



Center for Complexity and Management of Chronic Disease 2018 External Advisory Committee (EAC) Report

This document includes a special EAC report outlining challenges, progress, accomplishments and plans for the CSCD Center.

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CSCD Activities (2014-2018)

Pilots

The Center has supported nine pilot studies (past, ongoing, and recently approved) since its founding in 2014. As of January 3, 2018, all pilot study awards have now been made.

Pilot Project 1 (PP1, Dr. Jessie Casida)

An Evaluation of Mobile Care App as Self-management Tool in Patients with Left-Ventricular Assist Devices. Awarded September 1, 2014.

Summary: The purpose of this study is to evaluate the feasibility of the UM-VAD Care App as a SM tool for LVAD patients and/or caregivers, and to pilot test it in an out-patient MCS program.

Aims:

Aim #1 (Phase I): To evaluate the acceptability and usability of the UM-VAD Care App and the competency of its users. Self-report questionnaires and interviews will be used to accomplish this aim.

Aim #2 (Phase II): To obtain preliminary efficacy data of the UM-VAD Care App as a SM tool in patients with long-term LVAD. This phase will establish preliminary estimates of the effects of the App on (1) patient's and caregiver's self-efficacies, (2) adherence to the LVAD care regimen; (3) complications; and (4) the patients' overall health status and (5) QOL.

Progress:

- Phase 1 completed, results published and presented (N=18 patients and caregivers)
- Phase 2: Pilot RCT (on-going) with delays in recruitment/implementation due to multiple reasons including software, website, staffing, competing studies at U of M, and software limited to iOS users. App is now being expanded to Android software funded by a Foundation Grant.
 - Total number of subjects needed: 80 patients and caregivers
 - Enrollment total (April 1, 2018) 52 patients and caregivers
 - Number of subjects to be enrolled 28 patients and caregivers
(2 clinical sites were added to accelerate enrollment)
 - Anticipated completion of recruitment: August 1, 2018
 - Anticipated project completion (6 months follow-up): February 1, 2019

Monthly Recruitment (N)	Accrual (N)
Current	52
May (8 patients and caregivers)	60
June (8 patients and caregivers)	68
July (8 patients and caregivers)	76
August (4 patients and caregivers)	80

Pilot Project Products:

Publications:

- Casida JM, Aikens JE, Craddock H, Aldrich MW, Pagani FD. [Development and Feasibility of Self-Management Application in Left-Ventricular Assist Devices](#). ASAIO J. 2017 Sep 20. doi: 10.1097/MAT.0000000000000673. [Epub ahead of print]. PMID: 28937409



- **Casida, J. M.**, Craddock, H., Hoff-Nygaard, D., Kay, C., Pierzynski, A., Manker, D., & Cooley, L. (2017). Construction and evaluation of a *VAD Care App*® as self-management tool for patients with ventricular assist devices (VADs). *ASAIO*, 63(3), 48. Accessed June 8, 2017.

Presentations:

- Casida, J. M., & Carpenilli, A. (2016, April). "A Self-Care Management App for Patients with a Left-Ventricular Assist Device." *Presented to Mobile Monday Grand Rapids*, Spectrum Health, Grand Rapids, