC – Timothy Carey, MD, MPH, will serve as an 'associate editor' for the EPC, conducting edits and providing comments of EPC reports by other Centers for AHRQ.

Principal Investigator: Timothy S. Carey, MD, MPH

Funding Source: AHRQ via RTI

Project Period: 12/31/11-08/31/12

(extended through 08/31/17)

Total Funding: \$31,113

Comprehensive EPC Comparative Effectiveness Reviews for Effective Health Care

The RTI-UNC Evidence-based Practice Center (EPC) will build on existing work of the EPC program within the context of the Agency for Healthcare Research and Quality's Effective Health Care (EHC) program to expand the scope and delineation of a comprehensive approach to systematic review for evidence synthesis. The ultimate goal of EPC work is to present the "state of the science" on a given topic in a manner that can be directly applied to decisions made by users of health care information. These users include clinicians, patients and caregivers, policy-makers, funders and payers, and may be individuals or their related organizations.

This work focuses on a comprehensive approach to comparative effectiveness review (CER) and evidence synthesis through an expanded scope of work with three major work components: 1.) Develop and refine topics for CERs that are informative to stakeholder decisional needs; 2.) Conduct CERs with systematic and transparent methods; 3.) Identify and explicate future research needs that are important to answering real-world healthcare decisions. The RTI-UNC EPC will focus on mental health and substance abuse topics for this work.

EPC-IV Awards as of October 2014

Task 1: Associate Editor Reviews

UNC personnel will serve as an associate editor (AE) to ensure consistent quality of EPC program products, including systematic reviews and technology assessments. AE responsibilities include reviewing draft and revised reports, reviewing peer and public comments, and preparing decision letters addressed to the authors.

Area 4: 1) Dementia, including Alzheimer's disease, and depression and 2) Other mental health disorders

The RTI-UNC Evidence-based Practice Center (EPC) will conduct two topic developments, two topic refinements, two comparative effectiveness reviews on assigned topics in these subject areas. Specific topics assigned are:

- Topic Developments: Psychiatric Hospital Discharge, Binge Eating Disorder
- Topic Refinements: Outcomes of Serious Mental Illness, Medication Therapy Management
- Comparative Effectiveness Reviews: Pharmacotherapy for Adults With Alcohol-Use Disorders in Outpatient Settings, Medication Therapy Management

Area 5: 1) Care delivery, management, and coordination, including prevention and 2) Behavioral interventions

The RTI-UNC Evidence-based Practice Center (EPC) will conduct two topic developments, two topic refinements, one technical brief and two comparative effectiveness reviews on assigned topics in these subject areas. Specific topics assigned are:

- Topic Developments: Physician House Calls, Patient Experiences and Outcomes of Care
- Technical Brief: Models of Survivorship Care
- Topic Refinements and Comparative Effectiveness Reviews: Heart Failure and Preventing Readmissions, Pharmacokinetic/Pharmacodynamic Measures for Guiding Antibiotic Treatment for Nosocomial Pneumonia

Systematic Evidence Reviews to Support the U.S. Preventive Services Task Force (2012 – 2015)

[Subcontract with Kaiser Permanente Research Affiliates EPC]

- Screening for Carotid Artery Stenosis
- Screening for Depression in Children and Adolescents
- Screening for Speech and Language Delay

Systematic Evidence Reviews to Support the U.S. Preventive Services Task Force (2013 – 2016)

[Subcontract with Kaiser Permanente Research Affiliates EPC]

- Obstructive Sleep Apnea
- Tuberculosis
- Folic Acid Supplementation to Prevent Neural Tube Defects

Systematic Evidence Reviews to Support the U.S. Preventive Services Task Force (2014 – 2017)

[Subcontract with Kaiser Permanente Research Affiliates EPC]

- Screening for Herpes
- Osteoporosis
- Menopausal Hormone Therapy for the Primary Prevention of Chronic Conditions
- Vision Screening for Children
- Behavioral Interventions for Stress Management (Topic Refinement only)

Binge Eating Disorder – Topic Refinement and CER
Major Depressive Disorder – Topic Refinement and CER

Outcomes of Serious Mental Illness – Technical Brief Strategies to Improve Mental Health Care for Children and Adolescents – Topic Refinement and CER Management Strategies to Reduce Psychiatric Readmissions – Technical Brief

Evidence Profiles to Support Guideline Development for the American Psychological Association. Topic: Post Traumatic Stress Disorder - Using our report on treatments for adults with PTSD written for the Agency for Healthcare Research and Quality, UNC-CH will produce evidence profiles covering the treatments and comparisons included in the report. Each evidence profile will include rows for up to 7 outcomes. This work will be used to support the development of guidelines for the American Psychological Association on Post Traumatic Stress Disorder (PTSD).

Principal Investigator: Daniel Jonas, MD, MPH

Funding Source: American Psychological Association via RTI

Project Period: 03/01/14 - 05/31/14

Total Funding: \$10,452

Drug Effectiveness Review Project (DERP) – Utilizing the infrastructure of the RTI-UNC EPC, this research aims to summarize the available evidence comparing the efficacy, effectiveness, and harms of drugs in many widely used drug classes. DERP is a collaboration of public entities (including the OHSU Center for Evidence-based Policy and the Oregon Evidence-based Practice Center) who have joined together to produce systematic, evidence-based reviews, and to apply the findings to inform public policy and related activities in local settings. The RTI-UNC EPC has produced reviews on antidepressants, asthma medications, targeted immune modulators, inhaled corticosteroids, and constipation medications.

Principal Investigator: Daniel Jonas, MD, MPH (Carey, PI 2005-2007)

Funding Source: Oregon Health & Science University

Project Period: 01/01/04 – 06/30/13

(extended through 06/30/15)

Total Funding: \$1,873,139

Evidence Synthesis and Translation under MMA Section 1013 Area 4

UNC personnel at the RTI-UNC Evidence-based Practice Center (EPC) will collaborate with investigators at RTI to: 1) develop two topics through literature scans for comparative effectiveness reviews (CER); 2) develop key questions, background information, PICOTS (population(s), intervention(s), comparator(s), outcomes, timing, settings) and define terms for two topics assigned; 3) conduct a small systematic review of available literature for evidence for one of the assigned topics; 4) produce an organized report of the findings of the small systematic review, that presents available evidence for the identified key questions; 5) conduct a medium CER of available literature for evidence for one of the assigned topics; 6) produce an organized report of the findings of the medium CER, that presents available evidence for the identified key questions.

Principal Investigator: Daniel E. Jonas, MD, MPH
Funding Source: AHRQ via RTI
Project Period: 09/01/12 – 02/28/15
Total Funding: \$437,500

Evidence Synthesis and Translation under MMA

Section 1013 Area 5 - UNC personnel at the RTI-UNC Evidence-based Practice Center (EPC) will collaborate with investigators at RTI to: 1) develop two topics through literature scans for comparative effectiveness reviews (CER); 2) develop key questions, background information, PICOTS (population(s), intervention(s), comparator(s), outcomes, timing, settings) and define terms for two topics assigned; 3) conduct a small systematic review of available literature for evidence for one of the assigned topics; 4) produce an organized report of the findings of the small systematic review, that presents available evidence for the identified key questions; 5) conduct a medium CER of available literature for evidence for one of the assigned topics; 6) produce an organized report of the findings of the medium CER, that presents available evidence for the identified key questions; 7) produce a technical brief for an additional topic.

Principal Investigator: Daniel E. Jonas, MD, MPH
Funding Source: AHRQ via RTI
Project Period: 09/25/12 – 03/25/15
Total Funding: \$538,999

Decision Support Lab - Breast Cancer Project – The Decision Support Lab at The Cecil G. Sheps Center for Health Services Research will continue research on breast cancer treatment decisions during the 2012-2013 fiscal year. This work is part of the study “Measuring the Quality of Decisions in Breast Cancer” and involves survey research with breast cancer survivors. Validation in Newly Diagnosed Patients This phase of the study will validate the reconstruction decision quality instruments in women who have been diagnosed with early stage breast cancer. The instruments measure the degree to which patients are informed and the degree to which their decisions reflect their values. Approximately 100 patients from 2 sites will be enrolled in this phase of the study. Participants will receive the reconstruction decision instrument by mail approximately 4 weeks after their mastectomy. They will then receive a 1 year follow up survey a year after completion of the baseline survey. This longitudinal assessment will be important to examine how their knowledge and preferences may change over time. Data will be sent to the Center for Survey Research for analysis.

Principal Investigator: Clara Lee, MD
Funding Source: Foundation for Informed Medical Decision Making
Project Period: 07/01/12 - 06/30/14
Total Funding: \$34,999

Mentoring Junior Investigators: Comprehensive HIV Prevention – This career development award gave Dr. Golin the dedicated time to expand and build her patient-

oriented research in HIV/AIDS prevention by mentoring several promising, bright, young investigators at UNC in HIV prevention research. Dr. Golin’s objective is to create a formal UNC Program on Prevention of HIV in the Southern US by achieving four immediate goals are to: 1) enhance her capacity to evaluate structural determinants of health and cost effectiveness of HIV prevention intervention programs through formal and informal training and collaboration; 2) extend her patient-oriented investigations (exploring the interface between motivation, self-efficacy, and risky sexual behavior) by examining the role that interpersonal and structural determinants of the HIV epidemic play in influencing the effectiveness of HIV prevention programs; 3) evaluate the cost-effectiveness of the SafeTalk HIV prevention program; and 4) enhance her capacity to provide effective and outstanding mentoring to junior investigators. The patient-oriented research proposed in this application: 1) Examines interpersonal and community factors that moderate the effects of risk reduction programs among heterosexual HIV-infected individuals; 2) Explores perceptions of 32 imPACT participants and their social network members regarding contextual and dyadic factors that may have helped or hindered their response to imPACT; 3) Evaluates the cost-effectiveness of the imPACT program; 4) Explores views of HIV-negative women and their male partners living in high poverty, high HIV prevalence census tracts in Durham and Wake Counties in NC.

Principal Investigator: Carol Golin, PhD
Funding Source: NIH/Eunice Kennedy Shriver National Institute of Child Health & Human Development
Project Period: 09/17/13 - 05/31/18
Total Funding: \$789,405

Systematic Evidence Reviews to Support the U.S. Preventive Services Task Force (USPSTF) RFTO #21

– UNC-CH will be supporting and/or leading the development of systematic reviews for the US Preventive Services Task Force by providing leadership, clinical, methodological, and content expertise, and/or support for project tasks such as work plan and research plan development, literature searches, development of data abstraction forms, abstract and full text review, data abstraction, writing and preparing the draft and final reports, collating and responding to peer and public comments, and disseminating findings.

Principal Investigator: Daniel E. Jonas, MD, MPH
Funding Source: AHRQ via RTI
Project Period: 09/17/13 - 09/16/16
(extended through 08/17/17)
Total Funding: \$1,798,792

Health and Literacy in Child and Adult Assessment – This project is developing patient reported outcome (PRO) measures for adults and children across all levels of literacy. As a cooperative agreement with NIH, UNC is part of a network of sites to develop measures for adults. UNC is also focusing its efforts on an independent project to develop measures for children ages 8-17.

Patient Reported Outcome Measurement Information System (PROMIS) instruments are developed using item response theory with the potential for developing computerized adaptive testing. Supplemental funds were received in 2007 to expand the scope of the pediatric PRO item banks with the addition of much needed parent proxy-report item banks. These proxy-report banks will capture PROs for children who are too young (under age 8), cognitively impaired, too ill, or too fatigued to complete a self-report PRO instrument.

Principal Investigator: Darren A. DeWalt, MD

Funding Source: National Institute of Arthritis and Musculoskeletal and Skin Diseases, NIH

Project Period: 09/28/04 – 07/31/13

(extended through 07/31/14)

Total Funding: \$3,607,568

Secondary Program Area: Child and Adolescent Health Services Research

Develop Evidence to Inform Decisions About

Effectiveness: The DEcIDE Network – The DEcIDE network provides a variety of services and products to support the development of new scientific knowledge through research on the outcomes of healthcare items and services. Activities performed by the DEcIDE network reflect the general principle that clinicians and patients should have the best available evidence upon which to make choices in health care items and services. Hence, the network rapidly develops scientific evidence and new analytic tools to assist healthcare providers, patients, and policy makers with making informed decisions about the comparative effectiveness, appropriateness, safety, and outcomes of healthcare items and services, particularly prescription medications and medical devices.

Principal Investigator: Til Stürmer, MD, MPH (2009-13)

Past PI: Suzanne West, PhD, MPH (05-07) and Michael Murray, PharmD, MPH (07-09)

Funding Source: AHRQ

Project Period: 09/16/05 – 07/24/13

Total Funding: \$200,000

Topic Refinement and Systematic Review for

Treatment of Major Depressive Disorder - UNC-CH personnel at the RTI-UNC Evidence-based Practice Center (EPC) will collaborate with investigators at RTI to: Conduct a literature scan and review published and unpublished literature to develop key questions, background information, and PICOTS (population(s), intervention(s), comparator(s), outcomes, timing, settings) and to define terms in preparation for a systematic review of the treatment of Major Depressive Disorder; Conduct a large systematic review of available literature for evidence for the treatment of Major Depressive Disorder; and, Produce an organized report of the findings of the large systematic review that presents available evidence for the identified key questions.

Funding Source: AHRQ via RTI

Project Period: 10/31/13 – 09/16/15

Total Funding: \$239,250

Topic Refinement and Systematic Review for Management and Outcomes of Binge Eating Disorder – UNC-CH personnel at the RTI-UNC Evidence-based Practice Center (EPC) will collaborate with investigators at RTI to: Conduct a literature scan and review published and unpublished literature to develop key questions, background information, and PICOTS (population(s), intervention(s), comparator(s), outcomes, timing, settings) and to define terms in preparation for a systematic review of the Management and Outcomes of Binge Eating Disorder; Conduct a large systematic review of available literature for evidence for the Management and Outcomes of Binge Eating Disorder; and, Produce an organized report of the findings of the large systematic review that presents available evidence for the identified key questions.

Principal Investigator: Daniel E. Jonas, MD, MPH, and Kim Brownley, PhD

Funding Source: AHRQ via RTI

Project Period: 11/06/13 - 05/25/15

Total Funding: \$200,000

Technical Brief for Outcomes of Serious Mental Illness

– UNC-CH personnel with the RTI-UNC Evidence-based Practice Center (EPC) will collaborate with investigators at RTI to produce a technical brief based on a systematic and comprehensive review of published and unpublished literature to identify the types of evidence available regarding outcomes for serious mental illness. Research activities include developing a protocol for data collection, organization, and presentation; gathering input from key informants; forming guiding questions for the topic; developing a search strategy to scan for relevant published and unpublished literature; reviewing available resources; and producing a final peer-reviewed technical brief that provides an overview of key issues related to the topic.

Principal Investigator: Bradley Gaynes, MD, MPH And Daniel E. Jonas, MD, MPH

Funding Source: AHRQ via RTI

Project Period: 10/30/13 – 04/23/14

Total Funding: \$75,000

Technical Brief on Management Strategies to Reduce Psychiatric Readmissions

- The goals of this project are to describe and compare three core management strategies to reduce psychiatric readmissions—length of stay for inpatient care, transition support services (i.e., care provided as the individual moves to outpatient care), and alternatives to hospitalization (i.e., outpatient care provided in place of psychiatric hospitalization)—for patients at high risk of psychiatric readmission. We will search published and unpublished sources for information about the effectiveness of these strategies. We will also interview key informants, representing mental health providers, health services researchers, policymakers, payers, and patient advocacy groups, to confirm and augment our findings. The technical brief produced will describe the current status of the evidence base addressing these strategies.

Funding Source: AHRQ via RTI
Project Period: 05/29/14 - 01/02/15
Total Funding: \$90,000

EPC IV, RFTO 4: Systematic Evidence Reviews to Support the U.S. Preventive Services Task Force – The Research Triangle Institute – University of North Carolina Evidence-based Practice Center (RTI-UNC EPC) will complete systematic evidence reviews of scientific literature for the U.S. Preventive Services Task Force (USPSTF). Over the course of 3 years, the EPC will complete up to 15 work plan developments and systematic evidence reviews on various topics selected by the USPSTF. The timeline and length of each review will vary. Some topics may require meta-analyses. Each effort will include the identification of eligible literature, data extraction, qualitative and/or quantitative synthesis of data, assessment of quality for each included study and the strength of the available evidence for a given question, production of draft and final reports, an in-person presentation of the draft report to the USPSTF, responses to peer and public reviewers' comments, and production of a peer-reviewed manuscript.

Principal Investigator: Daniel E. Jonas, MD, MPH
Funding Source: AHRQ via RTI via Kaiser
Project Period: 10/01/12-03/31/17
Total Funding: \$563,911

Improving Performance in Practice Phase V – Improving Performance in Practice (IPIP) is a national effort to improve the quality of care provide by primary care practices for patients with diabetes and asthma and then spreading to other conditions. The effort is led by the American Board of Medical Specialties (ABMS) with participation from the boards and specialty societies of Family Medicine and Pediatrics. The proposed project is for implementation of the model in North Carolina and Colorado and spread to two other states. Dr. DeWalt is an integral member of the national quality improvement team that will support the ABMS and the states as they implement the program.

Principal Investigator: Darren DeWalt, PhD
Funding Source: Children's Hospital Medical Center of Cincinnati
Project Period: 09/01/10 – 08/31/12
(extended through 08/31/14)
Total Funding: \$589,233

Improving Cancer-Related Patient Decision Making – High quality clinical decision making is necessary to realize the full benefits of emerging cancer prevention and treatment strategies. Currently, patients and providers are often without the resources or skills to implement high quality decision making processes. Integrating expertise from the fields of cognitive psychology, health economics, and health services research can improve cancer-related decision making research and practice. This award will be used to support Dr. Pignone while he develops a strong multidisciplinary research program at UNC in cancer-related decision making that includes new

research and mentorship of junior investigators working intensively with 4-6 primary trainees and a similar number of secondary trainees at a time.

Principal Investigator: Michael P. Pignone, MD, MPH
Funding Source: National Cancer Institute
Project Period: 09/03/08 – 08/31/13
(extended through 08/31/14)
Total Funding: \$1,747,500

Improving Colon Cancer Screening for Diverse Populations - Diverse, vulnerable populations, especially Latinos, have low colon cancer screening rates. These groups are disproportionately affected by the many patient, provider, and system-level barriers that inhibit colon cancer screening. Latinos, the nation's largest and fastest growing racial/ethnic minority group, face additional language and cultural barriers. Reducing disparities in colon cancer screening among vulnerable populations is a significant cancer control priority. To increase colon cancer screening in vulnerable populations, effective interventions are needed that address multiple screening barriers. Patient-directed, multimedia decision aids effectively enhance colon cancer screening knowledge, self-efficacy, and intent. Patient navigators help address patient-specific barriers to cancer control services. We believe that an intervention combining decision aids and patient navigators will be highly effective in promoting colon cancer screening among vulnerable, primary care patient populations. In this study, we will show patients a computer-based decision aid video (in English or Spanish) before they see their primary care provider. The video explains colon cancer screening using easy-to-understand narrated segments, patient testimonials, graphics, and animations. After the patients watch the video and talk with their provider, they will receive support from a bilingual patient navigator who can help them complete the screening process, overcoming the many barriers to screening completion that currently exist. In this study, we will test the effectiveness of this combined intervention in vulnerable patients, especially Latinos, ages 50 to 75, the age group for which colon cancer screening is recommended. We will conduct the study in primary care patient settings that serve diverse, vulnerable populations in both North Carolina and New Mexico to ensure the intervention is effective in different healthcare settings and in different Latino communities. If this practical and innovative intervention is found to be effective, it has potential to be widely implemented and could contribute substantially to reducing colon cancer mortality.

Principal Investigator: Daniel Reuland, MD, MPH
Funding Source: American Cancer Society
Project Period: 07/01/13 - 06/30/18
Total Funding: \$856,229

Communication about Glaucoma and Patient Outcomes – Between 9 and 12% of all blindness in the United States is attributed to glaucoma. The absence of symptoms in glaucoma patients increases the risk of regimen non-adherence among these patients.

Approximately 50% of individuals who start on glaucoma medications discontinue them within 6 months. Provider-patient communication about glaucoma and its treatment can be a critical factor that impacts initial treatment adherence and persistence. Little is known about provider-glaucoma patient communication. This project will examine how the provider-patient communication that occurs when patients are initially started on glaucoma medication treatment impacts medication adherence, medication persistence, and intraocular pressure (IOP) during the 8 month period after the drops are started. The findings from this study can be used to educate providers and patients about how to optimize communication during glaucoma visits to assure improved patient outcomes.

Principal Investigator: Betsy Sleath, PhD

Funding Source: National Eye Institute

Project Period: 05/01/09 – 04/30/13

(extended through 04/30/15)

Total Funding: \$3,134,760

Decision Support Lab - Medical Editor – Dr. Pignone will serve as a Medical Editor and as UNC-CH Principal Investigator for the grant. His duties include: 1) Participating in evaluations of new and existing decision aids developed by the Foundation, through administrative support, oversight, and participation in data analysis and reporting. 2) Serve as the Medical Editor for the following decision aids: colon cancer screening, "Living with Coronary Artery Disease", and heart failure. 3) Participate in further development and evaluation of decision making tools for the primary prevention of heart disease as determined by the Foundation. 4) Prepare Health News Reviews. 5) Participate in the IPDASi process as co-chair, including subsequent validation of the items included in the IPDAS instrument. 6) Facilitating the expansion of decision support and decision aid use in Australia for the Foundation.

Principal Investigator: Michael Pignone, MD, MPH

Funding Source: Foundation for Informed Medical Decision Making

Project Period: 07/01/09 – 06/30/14 (ongoing)

Total Funding: \$55,419

Validation of a Mortality Prediction Model for Prolonged Mechanical Ventilation – Many patients who survive the first few days of critical illness do so with multiple residual organ failures. These patients become dependent on mechanical ventilation and other organ support systems initiated in the ICU. Patients requiring prolonged mechanical ventilation (PMV) account for up to 20% of mechanically ventilated patients and consume up to 40% of all ICU resources. The patients have survived the initial severe stages of their illness, yet they remain dependent on life support systems, progress is slow, and complications are frequent. Physicians are often confused and uncertain about prognosis for PMV patients, therefore they usually do not share prognostic information with patients' families. In order to clarify prognosis for these complicated patients, a prognostic model that identifies PMV patients who are at high risk of death at 3 months and 1 year was developed and validated at a

single tertiary care medical center. This model is based upon 4 easily measured variables and converts to a clinical prediction rule called the ProVent Score. External validation of the model is required before general clinical application can be considered. This study proposes to validate the PMV prognostic model in two external cohorts with the following Aims: 1.) To validate the PMV prognostic model and ProVent Score in a heterogeneous group of patients from multiple medical centers. 2.) To evaluate the performance of the ProVent Score and develop new models in patients who are earlier in the course of PMV. 3.) To validate the ProVent Score in patients with Acute Lung Injury and the Acute Respiratory Distress Syndrome. The cohort for the first two Aims will consist of 600 consecutive PMV patients identified at 5 diverse tertiary care hospitals. Data will be obtained by review of medical records, and one-year survival will be confirmed by the National Death Index. The second cohort will consist of all patients in the NHLBI ARDS Clinical Trials Network FACTT trial who received PMV. A valid PMV prognostic model will allow investigators to standardize illness severity in future studies of interventions for PMV patients, and a clinically useful prognostic score will enhance the confidence of clinicians in communicating prognosis to patients and families.

Principal Investigator: Shannon Carson, MD

Funding Source: NIH

Project Period: 09/01/09 – 06/30/14

(extended through 06/30/15)

Total Funding: \$584,876

PROMIS Pediatrics: Longitudinal Validation and Linking Pediatric and Adult Items Banks – The overall objectives of this project are to validate the PROMIS pediatric item banks in 4 pediatric chronic illnesses, and to link pediatric and adult item banks. We developed 9 pediatric item banks during the first PROMIS grant cycle and have performed cross-sectional testing in children with several chronic illnesses. The proposed work is the natural next step toward integration of PROMIS scales into clinical research. We propose longitudinal studies in children with asthma, cancer, nephrotic syndrome, and sickle cell disease. Each study follows children through a clinical transition known to affect health-related quality of life, and each study will examine the responsiveness of the PROMIS instruments and estimate the minimum important difference (MID) for children. As part of these studies, we have proposed to test a new method for establishing MID and to compare that method with traditional distributional and anchor-based methods. The second overall objective is to link PROMIS pediatric item banks with PROMIS adult item banks. We designed most of the pediatric banks to measure the same underlying trait as their counterpart adult banks (e.g., fatigue), but used the concepts and language of children. We will administer pediatric and adult short forms to adolescents with chronic illnesses with a cross-sectional data collection. For this objective, we will use factor analysis and structural equation modeling to establish the empirical relationships between the pediatric and adult

item banks and domains, and, to the extent supported by those relationships, use item response theory to link the pediatric and adult item banks. This study will enable researchers to have comparable scores between children and adults participating in the same study and enable longitudinal studies that follow children into adulthood.

Principal Investigator: Darren A. DeWalt, MD

*Funding Source: National Institute of Arthritis
Musculoskeletal and Skin Diseases*

*Project Period: 09/30/09 – 07/31/13
(extended through 07/31/14)*

Total Funding: \$3,609,406

DEcIDE Comparative Effectiveness of IV Iron Formulations in End Stage Renal Disease

– Anemia is a highly prevalent condition among the approximately 500,000 people in the US with end-stage renal disease (ESRD) and is associated with increased morbidity, mortality, and healthcare costs. The anemia of ESRD is managed primarily through treatment with recombinant human erythropoietin and the administration of intravenous iron. Currently, two formulations of iron are in widespread use in dialysis patients: iron sucrose and sodium ferric gluconate. Although these compounds are distinct molecular entities and possess different pharmacokinetic properties, there are no data from large populations on the head-to-head safety or effectiveness of these formulations. There is also little evidence regarding the optimal dosing of intravenous iron. For example, iron can be administered via periodic maintenance doses or given through bolus administrations: a sequence of administrations in which a large amount of iron is given over consecutive dialysis sessions. Sub-optimal use of iron could worsen anemia, lead to hypersensitivity reactions, or lead to excess labile iron in the plasma that may increase risk of cardiovascular events or serious infections. For reasons of cost, it is unlikely that any of these questions will be definitely addressed in a large head-to-head comparative randomized trial. Therefore, we propose to address these important evidence gaps through a large-scale observational study of two large cohorts of dialysis patients.

*Principal Investigator: Til Stürmer, MD, MPH, Task PI
Alan Brookhart, PhD, Task Order PI*

Funding Source: AHRQ

Project Period: 07/15/10 - 07/14/13

Total Funding: \$2,836,647

Comparative Effectiveness of Management Options for Localized Prostate Cancer

– This project will use secondary analysis of existing data, retrospective analysis of SEER/Medicare data and prospective cohort data to comparative the effectiveness of management options for early prostate cancer. 1: To directly compare the disease-free and overall survival in men with localized prostate cancer treated by retropubic prostatectomy, minimally-invasive prostatectomy, 3D conformal radiation therapy, intensity-modulated radiation therapy, proton radiation therapy, and brachytherapy, stratified by prostate cancer risk group, race, and age group. 2: To directly compare

the prostate-cancer specific and overall quality of life in men with localized prostate cancer treated by the same treatment modalities, stratified by age group. 3: To directly compare the disease characteristics, disease-free survival and quality of life outcomes in African American men and men living in Federally-designated Medically Underserved Areas. 4: To examine disease, other clinical and demographic factors that affect the decision making process of men with newly-diagnosed prostate cancer.

*Principal Investigator: Til Stürmer, MD, MPH, Task PI
Paul Godley, MD, PhD, MPP, Task Order PI*

Ronald Chen, MD, MPH, Task Order PI

Funding Source: AHRQ

Project Period: 07/15/10 - 07/14/13

Total Funding: \$3,378,263

Developing Evidence to Inform Decisions about Effectiveness Research Network-2 (DEcIDE-2)

– This program is supported by the Agency for Healthcare Research and Quality (AHRQ) to assist AHRQ and other Federal Agencies with patient-centered outcomes research, including studies on comparative clinical effectiveness as authorized by Section 1013 of the Medicare Modernization Act of 2003 (MMA) and subsequent legislation such as the American Recovery and Reinvestment Act (ARRA). The DEcIDE-2 Research Network will continue to provide a variety of research services and scientific products to support the generation of new scientific evidence on patient-centered outcomes of healthcare items and services, with a focus on comparative clinical effectiveness research. Activities performed by the DEcIDE Research Network reflect the general principle that clinicians and patients should have the best available scientific evidence upon which to make individual decisions about health care items and services. Notably, a hallmark of the DEcIDE Research Network program is to provide high quality research that contributes to the evidence base and serves to inform healthcare decision-making. Hence, the DEcIDE Research Network program will continue its focus on original research that generates objective scientific evidence and new analytic tools for assisting patients, clinicians, purchasers, policy-makers, and others in making informed health care decisions. NOTE: None of the task orders awarded under the IDIQ contracts will be subject to ARRA funding and reporting requirements. Major activities a DEcIDE-2 research center may perform: 1. Conduct multi-center prospective observational and interventional studies. 2. Analyze, link, and develop electronic health data for research. 3. Perform retrospective analytical studies to inform and support research as well as research prioritization and decision-making. 4. Develop and apply new research methods, instruments, and methodologies. 5. Provide technical assistance to AHRQ and other assignments as requested.

Principal Investigator: Til Stürmer, MD, MPH

Funding Source: AHRQ

Project Period: 07/26/10 – 07/24/13

Total Funding: \$0

Accelerating adoption of CER results with patient decision support interventions – The promise of comparative effectiveness research (CER) is that it will lead to improved clinical decision-making and better performance of the US healthcare system (REF). But whether CER can fulfill its potential and translate the results into evidence-based clinical decisions depends on adoption of CER results into daily practice. Decision support interventions (DESI) that communicate CER results to patients have been shown to improve clinical decision making in clinical trials; however, additional work is needed to identify the most efficient ways of implementing DESIs so that CER results can inform routine clinical practice. Despite the growing evidence base supporting the use of DESIs, the implementation of these tools in routine clinical practice remains in its infancy. With grant support from the Foundation for Informed Medical Decision Making, the researchers have spent the past 4 years exploring various approaches to implementing DESIs in primary care practices. These efforts have highlighted two key issues in implementing DESIs: (1) ensuring that DESIs are provided to eligible patients by their healthcare teams, and (2) ensuring that patients review a DESI once it has been provided to them. We propose to build on our extensive knowledge and experience to test alternative strategies for implementing DESIs in primary and specialty care in two geographically and structurally diverse health care systems - the Palo Alto Medical Foundation, a community-based multi-specialty care system (prime) and the University of North Carolina, Chapel Hill (subcontract), an integrated academic health care system. The goals of the proposed research are: (1) to test alternative approaches to distributing and increasing patient use of decision support interventions (DESI) for prostate cancer screening, and (2) to test the efficacy of a DESI for prostate cancer treatment.
Principal Investigator: Carmen Lewis, MD, MPH
Funding Source: Palo Alto Medical Foundation
Project Period: 09/01/10 – 08/31/13
Total Funding: \$1,155,169

Demonstration of Health Literacy Universal Precautions Toolkit Task Order #10 – Dr. DeWalt is an internationally recognized expert in health literacy and first author of the Health Literacy Universal Precautions Toolkit. He will direct the scientific content of the Maintenance of Certification (MOC) Part II module and also chair the committee of content experts who will review, select, and revise the content to be included in the module. The deliverables for this project include: an environmental scan report of existing health literacy education activities; a health literacy MOC training outline; a health literacy MOC training module (English and Spanish); a list of organizations giving CME credit, and a report on the dissemination activities for the training module.
Principal Investigator: Darren DeWalt, MD, MPH
Funding Source: AHRQ via University of Colorado
Project Period: 08/01/11 - 09/21/14
Total Funding: \$129,646

Family Members Influence Quality and Delivery of Care for Heart Failure Patients – There is a fundamental gap in how the presence of family companions in medical visits influences indicators of quality of care, such as patient-centered communication (e.g., communication that reflects respect for patients' values and incorporates patient's concerns and preferences into decision-making), specifically for patients with heart failure - a particularly vulnerable population by virtue of its high morbidity and mortality. The long-term goals of this project are to improve the quality and delivery of care and subsequent health outcomes for Heart Failure (HF patients). The overall objective here, which is our next step in pursuit of our long-term goal, is to determine whether family accompaniment influences processes of care within the medical visit and use this information to inform intervention development. The rationale for the proposed research is that once we know how family members influence quality and delivery of care we can fulfill the call to action of policy makers and health care models to "create an integrated, coherent plan for ongoing medical care in partnership with patients and their families."
Principal Investigator: Crystal Wiley Cene, MD, MPH
Funding Source: NIH
Project Period: 06/14/11 - 04/30/14
Total Funding: \$484,888

An Economic Framework for Evaluating Biomarkers Used to Target CVD Prevention – Dr. Pignone will help update the UNC-CH/RTICHD Prevention Model for use with novel cardiovascular risk markers. He will then work in collaboration with colleagues at RTI and UCSF to test, through modeling, the cost-effectiveness of using coronary artery calcium in addition to the standard Framingham risk assessment to guide cardiovascular prevention decisions. In doing so, the team will test a variety of different clinical and policy scenarios and systematically examine the effects of key individual variables on the results. Dr. Pignone will also participate in manuscript preparation and revision.
Principal Investigator: Michael Pignone, MD, MPH
Funding Source: AHRQ via University of California at San Francisco
Project Period: 07/01/11 - 7/31/13
(extended through 07/31/14)
Total Funding: \$82,243

Comparative Effectiveness of Dissemination and Translation Techniques to Facilitate the Use of Comparative Effectiveness Reviews – This project includes three major components: 1) defining the comparative effectiveness of various dissemination and translation strategies for systematic reviews, 2) understanding the impact of various strategies for communicating evidence associated with scientific uncertainty (e.g. alternate presentations of imprecision, risk of bias, inconsistency) and how target audience characteristics and contextual factors affect the impact of these strategies, and 3) understanding the impact of various strategies to promote informed and shared

decision making in the face of scientific uncertainty (e.g. decision aids, physician training, patient training, consumer training) and how target audience and contextual factors affect the impact of these strategies. For each component, we will perform preliminary evidence reviews and work with key content and technical experts in the field to refine questions for systematic evidence review. We will then conduct systematic evidence reviews for each key component relying on standard EPC protocols. We will identify relevant literature by searching MEDLINE®, CINAHL, PsychINFO, ERIC, and Cochrane Library databases. The investigative team will jointly discuss and grade the overall body of literature, generate recommendations for future research, and help disseminate findings to the research community and other stakeholders.

Principal Investigator: Timothy S Carey, MD, MPH, and Stacey Sheridan, MD

Funding Source: AHRQ via RTI

Project Period: 09/05/11 – 01/31/14

Total Funding: \$135,001

Merck Program for Assistance with Transitions from Hospital to Home (PATHH) – The purpose of the study is to determine impact of the Hospital Transition in Care (HTiC) Service on the following patient outcomes: 1) 30-day hospital readmission rate 2) Emergency room visits within 30-days after discharge 3) Patient satisfaction 4) Patient knowledge of discharge Instructions 5) Patient adherence with discharge plans. In addition, the project seeks to test the technology and integration required to successfully execute, operate, and scale the HTiC Service and to identify opportunities to improve its design.

Principal Investigator: Carlton Moore, MD

Funding Source: Merck Sharp & Dohme

Project Period: 12/01/11 - 12/31/13

(extended through 8/31/14)

Total Funding: \$1,250,759

Evaluation of Stage 3 Meaningful Use Objectives –

The purpose of this work is to gain an understanding of the proposed stage 3 meaningful use (MU) objectives in the areas of care coordination (CC) and patient and family engagement (PFE). To accomplish this, RTI International is partnering with the University of North Carolina Health Centers (UNCHC in Chapel Hill, NC) for a 12-month project. The project objective is to obtain important practical feedback from hospital and ambulatory clinic sites about the draft Stage 3 MU objectives, the EHR innovations to support the objectives, and the anticipated value provided to organizations pursuing the objectives in the areas of CC and PFE. The specific objective of this project is to answer three questions: (1) How can the evaluated Stage 3 MU objectives be improved at the policy level? (2) What EHR innovations would support meeting the evaluated Stage 3 MU objectives? (3) What will increase the value for hospitals and/or ambulatory practices of implementing the proposed Stage 3 MU objectives? In order to explore proposed PFE and CC

MU objectives, hospital-based and ambulatory care sites in North Carolina were selected for their early implementation experience in these areas will be recruited and evaluated using direct observation and staff interviews. A total of 10 sites, 5 with a focus on patient and family engagement and 5 with a focus on care coordination, along with focus groups conducted at two regional extension centers (RECs) will be included to gain a broad range of experiences. Following data collection activities and qualitative data analysis, findings will be synthesized into a final report.

Principal Investigator: Carlton Moore, MD, MS

Funding Source: AHRQ via RTI

Project Period: 09/26/13 - 09/25/14

Total Funding: \$99,823

Comparative Effectiveness of CyberKnife Robotic Radiosurgery for Prostate Cancer now called: Comparative Effectiveness of Management Options for Localized Prostate Cancer –

The Agency for Healthcare Research and Quality (AHRQ) has funded a large, 3-year study at the University of North Carolina (UNC) to examine the comparative effectiveness of prostate cancer treatments. This is a prospective cohort study of about 1,500 patients in North Carolina who will complete surveys at baseline (pre-treatment) and then prospectively during follow-up. There are few patients treated with Cyberknife radiation therapy in the state of North Carolina, so this treatment modality will not be fully examined in the cohort study. The Cyberknife Robotic Radiosurgery "parallel study" is a collaboration with other institutions across the United States to enroll 100 patients onto a prospective cohort, who will be followed using identical methods as the North Carolina cohort. This will allow comparisons of quality of life, disease control and survival of patients treated with this newer treatment modality against those of other treatments.

Principal Investigator: Ronald Chen, MD, MPH

Funding Source: Accuray Incorporated

Project Period: 06/01/12 - 05/31/15

Total Funding: \$100,000

UNC Research Center of Excellence in Clinical Preventive Services –

The Agency for Healthcare Research and Quality (AHRQ) awarded a 3-year study at the University of North Carolina (UNC) to examine the comparative effectiveness of prostate cancer treatments. This was in response to the important problem of overuse of some screening services, which can expose patients to avoidable harms and contribute to high health care costs. The Center seeks to understand and encourage appropriate use of screening through an integrated research agenda and the activities of the Core Office. Three primary research projects are currently in the field. In Project 1, qualitative interviews have been conducted to determine patients conceptualize the potential harms of preventive screening, and a randomized trial will test the effect of different presentations of potential harms on patient intent to undergo prostate cancer screening,

colorectal cancer screening, or osteoporosis screening. Project 2 aims to understand physicians' knowledge, attitudes, and decision making about potentially harmful screening clinical preventive services, through qualitative interviews and a quantitative survey. Project 3 is investigating, in a randomized trial, the effect of a patient decision support intervention on colorectal cancer screening decision in older patients.

The Center's Core Office administers the research efforts, and is charged with promoting research innovation in appropriate use and potential harms of screening, fostering collaboration with a variety of partners, advancing awareness of the topic among practitioners, other researchers, and policy makers, and providing a theoretical and practical foundation for the education of future clinicians.

Principal Investigator: Russell Harris, MD, MPH

Project Lead Investigators: Carmen Lewis, MD, MPH, Stacey Sheridan, MD, MPH, Maihan Vu, DrPH

Funding Source: AHRQ

Project Period: 09/30/11 – 09/29/14

Total Funding: \$4,500,000

Regional Patient Safety Officer Conference - Learning Together Today and Tomorrow

Two substantial problems many PSOs face are limited access to peers and limited exposure to social sciences research. The Regional Patient Safety Officer Conference for Patient Safety Officers (PSOs) from the Virginia, North Carolina, and South Carolina will address these limitations. The first aim of this conference is to bring PSOs from the region together to build and maintain social capital through a conference design based on adult learning theory that includes reflective dialogue and the conceptualization of a virtual networking site to maintain the social structure. This networking site will be created for their use following the conference. Research results will be shared and discussed using adult learning theory methodologies that will actively engage the participants in immediately using the new information. The second aim is to disseminate and learn from social science research that is not widely available at other health care conferences to increase PSOs' knowledge and skill for organizational and cultural change. Conference topics will be drawn from behavioral economics, human resource development, public health and information science. The third aim is to provide opportunities for graduate-level students interested in patient safety research to connect with PSOs as potential research partners. PSOs and student participants will share storyboards on their background, organization, and research interests during the conference. Connecting students with PSOs is important because this can result in research collaborations, access to real data for the students or identification of research questions that might result in findings that are rapidly applied for organizational improvement. This one-day conference to be held in Cary, NC at the NC Center for Hospital Quality and Patient Safety with an opportunity for post conference networking at a nearby art museum is planned for

approximately 40 PSOs and 10 graduate-level students. It is anticipated that PSO participants will have a variety of years of experience, background, and training, and work in hospitals and health care systems that are representative of all existing hospitals and health care systems. It is anticipated that student participants will be from schools of nursing, medicine, public health, and pharmacy that have graduate level programs.

Principal Investigator: Tina Schade-Willis, MD

Funding Source: AHRQ

Project Period: 08/01/12 – 07/31/13

Total Funding: \$38,502

Developing Evidence to Inform Decisions About Effectiveness Research Network: Developing and Evaluating Methods for Record Linkage and Reducing Bias in Patient Registries

Non-experimental comparative effectiveness research (CER) and patient-centered outcomes research (PCOR) provide important information about "real world" combinations of interventions for heterogeneous patient populations. To overcome the limitations of single databases, data from sources such as administrative claims can be linked securely and confidentially with data from patient registries. Registry linkage can facilitate exposure and control group identification, improve measurement of risk factors and outcomes, or allow researchers to monitor events without contacting participants directly. However, at least four major challenges persist. First, unique personal identifiers for linkage are not always available. Second, non-experimental studies are subject to validity threats such as confounding by indication, selection bias, and misclassification of exposures or outcomes. Third, linkage errors can systematically bias estimates of treatment effectiveness. Fourth, although researchers have continued to develop new methods for deterministic and probabilistic linkage, these methods have not been tested thoroughly, and comprehensive guidelines are lacking. This project addresses these challenges by pursuing three major objectives: (1) Develop a framework and guidance for researchers on record linkage of registries to other data sources; (2) Develop and test new methods to improve confounding control and generalizability in CER/PCOR using linked data; and (3) Develop a method to improve instrumental variables analysis using linked registry data.

Principal Investigator: Til Stürmer, MD, MPH, Task PI Alan Brookhart, PhD, Task Order PI

Funding Source: AHRQ

Project Period: 9/27/12 - 7/24/14

Total Funding: \$1,112,042

Using Health Outcomes in Establishing the Effectiveness of Clinical Preventive Services

UNC-CH personnel will work with American Institutes for Research (AIR) and other organizations subcontracting with AIR to develop a protocol; engage technical experts and stakeholders; review US Preventive Services Task Force (USPSTF) recommendations and methods used by other groups; synthesize, catalog, and analyze findings to develop options for the USPSTF; write a draft and final

report, and present results to the USPSTF. The aim of the project is to inform the methods that the USPSTF uses to evaluate the effectiveness of clinical preventive services through the conduct of an in-depth study of how the USPSTF considers intermediate outcomes and final health outcomes in determining the effectiveness of a clinical preventive service. The final stage of the award focuses on articles and publications.

Principal Investigator: Russ Harris, MD, MPH

Funding Source: American Institute for Research (AIR)

Project Period: 09/30/12 - 09/29/13

Total Funding: \$155,653

Creation and demonstration of a collaborative, multi-site, palliative care research network to reinvigorate biomedical research in Palliative Medicine – We propose to cultivate new collaborations among established investigators, and to assemble a new multidisciplinary team, to facilitate the conduct of innovative, high-impact, clinically relevant research in one of the most challenging biomedical and behavioral areas – palliative care. While developing policies and procedures for inter-institutional, collaborative research, this project will also test the collaborative network and refine its methods through the design and conduct of a specific study addressing clinical uncertainty regarding withdrawal of lipid-lowering agents in the palliative care setting. This study, conducted in the context of a new national cooperative research network, will broaden our research base and enhance cross-fertilization. At the conclusion of the funding period, we expect to have both (1) completed the planned investigation, and (2) created a unique and innovative palliative care cooperative group that is sustainable, poised to conduct multiple future studies, and prepared to serve as a venue for recruiting new investigators and new expertise into the palliative care research community. An embedded clinical trial will serve as a focal point for development of the cooperative group. We propose a randomized comparative effectiveness study that is intended to provide important evidence regarding a standard, but unstudied, palliative care practice – withdrawal of medications for medical comorbidities as death nears. We focus on HMG Co-A reductase inhibitors (a.k.a., statins), prescribed for the primary or secondary prevention of hyperlipidemia, since they are common medications and their withdrawal is a source of major debate. Recommendations for their withdrawal have been proposed, but never tested. Specific aims include: 1. To determine if there is a difference in time-to-event in patients who are discontinued on statins vs. maintained on statins, as assessed via a composite endpoint encompassing death and major cardiovascular events (e.g., myocardial infarction, stroke). 2. To determine whether there are differences in patient- and family-perceived burden, and quality of life of patients and family/caregivers, when patients have statins withdrawn versus when patients continue on statins. 3. To assess the difference in cost between patients who have statins withdrawn versus those who continue on statins. UNC-CH will be a subcontractor for this work.

Principal Investigator: Laura Hanson, MD, MPH

Funding Source: NIH

via Duke University Medical Center

Project Period: 09/01/10 – 09/29/13

Total Funding: \$572,768

Implementing Best Practice in Palliative Care – Palliative care and hospice focus on the relief of suffering and achieving the best possible quality of life, including ameliorating symptoms, relieving psychological distress, and promoting spiritual well-being for patients their caregivers. The new National Institute of Nursing Research funded national research network, the Palliative Care Research Cooperative Group (PCRC), is an efficient mechanism for evidence development including comparative effectiveness research. Quality monitoring and performance improvement initiatives are an important approach to reinforce evidence implementation. Over the past 5 years, a regional electronic point-of-care quality monitoring program called QDACT-PC has been developed and piloted in North Carolina; it has been demonstrated to be well-liked by clinicians, usable, feasible, and able to generate reliable information that can be used to benchmark conformance with palliative care quality metrics and reinforce best practice. Specific aims of the project include: **AIM 1: To develop and nationally implement a uniform approach to palliative care quality monitoring using a PCRC specific version of QDACT-PC (QDACT-PCRC).** Upgrades include the addition of new data elements and question modules about caregivers, clinical sites characteristics, hospital-based palliative care, and assessment of the 5 items newly endorsed by the American Academy of Hospice & Palliative Medicine through the American Board of Internal Medicine (ABIM's) Choosing Wisely campaign. **AIM 2: To define benchmarks for key quality measures in palliative care using network-wide data from the QDACT-PCRC as a mechanism for delivering clinical decision support.** Using descriptive baseline data collection from all network sites, investigators will generate the first multi-site data on NQF endorsed and other quality measures for palliative care. **AIM 3: To test the use QDACT-PCRC as a mechanism for delivering clinical decision support that reinforces agreed best clinical practice.** Using an overarching PDSA approach, we will use a collaborative process to define areas for quality improvement based upon measures with greatest practice variation identified in Aim 2. For each area we will develop an improvement program including clinical decision support to be delivered via QDACT-PCRC, implement the intervention, monitor impact and update the intervention and process until goals are achieved. This project will generate a national system of real-time point-of-care quality monitoring for palliative care, with demonstrated capabilities to support quality improvement and implementation of best evidence.

Principal Investigator: Laura Hanson, MD, MPH

Funding Source: AHRQ via Duke

Project Period: 09/30/13 - 09/29/18

Total Funding: \$284,136

Refinement and expansion of the Palliative Care

Research Cooperative Group – The overarching objective of this U24 grant application is to amplify the role of the national Palliative Care Research Cooperative (PCRC) as a resource for efficient conduct of high-quality, collaborative, and multisite PCEOL research. Our intention is to advance the PCRC to its next phase of development by leveraging and building upon the prior NINR investment and all accomplishments of the PCRC to date. The requested funds will allow us to advance the PCRC such that it will be recognized as a hub of expertise, interest, and activity in PCEOL research and key player in the development of the PCEOL research workforce. It will serve as an access point for: (a) critical PCEOL research infrastructure, including research cores, statistical support, data systems and procedures, measures and methodological guidance and technical support; and, (b) diverse PCEOL-relevant populations including patient, caregiver, and the historically underserved. We intend for the PCRC to set the gold standard for multisite PCEOL research. **Specific Aim #1:** To develop national **research capacity** for collaborative, multisite, PCEOL research in a way that maximizes the quality and efficiency of research, and the effectiveness of cooperative groups. **Specific Aim #2:** To provide integrated **support for PCEOL research**, specifically, for the conduct, analysis, and dissemination of clinically meaningful, high-quality, efficient, patient-centered, multisite studies.

Principal Investigator: Laura Hanson, MD, MPH

Funding Source: National Institute of Nursing Research via Duke

Project Period: 07/01/13 - 06/30/18

Total Funding: \$702,200

Integration of Patient Reported Outcomes Measures Into Pain Management Practices for Patients With Hemophilia

– More than 100 million people in the United States suffer from pain each year, at an estimated cost of \$600 billion for pain treatments and lost productivity. 1) Deaths due to opioid pain medications are rising at an alarming rate. 2) Patients with hemophilia are particularly afflicted by pain, with more than half of adults and nearly 10% of children experiencing chronic pain, either constant, episodic, or both. 3,4) Despite pain's negative and often disabling impact, our current system for providing care to these patients is failing: up to half of hemophilia patients with pain report their pain is not well controlled. 5,6) In addition, pain remains an essential clinical marker for bleeding episodes in both pediatric and adult patients with hemophilia, often serving as a direct proxy measure of bleeding episodes. Although pain is often used as a primary measure of the efficacy of therapeutic interventions, we do an inadequate job of assessing, documenting, and following pain and its impact on patients' well-being. 7) This shortcoming is largely due to lack of practical, well-validated, self-report measurement tools for pain in patients with hemophilia. It is not known whether incorporating patient-reported

measures of pain into the clinical care of patients with hemophilia will affect health-related outcomes that matter to our patients.

Principal Investigator: Tyler Buckner, PhD

Funding Source: National Hemophilia Foundation (Clinical Fellowship Program)

Project Period: 07/01/13 - 06/30/15

Total Funding: \$188,333

Comparing Traditional and Participatory Dissemination of a Shared Decision Making Intervention

– Despite rapid advances in medical knowledge, significant gaps remain in our ability to rapidly translate new evidence into everyday practice. Indeed, the most common dissemination technique is passive diffusion that includes journal publications, didactic presentations at conferences, and educational material distribution. This process often fails to produce timely or sustainable practice level changes. The Asthma Shared Decision Making Tool Kit was adapted and implemented by investigators from the Carolinas Medical Center across a regional network of 6 Pediatric, Family Medicine, and Internal Medicine ambulatory 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 participatory approach to dissemination that provided an ideal framework for rapid dissemination of the toolkit across 6 practices. Use of the tool kit revealed improved patient outcomes including improved medication adherence, decreased asthma exacerbations and increased patient involvement in the creation of an asthma care plan. To translate these findings more rapidly into clinical care, methods to disseminate the tool need to be tested for effectiveness. **Methods:** For this study, we will leverage a partnership between the statewide Medicaid network and the NCNC, a state-wide meta-network of practice based research networks centered around Duke University, UNC Chapel Hill, East Carolina University and the Carolinas Medical Center (see www.ncnc.unc.edu) to identify best practices for dissemination of the shared decision making toolkit. We will test this novel method for dissemination on a larger scale by randomizing 30 primary care practices from these 4 NCNC PBRNs to one of three arms representing different levels of exposure to the tool kit and facilitation methods: (1) Control with no dissemination; (2) Traditional dissemination with one didactic session and introduction to the educational materials; and (3) Facilitator-Led Participant Owned” (FLOW) approach to dissemination. The FLOW approach includes on site project meetings for up to 12 weeks to assist with the adoption and implementation of the shared decision making tools and processes to enhance shared decision making with patients. **Results/Outcome measures:** The primary outcome measures will be: number of emergency room visits and hospitalizations for asthma related symptoms at the practice level and aggregate patients' perceptions of involvement in their asthma care decisions. **Secondary outcome measures will include:** beta agonist overuse, controller medication use, oral steroid use and

practice level use of shared decision making. We will compare the results within each of the exposure arms. Conclusions/Impact: This study will provide crucial data to support the effectiveness of a novel method for dissemination of an evidence-based toolkit into a primary care practices.

Principal Investigator: Jacquie Halladay, MD, MPH
Funding Source: PCORI via Carolinas Medical Center
Project Period: 09/01/13 - 08/31/16
Total Funding: \$318,201

Child Health Accountable Care Collaborative Predicted Impacted Patients Improvement Cycle – To increase the successful dissemination of the CHACC protocol statewide, the CHACC study team will examine the diagnostic and clinical characteristics of children with multiple hospitalizations, using electronic health record information. Both characteristics of the hospitalization and post-hospital service use were examined for Medicaid enrolled children.

Principal Investigator: Marisa Domino, PhD
Funding Source: North Carolina Community Care Networks (N3CN)
Project Period: 02/01/14 - 06/30/14
Total Funding: \$113,106

Program on Mental Health & Substance Abuse Services & Systems Research

Marisa Domino, Ph.D., Program Director

There is growing recognition of the importance of mental health and substance abuse treatments, due to the high prevalence of disease and disability burden, as well as interactions with other chronic conditions. Providers in both the private and public sectors are searching for effective models of short- and long-term care for people with acute and chronic mental illness and substance abuse disorders. Many of the issues confronting policy makers and service providers at the global, national, state, and local levels require new knowledge and research about:

- the effectiveness and cost-effectiveness of a large number of potential interventions in use by service providers;
- clinical and social outcomes for service recipients;
- the structures, processes, and effects of managed behavioral healthcare programs; and
- the integration of mental health services with other substance abuse, primary care, criminal justice, and social welfare systems.

The Sheps Center's work in this area involves studies taking place in North Carolina and throughout the world.

The following research projects were active during the year:

Research Training in Mental Health Services & Systems – Program for social/behavioral scientists and clinicians seeking pre- and post-doctoral advanced training in mental health services research has two components: core activities and individualized study. The core component involves a weekly research seminar, participation in departmental seminars and grand rounds at the collaborating institutions, and other research seminars/workshops at UNC-CH or Duke. The individualized study component is tailored to the special interests and needs of each fellow and their prior experience. It is based on an apprentice-type model whereby each fellow is linked to one or more mentor(s) who works with the fellow to develop his/her own research and skill development program. The program is jointly sponsored by the Department of Psychiatry and Behavioral Sciences, Duke University Medical Center.
Program Director: Joseph P. Morrissey, PhD
Funding Source: National Institute of Mental Health, NIH
Project Period: 07/01/90 – 06/30/18
Total Funding: \$5,660,590
Type: Training

Robeson County Bridges for Families – For this evaluation, the investigator will interpret data for the perinatal programs and other evidence-based programs that have been approved by the NC Practice Improvement Collaborative for statewide rollout. This project is a part of a larger scope (annual \$500k). Dr. Greene leads a management team made up of representatives from three state agencies and non-profit partner agencies, as well as a local management team with leaders from service agencies, the court, and the county government. There are over 60 local partners involved in implementation and numerous additional state and local partners for which Dr. Green provides project leadership.

Principal Investigator: Sherri L. Green, PhD, LCSW
Funding Source: Governor's Institute on Alcohol and Substance Abuse Inc.
Project Period: 08/01/08 – 06/20/12
(extended through 09/30/14)
Total Funding for 10/12-9/30/14: \$97,993

Perinatal and Maternal SA Initiative – Dr. Sherri Green, and her research team, will provide evaluation support, technical assistance, and policy research for the North Carolina Perinatal and Maternal Substance Abuse Initiative. Associated research activities will result in information that helps the state improve the quality of substance abuse services in North Carolina (\$108,775). The contract also covers activities associated with the position of principal investigator and collection and management of evaluation data for the Robeson County Bridges for Families (RCBF) Program. Funding for activities associated with the RCBF program come from the US Department of Health and Human Services, Administration for Children and Families.
Principal Investigator: Sherri L. Green, PhD, LCSW
Funding Source: Governor's Institute on Alcohol and Substance Abuse Inc.

Project Period: 7/1/11 - 06/30/14
Total Funding: \$188,628

Expansion of Research Capability to Study Comparative Effectiveness in Complex Patients (CMS MAPCP Project) – The project will do the following:

1. Collaborate with NCCNC staff to create an integrated database linking three data sets maintained by the NC Department of Health and Human Services: HEARTS (state psychiatric hospital admissions), IPRS (outpatient mental health services), and Medicaid claims. Sheps Center staff will provide technical assistance in identifying relevant mental health data elements in each data system, composite measures of service use, the development of codebooks for the integrated database, and the creation of an oversight structure for managing the integrated database and making it available to the research community in NC and elsewhere. 2. Conduct a small proof of concept study to confirm the accessibility and usability of the integrated data base. This study will focus on medical homes for patients with mental illness and explore variations in primary care visits, services received and outcomes for patients with varying levels of psychiatric illness as contained in the integrated database.

Principal Investigator: Marisa Domino, PhD

Funding Source: AHRQ via North Carolina Community Care Networks, Inc (NCCCN)

Project Period: 9/30/10 - 03/31/14
(extended through 12/31/14)

Total Funding: \$488,593

An Approach to Capture Divergent Stakeholder Views on Future Research Needs – Involvement of a wide range of stakeholders in identifying future research needs in a clinical area is a relatively new concept, and best practices for doing so are untested and evolving. One approach has been to rely on a small group of thought-leaders, the underlying assumption being that they can represent the disparate views in their community. It is possible on the one hand that a small group of stakeholders is likely to miss important variation in opinion; on the other hand, there may be a point at which too many stakeholders creates redundancy. Given the wide range of disease and disorders characterized by divergent stakeholder opinion, developing methods that capture variation in stakeholder opinion, as a foundation for prioritizing future research needs, is critical for PCORI's mission. The proposed study seeks to develop an evidence base for determining priorities among stakeholders with divergent opinions using the treatment of autism in childhood as an example. This will be accomplished by means of three aims: 1. Conduct an assessment of future research needs using point allocation and conjoint analysis among a small group of stakeholder thought-leaders, 2. Conduct an assessment of future research needs using point allocation and conjoint analysis based on a large web-based survey of stakeholder constituents across the US, and 3. Assess the concordance of the two approaches and their relative advantages with respect to stakeholder buy-in with the protocol and satisfaction with the outcomes.

Program Highlight: UNC-CH/ Duke Training Program in Mental Health Services & Systems Research

The goal of the UNC-CH / Duke Training Program in Mental Health Services & Systems Research is to expand the pool of investigators capable of undertaking policy-relevant mental health services and systems research. From its inception, the Program has sought to assist persons with a doctoral degree in one of the social sciences, psychology, psychiatry, public health, social work and related fields to gain experience in applying research methods to the systematic analysis and evaluation of mental health care services and public policy issues. Fellows work closely with faculty mentors who supervise their research that is usually associated with funded faculty projects or recently completed projects. The emphases of the training program remain on the organization, financing, utilization, quality, and evaluation of mental health care services; public policies for ensuring access to such services; and the social epidemiology of mental disorders. As before, the Program remains committed to multidisciplinary training, a public sector orientation, and a special focus on persons with a severe and persistent mental illness.

Two groups of faculty participate in the Training Program: core faculty and resource faculty. Currently there are 6 core faculty and 16 resource faculty associated with the Training Program. Members of the core faculty group are more closely involved in the week-to-week conduct of the training program, attend seminars, and present their ongoing research. Senior members of the faculty serve as mentors for trainees, either in a solo capacity or in combination depending upon the fellow's research interests and involvements. Resource faculty include people who serve as occasional seminar speakers, consult with fellows on specific issues related to their areas of expertise, and facilitate access to clinical settings or other sources of research data. The latter group may also attend selected seminars when the topic deals with an area of interest to them. The time to be devoted to the proposed training program by these faculty members are part of normal teaching and research activities of each faculty member participating in the program and does not constitute a cost-sharing situation.

Using conjoint analysis to discover stakeholder priorities for future research needs will identify what aspects of research are valued and their relative importance, providing a metric with which to assess new research opportunities. Conjoint analysis also provides a way to identify constituencies with divergent views, providing a structure for hosting cross-constituency dialogue. Comparison of conjoint analysis with a point allocation approach will elucidate whether attention to underlying values refines priority rankings. Comparison of the

approaches in small and large groups will assess the net value of the large group approach. The proposed study addresses PCORI's interests in developing methods for bringing together stakeholders to prioritize research questions, identifying stakeholder-identified gaps in comparative effectiveness knowledge and elucidating national stakeholder priorities for patient-centered outcomes research

Principal Investigator: Kathleen Thomas, PhD

Funding Source: PCORI

Project Period: 07/01/12 - 12/31/14

Total Funding: \$692,734

The Cultural Authority of Science in the Public Sphere: Creating Data Streams for Further Advances – Intellectual Merit.

Survey research on public attitudes toward and understanding of science has been plagued by a lack of theoretical focus. To address this gap, the objective of this application is to develop new measures that previous surveys on this topic have yet to address. The rationale for this project is that it will create the foundation for a vibrant research community that can examine how social groups vary in their trust/distrust of organized science. The proposed research will accomplish the overall objective of this application by pursuing the following specific aims: Aim #1: Bring together scholars from multiple backgrounds to discuss the core issues related to the cultural authority of science, provide new perspectives on existing data, and suggest measures for future surveys. This aim will be completed by organizing an expert panel that will bring together scholars who possess specialized knowledge related to the overlap of social theory and public opinion, social studies of science, survey research on public understanding of science, current data archives, and the development of public opinion questionnaires. Robert Bell—Executive Secretary of the NSF's Survey of Public Attitudes Toward and Understanding of Science and Technology—has indicated that the NCSES division of the NSF is intensely interested in this proposal and would consider co-funding the project. Aim #2: Develop new measures and collect new data to examine the social and cultural factors that shape the cultural authority of science in the public sphere. Building on the knowledge gained from the expert panel described above, the next step will be to collect new survey data using a nationally representative sample of U.S. adults. The survey will consist of new items that previous national surveys have overlooked and will allow us to address new empirical issues and develop new measures for future NSF surveys. The proposed project will contribute an in-depth understanding of the cultural authority of science in the public sphere that both integrates theoretical ideas from social scientists and emphasizes a multidimensional approach to these issues. This contribution is significant, because it will transform future survey research as a means for studying the role of science among diverse social groups in society. Broader Impacts. The outcomes of this project will have wide-ranging benefits. The benefits to students learning and training will be twofold. First, the presentation of results

students will accompany an invitation to become involved in the PI's research program. Second, the data collected in aim 2 will be made available to students for their own research. The inclusion of underrepresented groups is always a great concern to social scientists and the PI shares in the NSF's commitment in this regard. Due to the centrality of race/ethnicity, class, and gender to the proposed research, the PI is committed to recruiting individuals from these groups to participate in all aspects of the proposed research. The enhancement of infrastructure is also built directly into both aims of this study. First, the outcome of the expert panel will be a summary report that will be publically available. Second, aim 2 involves the development of a new questionnaire and dataset that will be shared with other researchers. These outcomes will directly benefit the NSF's survey and the broader social science research community. In addition, research will be presented at professional meetings and disseminated to local and national news media. Furthermore, understanding the mechanisms that divide the public sphere will help the NSF and other scientific organizations engage the public and improve public participation in science, both among adults and children.

Principal Investigator: Joseph Morrissey, PhD, and Gordon Gauchat, PhD

Funding Source: National Science Foundation

Project Period: 08/01/12 – 07/31/14

Total Funding: \$113,999

Adequate Health Insurance for Children with Autism: Evidence and Implications for Defining Essential Benefits – Families raising children with autism

contribute significant amounts out-of-pocket to the cost of care and that this pay-as-you-go strategy is associated with disparities in use for vulnerable families (Thomas, Williams et al, 2013; Parish, Thomas, Williams et al, 2013). As a result, in comparison to other children with special health care needs, families of children with autism are more likely to report unmet need for care and financial difficulties (Thomas et al, 2012; Parish, Thomas et al, 2012a&b). There is evidence from national data that children with special health care needs who have both private insurance and Medicaid are less likely to experience barriers to care than those with private insurance alone, but there is a major research gap about the extent to which combined coverage provides adequate insurance for children with autism, how it improves access to care, and its impact on the mix and level of mental and other health care services they use. The long-term goal of this research is to improve access to care and outcomes for children with autism. The objective of the proposed study is to inform state deliberations about new definitions of essential benefits for mental health and other health care services by i) identifying the segment of children with autism who have the most adequate health insurance and ii) examining their health service use. We hypothesize that having combined coverage will be associated with greater insurance

adequacy and increase the breadth and amount of service use particularly for mental health services.

Principal Investigator: Joseph Morrissey, PhD, and Kathleen Thomas, PhD

Funding Source: Maternal & Child Health Bureau/HRSA

Project Period: 09/01/13 - 08/31/14

Total Funding: \$99,496

Program on Rural Health Research

George 'Mark' Holmes, Ph.D., Program Director

The **Rural Health Research Program (RHRP)** is built on the forty-four year history of rural health services research at the University of North Carolina's Cecil G. Sheps Center for Health Services Research. The program draws on the experience of a wide variety of scholars and researchers, analysts, managers, and health service providers associated with the Center. The Program also has an ongoing partnership with the NC Foundation for Advanced Health Programs, Inc. and the Office of Rural Health and Community Care in the NC Department of Human Resources.

The RHRP is working to address problems in rural health care delivery through basic research, policy-relevant analyses, the geographic and graphical presentation of data, and the dissemination of information to organizations and individuals in the health care field who can use this information for policy or administrative purposes. The Program's research involves primary data collection, analysis of large secondary data sets, and in-depth policy analysis. The Program brings together a diverse, multidisciplinary team including clinicians in medicine, nursing, pharmacy, allied health, mental health, and other professions and disciplines along with experts in biostatistics, geography, epidemiology, sociology, anthropology, and political science to address complex social issues affecting rural populations.

The North Carolina Rural Health Research Program's project portfolio currently includes the *NC Rural Health Research and Policy Analysis Center* and the *Medicare Rural Hospital Flexibility Program*. There is also an active dissemination component and emphasis on the use of geographic methods in research.

The following research projects were active during the year:

Medicare Rural Hospital Flexibility Program

Evaluation – The Sheps Center's current role in this evaluation focuses on three areas. 1) *Development of a Financial Performance Measurement System*: This project uses research and expert opinion to select dimensions and indicators of financial performance, develop appropriate bases or methods of peer comparison, investigate the relationship between quality of care and financial performance, and identify characteristics of high performing Critical Access Hospitals (CAHs). 2) *CAH Conversion Tracking*: The Sheps Center continues its work tracking CAH conversions. 3) *Quality Financial Relationships*: This joint project with the University of

Minnesota will investigate the relationship between CAH financial performance and quality of care.

Principal Investigator: Mark Holmes, PhD

Funding Source: Office of Rural Health Policy, HRSA via University of Minnesota

Project Period: 09/01/03 – 08/31/13

(extended through 08/31/14)

Total Funding: \$1,480,000

Secondary Program Area: Health Care Economics and Finance

North Carolina Rural Health Research and Policy Analysis Center (NC RHR & PAC)

– Extending and expanding the work of the North Carolina Rural Health Research Program at UNC-CH, this project primarily focuses on Federal insurance programs (Medicare and Medicaid) and their effect on rural populations and providers. In addition, faculty and professionals working with the NC RHR & PAC respond to short-term queries using the unique availability of multiple national and special datasets to investigate key rural health policy issues. The following six projects are under investigation: 1) rural health clinics: Medicare & Medicaid profile, 2) the 21st century rural hospital: outpatient services and access to care, 3) hospital readmission following care in a swing bed, 4) swing beds versus skilled nursing facilities: Medicare expenditures for episodes of care, 5) early rural experiences of changes to Medicaid, 6) identifying limitations of prospective payment system (PPS) reimbursement for rural hospitals. The NC RHR & PAC has also been designed to have staff, data, and resources to address other issues as they become salient.

Principal Investigator: Mark Holmes, PhD

Funding Source: Office of Rural Health Policy, HRSA

Project Period: 08/15/04 – 08/31/16

Total Funding: \$5,280,000

Secondary Program Areas: Aging, Disability, & Long-Term Care & Health Care Economics & Finance

Rapid Response to Requests for Rural Data Analysis and Issue Specific Rural Research Studies

– The North Carolina Rural Health Research & Policy Analysis Center (NC RHR & PAC) of the Cecil G. Sheps Center at the University of North Carolina proposes to provide rapid response for rural-focused data analysis and to conduct issue-specific rural research studies in response to emerging policy issues. The NC RHR & PAC is uniquely qualified to provide this service, as it builds on previous and current work conducted during twenty-one years as a Federal Office of Rural Health Policy (ORHP) Rural Health Research and Policy Analytic Center. The NC RHR & PAC has created a national identity as a rural center that can quickly respond to requests for data analysis, and one that produces rapid turn-around policy-relevant research and analysis to inform the rural health policy community. The NC RHR & PAC will partner in this effort with the Rural Policy Research Institute Center for Rural Health Policy Analysis. In order to ensure that rural policy is designed to protect and improve the health of rural residents, data on the unique characteristics of rural people, health care providers, and the health care

infrastructure, and the potential impact of policy and challenges rural areas face in health care delivery must be made available to policy makers, rural organizations and ORHP. The maintenance of data archives that are sufficiently broad to be able to address whatever issues surface requires many data sets, programmer experience using them, statistical knowledge, understanding the geographic issues surrounding different definitions of rural and levels of geography, how to merge data and use GIS, and substantial computing capacity. Organizations and agencies whose task is to focus on rural health policy do not have this capacity, and must rely on organizations that do. The NC RHR & PAC and other members of the project team have been serving this role for the rural policy community for a number of years, and propose to continue to do so. The development and evolution of rural health policy occurs in a rapidly changing context, and the support of rural health policy can also require issue-specific studies involving greater time and resources and more complex study design than rapid response data analysis. Under this cooperative agreement, the NC RHR & PAC, with its collaborator, will also provide these vital services to individuals and organizations involved with rural health policy.

Principal Investigator: George Pink, PhD

Funding Source: HRSA

Project Period: 09/01/10 – 08/31/16

Total Funding: \$450,000

Center for Healthy North Carolina Evaluation – Dr. Radford will serve as the Consulting Evaluator for the NC Public Health Foundation (NCPHF) Center for Healthy North Carolina. Her major responsibilities will include the following: 1. Assist NCPHF staff in conducting a gap analysis of HNC2020 technical assistance options and developing a set of recommendations to guide the development of state, regional, and local focus areas 2. Develop evaluation metrics in collaboration with NCPHF staff as needed in response to recommendations from the NC Institute of Medicine's Evidence Based Strategies for Public Health Task Force. 3. Work with NCPHF and DPH staff to develop a multi-year qualitative evaluation plan including process and outcome measures for use in evaluating the Center for Healthy North Carolina and the programs/initiatives implemented by the Center's community partners. 4. Consult with key community partners (as identified by NCPHF) to develop evaluation plans for local HNC 2020 effort and to maximize the utilization of available data. 5. Meet with NCPHF staff as needed to discuss data, analyses, program needs and modify deliverables as needed.

Principal Investigator: Andrea Radford, DrPH

Funding Source: NC Public Health Foundation

Project Period: 07/01/12 - 09/30/13

Total Funding: \$33,000

Technical Assistance to the ORHCC – The purpose of this contract is to provide financial support for technical assistance and consultation which will assist in fulfilling the ORHCC mission. The Office of Rural Health and Community Care (ORHCC) assists underserved communities and populations to develop innovative strategies for improving access, quality, and cost effectiveness of health care. The mission of the ORHCC is to provide access for underserved populations who would otherwise be unable to receive the needed health care services due to geographic, economic, or other barriers. Distribution of primary care providers in North Carolina has historically been skewed toward the cities and larger towns. Rural residents, who often suffer from transportation issues, find accessing affordable primary care services difficult. Safety net clinics and Critical Access Hospital networks have provided a local solution to this problem by providing rural residents with access to quality primary care services that are both cost effective and easily accessible. The purpose of this contract is to provide financial support to the UNC CH – The Cecil G. Sheps Center for Health Services Research for technical assistance and consultation which will assist in fulfilling the ORHCC mission.

Principal Investigator: Kristin Reiter, PhD

Funding Source: NC Office of Rural Health and Community Care

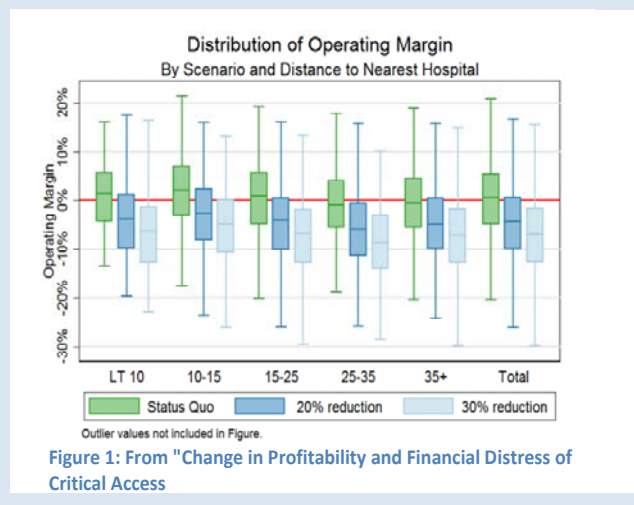
Project Period: 07/01/12 - 08/31/13

(extended through 8/31/14)

Total Funding: \$69,195

Program Highlight: Rural Hospital Closures

In 2013-2014, there was increased attention to the finances of rural hospitals as closures rates increased and various policy proposals called for decreased Medicare reimbursement. Continuing the Center's decades of interest in rural hospital closures (e.g. Tom Ricketts and Becky Slifkin), investigators in the Rural Health Research Program, developed a number of products aimed to inform and educate policymakers and the public on the issues. In Fall 2013, investigators released a series of briefs demonstrating that small rural hospitals have lower profitability than other hospitals and modeled the effect of some proposed policy changes on hospital profitability. The proposed cuts – such as a 20 percent cut to Medicare reimbursement – would lead to a marked increase in the proportion of hospitals losing money – from about 50 percent currently to about 75 percent. Other briefs examined the distance to the next closest hospital (if the financially challenged one closes), rural-urban differences in Medicare post-acute cost, and geographic variation in profitability.



Program on Health Workforce Research and Policy

Erin Fraher, Ph.D., Program Director

The **Program for Health Workforce Research and Policy** is a new Sheps Center program and it builds the science behind the research of health workforce analysis. The program is grounded in data, research and modeling techniques, and infused with interdisciplinary theory and methods. This research drives real world policy decisions that affect clinicians, employers, patients, and the public. The program provides policy makers with data-driven evidence concerning their questions, and collects data on North Carolina health professions that are analyzed and presented to local, regional, state and national audiences. The investigators teach and mentor the next generation of health workforce researchers, undergraduate, and graduate students from across many disciplines of the University. This breadth of professional and practical

expertise to draw upon allows us to research, collect, and produce information that timely, practical, and relevant. At Sheps Center, we manage and maintain the North Carolina Health Professions Data System (NCHPDS), the nation's oldest health workforce data collection program, with assistance from the North Carolina Area Health Education Centers Program (NC AHEC) and the nine statutory licensing boards in the state. The Program is also home to the Carolina Health Workforce Research Center, one of the three national Health Workforce Research Centers funded by the U.S. Department of Health and Human Services.

Our program is in a unique position to draw upon the resources of the entire North Carolina higher education system and their health professions schools, which allows us to respond to information and analysis questions quickly and effectively. Collaborators include North Carolina AHEC, UNC School of Medicine, the UNC School of Nursing, UNC Gillings School of Global Public Health, North Carolina Schools of Dentistry and the School of Pharmacy at the University of North Carolina, Duke University, the North Carolina Community College System, the Foundation for Nursing Excellence, and many others. The Program on Health Workforce Research and Policy works closely with the Rural and Primary Care Programs in the Sheps Center.

The following research projects were active during the year:

North Carolina Health Professions Data System (HPDS) – The HPDS is often held up as the gold standard as one of the most comprehensive and continuously maintained state-level data systems in the nation that tracks the supply and distribution of health professionals. This up-to-date inventory of licensed health professionals in the state contains annual data on 19 licensed health professions from 1979 to present. The data have been used continuously for planning and evaluation of health professions supply, characteristics and distribution. Each year, HPDS staff produce an annual North Carolina Health Professions Data Book, and they produce data, presentations, fact sheets, reports and manuscripts in an effort to inform state policy. These publications and materials are widely used by the legislature, state policymakers, researchers, media, and professionals in the health care industry as the official source of health professions statistics in North Carolina. The HPDS website can be accessed at <http://www.shepscenter.unc.edu/hp>.

Project Director: Erin P. Fraher, PhD, MPP

Funding Source: NC Area Health Education Centers Program and UNC-CH Office of the Provost (Health Affairs)

Project Period: 10/74 – on-going

Total Funding: \$276,558

Type: Technical Assistance

Program on Health Workforce Research and Policy: Service to North Carolina

Researchers from the Program on Health Workforce Research and Policy provided expertise to the NC General Assembly regarding anticipated changes in the availability and demand for health providers this year. Dr. Erin Fraher and her colleagues gave five presentations about trends, opportunities and challenges needed in the education and deployment of physicians, nurses, optometrists and other health care workers.

The team's testimony was used as the basis for proposed legislation to revise the rules governing physician supervision of Certified Nurse Midwives in the state. The optometry presentation spurred legislation requiring the UNC Board of Governors to examine the feasibility of developing a new school of optometry in the state. The UNC General Administration subsequently commissioned the Program to produce a report describing the supply and distribution of optometrists in the state. Based on these data, the Board of Governors, in November 2014, recommended not developing a new school, a recommendation which, if adopted by the General Assembly, will save the state an estimated \$12-\$40 million in initial start-up costs and an estimated \$8-19 million in annual operation costs.

Data from the workforce program is also used by many national, state and local agencies. The program is working with the National Governors' Association (NGA) workforce policy academy. Tom Ricketts, Erin Fraher and Katie Gaul are working closely with staff from the Governor's office, the Department of Health and Human Services and national NGA staff to identify strategies and form a plan to ensure the workforce is in place to meet the diverse health care needs of the Medicaid population.

An Open Source Model for Projecting Physician Shortages in the United States

– The question of whether the United States is facing a physician shortage is a hotly contested topic. Some projections have estimated a shortfall of between 85,000-200,000 physicians by 2020 but other analysts have suggested that supply is not the issue, rather it is the distribution of physicians both geographically and between specialties that is most problematic. In this project, staff developed an open source projection model that can be used by medical and policy leaders to assess whether current and future physician supplies will meet population health care needs. The model is intuitive, easy to use, and incorporates numerous parameters that can be adjusted under a variety of scenarios to forecast the supply and demand for physician services at the county, state and national levels. Scenarios allow the user to change assumptions about the expansion of Medicaid under the *Affordable Care Act*, about physician retirement rates, FTE rates, increased use

of NPs and PAs, and redistribution of Graduate Medical Education slots. Data can be visualized as maps, line graphs and population pyramids, and can be downloaded in graphic and tabular formats.

The model has benefitted from the input of an expert advisory board comprised of clinician leaders from a variety of disciplines and specialties. The model is transparent and dynamic so it can be used by practicing physicians in leadership roles in their states and communities, the Physicians Foundation, state medical societies, national and state specialty society groups, public health officials, policy makers and health workforce experts to better understand and debate the effect that different data sources, workforce assumptions and policies will have on physician workforce estimates.

The model, released in July 2014, can be accessed at

<https://www2.shepscenter.unc.edu/workforce>.

Principal Investigator: Erin Fraher, PhD, MPP

Funding Source: The Physicians Foundation

Project Period: 07/01/11 - 06/30/13

(extended through 9/30/17)

Total Funding: \$1,596,634

Health Workforce Research Center Program

– The mission of the Carolina Health Workforce Research Center (Center) is to conduct and disseminate policy-relevant research for use by the National Center for Health Workforce Analysis, other federal agencies, health care consumers, practitioners, employers, educators, states and communities. This information will provide the evidence base needed to design programs and policies that support the flexible deployment of the workforce required by a reformed health care system. The Center's work focuses on numerous aspects of worker flexibility: existing workers taking on new roles within new models of care; existing workers shifting employment settings; existing workers moving between needed specialties; existing workers altering the types of health services they offer; the emergence of new types of health professionals taking on new roles within new models of care; and the broad implementation of team-based models of education and practice.

Principal Investigator: Erin Fraher, PhD, MPP

Funding Source: Bureau of Health Workforce/HRSA

Project Period: 09/01/13-08/31/17

Total Funding: \$1,991,138

Health Workforce Research Center Program - TA Center

– The Sheps Center has given focused support to state level health workforce data systems. These systems, once implemented, provide data to policy makers, educators, employers and other stakeholders for use in making data-driven decisions and practicing more deliberate health workforce planning. The Sheps Center has partnered with the Center for Health Workforce Studies at SUNY-Albany to create the Health Workforce Technical Assistance Center (HWTAC, <http://www.healthworkforceta.org/>). Through the HWTAC, Sheps Center staff are continuing to provide essential assistance to states and help develop webinars

and informational materials to support states in their efforts. Activities include, but are not limited to, providing information, guidance and feedback on data collection, analysis and dissemination efforts; participating in webinars and conference calls; facilitating stakeholder meetings; and providing more comprehensive assistance to individual states as resources permit.

Principal Investigator: Katie Gaul Frizzelle, MA

Funding Source: Bureau of Health Workforce/HRSA via Health Research, Inc.

Project Period: 09/01/13-08/31/14

Total Funding: \$84,013

The Future of Nursing: Campaign for Action

Research Manager – The goal of this project is to develop local, state and national capacity for evidence-based nursing workforce policy. Our project is well-aligned with the Campaign for Action (CFA) aim to “improve health workforce data collection to better assess and project workforce requirements.” Projects have included the development of a three-part series of briefs on developing state-level nursing workforce data systems, defining the number of NPs practicing in primary care, and preliminary work on a systematic literature review and brief on nurses’ role in care coordination.

Principal Investigator: Erin Fraher, PhD, MPP

Funding Source: Robert Wood Johnson Foundation

Project Period: 04/15/13-04/14/14

Total Funding: \$50,000

Examining the Pharmacist Workforce in North

Carolina – This project examined trends in the pharmacy workforce in North Carolina and produced a report entitled, “Pharmacists in North Carolina: Steady Numbers, Changing Roles.” In addition to examining trends in the supply of and demand for the North Carolina pharmacy workforce, it discusses new and emerging roles for pharmacists and pharmacy technicians that may emerge in the future in response to new models of healthcare delivery.

Principal Investigator: Erin Fraher, PhD, MPP

Funding Source: UNC General Administration

Project Period: 08/15/13-6/30/14

Total Funding: \$21,975

Technical Assistance to States – The National Governors Association (NGA), through a cooperative agreement with HRSA, provided technical assistance (TA) to select states in addressing health workforce issues. Many of these states were developing State Innovation Plans as part of the CMMI State Innovation Model (SIM), of which workforce was a required component. The NGA selected four states to which they provided TA on health care workforce planning. In this project, Sheps Center staff served as experts in the field of health workforce planning to help inform the TA efforts for Connecticut and Illinois.

Principal Investigator: Erin Fraher, PhD, MPP

Funding Source: National Governors Association

Project Period: 07/01/13-11/30/13

Total Funding: \$8,000

Research Review for the ABMS Evidence Library – The American Board of Medical Specialties Research and Education Foundation (ABMS REF) has compiled an ABMS Evidence Library. The Evidence Library is an online database that systematically presents empirical evidence gathered from peer-reviewed research studies and articles that supports the value of Board Certification and Maintenance of Certification (MOC). The ABMS REF had a backlog of approximately 300 articles to input into the Evidence Library. The Sheps Center assisted the ABMS REF in clearing the backlog by reviewing and annotating approximately 150 prioritized articles, and submitting them for final review to ABMS REF staff for inclusion in the Evidence Library.

Principal Investigator: Erin Fraher, PhD, MPP

Funding Source: American Board of Medical Specialties Research and Education Foundation

Project Period: 08/15/13-12/14/13

Total Funding: \$19,500

Program on Women’s Health Services Research

Wendy R. Brewster, M.D., Ph.D., Director

The **Program on Women’s Health Services Research**, which emphasizes research related to improving the delivery of health services to women, is part of the *UNC-Chapel Hill Center for Women’s Health Research*. The Center provides research services for women’s health investigators to optimize research quality and improve the health of women. Together, they are working to serve the women of North Carolina and the nation by:

- documenting the health status of women,
- studying models for improving care,
- evaluating promising new treatments, and
- developing effective prevention programs.

The Center, founded in March 2000, is a joint effort of the *School of Medicine* and the *Cecil G. Sheps Center for Health Services Research*. Experienced staff and start-to-finish resources are available to assist UNC investigators plan, launch, and conduct women’s health research. The Center’s operating principle is to provide connections among research peers, foster career development and infrastructure, and assure the visibility of women’s health research.

No specific program was within Women’s Health Services Research this year, although many of the perinatal programs designated in the Child and Adolescent Health Program overlap substantially.

Program on General Health Services Research

Although not directly related to one of the Center’s program focus areas, the following research projects were active in the **Program on General Health Services Research** during the past year:

A Systematic Review of Empathy Development in Medical Education – Understanding how empathy can be developed in medical education is an important component of advancing humanistic medicine. Two recent reviews of changes in empathy among medical students and residents reached disparate conclusions. In a systematic review, Neumann and colleagues (2011) determined that empathy declines during medical training as students engage more with patients. Colliver et al (2010) conducted a meta-analysis drawing on much of the same research and concluded that declines in empathy during medical training are minimal—perhaps even nonexistent. Colliver and colleagues argued that the instruments used to study “empathy” may not be measuring anything meaningful to clinical practice or to patient satisfaction. (For example, most past research has utilized student self-assessments, which may be an ineffective way to measure empathy). The discrepancy between these two reviews poses serious concerns for researchers and educators seeking to maximize empathy in medicine. We propose a systematic review of how empathy is operationalized in medical education research, complemented by a critical analysis that considers how it might be. What are we measuring when we measure empathy? What could we measure?

Program Director: Timothy S. Carey, MD, MPH, and Sandra Sulzer, PhD

Funding Source: The Arnold P. Gold Foundation

Program Period: 08/31/13 - 02/27/15

Total Funding: \$6,000

Type: Training

UNC-CH Training Program in Health Services Research – The program offers academic training and directed research experience in the application of the concepts and research methods of a number of disciplines to the study of the organization, financing, utilization, provision, and effectiveness of personal health services. Predoctoral training is offered in collaboration with the Departments of Epidemiology, Health Policy and Administration, Health Behavior, and Maternal and Child Health at the UNC-CH School of Public Health. Upon completion of this program, both pre-doctoral and post-doctoral fellows have a generalized background in contemporary health policy issues, the historical significance of these issues, a solid understanding of the most common statistical and study design methods applicable to health services research and policy analysis, a set of materials to use as supporting references in their own work, experience in the design and conduct of health services research under supervision of at least one mentor with expertise in relation to the subject and methods being used, and a set of data ready to be published. This training program, recently refunded, has been continuously supported since 1989.

Program Director: Timothy S. Carey, MD, MPH

Funding Source: AHRQ,

National Research Service Award

Program Period: 09/01/89 – 06/30/18

Total Funding: \$2,513,809 Type: Training

Program Highlight: Training Program in Health Services Research

The overall objective of the UNC-CH Training Program in Health Services Research has remained the same over the past year. Faculty remain stable with Dr. Tim Carey continuing as Program Director and Dr. Kathleen Thomas as Associate Director. We recruit from a variety of disciplines and both faculty and fellows enjoy the variety of perspectives. The fellows learn from each other, sharing their applications of disciplinary perspectives to the common problems of health services. Current fellows include the disciplines of sociology, health policy and management, pharmacy, epidemiology, and clinical medicine including a surgeon.

Each year we modify seminar content and mentoring of fellows as individuals and the group progress. The seminars involve a mixture of activities. Fellows present work-in-progress sessions. Faculty presentations have been a mixture of presentations by core faculty as well as presentations by guest faculty. In the Fall of 2013 our seminar focused on Talking with Stakeholders about Research (the fall and spring seminar topics and presenters can be found in Appendix D). This topic was particularly relevant for patient centered outcomes research as well as planning dissemination and implementation activities for any kind of research results.

In the spring of 2014 we heavily focused on career development in health services research.

The topic of research ethics is an important part of the UNC-CH training program. Topical issues related to the responsible conduct of research are integrated with other core seminar issues throughout the formal weekly seminar sessions so that our trainees see these issues as an important part of the fabric of their professional lives. The curriculum from these sessions is included in Appendix D. This seminar included topics such as conflict of interest, advocacy and research, authorship issues, scientific misconduct and confidentiality issues. A particular area of emphasis this year was appropriate use of data and management of data use agreements.

Primary Care Research Fellowship – The goal of this fellowship is to train primary care physicians for research-focused academic careers. This two to three year fellowship provides participants with the knowledge, skills, and experience to plan, fund, complete and disseminate quality research. The curriculum includes course work in the UNC School of Public Health, seminars in the campus’ K-30 sponsored research curriculum, weekly works-in-progress seminars, in-depth hands-on involvement and leadership in research projects, and mentoring by clinical and research faculty. Housed within the Sheps Center, the program also receives support from the primary care clinical departments of the

UNC School of Medicine. The program was recently funded for another 5 years.
Principal Investigator: Donald E. Pathman, MD, MPH
Funding Source: AHRQ,
National Research Service Award through the Bureau of Health Professions
Program Period: 07/01/98 – 06/30/14
Total Funding: \$3,500,338 Type: Training

National Information System on Health Services Research (HSRProj) – This project develops and maintains a health services research information system that collects available information on ongoing research projects funded by both public and private sector agencies for the National Library of Medicine. Through HSRProj, individuals can access information about ongoing health services research projects before results are available in published form.

Principal Investigator: Christiane Voisin, M.S.L.S.
Funding Source: National Library of Medicine, NIH via Academy Health and The Foundation for Health Services Research
Project Period: 05/01/04 – 07/01/14 (on-going)
Total Funding: \$1,729,092 Type: Technical Assistance

Prevention/Care Management Technical Assistance Center (Master Task) – Note: This is a Master Task submission; there are no specific tasks for this master contract proposal. UNC Sheps shall furnish personnel, information and materials as reasonably necessary, and shall devote reasonable business efforts to assist AIR in developing and preparing sections of the PCM TAC RFTO Proposal(s) and any modifications thereto related to NCQA's relevant Scope of Work. • UNC Sheps shall work with AIR to determine whether or not to submit proposals to future RFTO bids. • UNC Sheps will work with AIR on any future work that warrants their area of expertise.

Principal Investigator: Russell Harris, MD, MPH
Funding Source: AHRQ via AIR
Project Period: 08/01/10 – 09/29/14
Total Funding: \$0

Support of Transparency Efforts by the USPSTF – The overall purpose of this task order is to support AHRQ's Prevention/Care Management (PCM) Portfolio by expanding transparency efforts of AHRQ in its role as supporter and convener of the USPSTF. Specific tasks supported by UNC Chapel Hill key and other personnel:

Task 1. Administration, Task 2. Process Development, Task 3. Reviewing and Synthesizing Public Comments, Task 4. Communication, Task 5. Product Dissemination.
Principal Investigator: Russell Harris, MD, MPH
Funding Source: AHRQ via AIR
Project Period: 09/30/10 – 03/22/14
Total Funding: \$692,318

Carolina Advance Health Evaluation – The purpose of these activities will be to provide technical assistance to TPN and the establishment and monitoring of CAH. 1) Planning and evaluation of patient satisfaction data. 2) Qualitative evaluation of organization and modification of CAH. 3) Assistance in quality of care evaluation.
Principal Investigator: Timothy S. Carey, MD, MPH
Funding Source: Triangle Physician Network, LLC
Project Period: 09/01/11 - 08/31/14
Total Funding: \$141,709

Measure & Instrument Development and Support (MIDS), Umbrella IDIQ – Note: This is a Master Task submission; there are no specific tasks for this master contract proposal. The purpose of this MIDS Task Order (TO) is to obtain services for the development, re-evaluation, and implementation of the Centers for Medicare and Medicaid Services (CMS) and support the CMS quality and payment programs/initiatives. The Sheps Center will contract with AIR in building infrastructure for CMS to support work to develop outcome, process, structural, cost and composite quality measures suitable for endorsement by a consensus endorsement entity and reflective of quality care for healthcare settings. This contract also includes the identification or development of the data elements and items necessary to implement data collection for the proposed measures across the health care continuum, as well as the data collection vehicles. UNC-CH will work with AIR to determine whether or not to submit proposals to future RFTO bids, on any future work that warrants our area of expertise. UNC-CH's areas of expertise potentially utilized in RFTO bids include, but may not be limited to: environmental scan and empirical review to describe existing measures, uses and gaps; instrument/item Quality Measure development; and, data testing and validation.
Principal Investigator: Timothy S. Carey, MD, MPH
Funding Source: CMS via AIR
Project Period: 10/01/13 -09/30/18
Total Funding: \$0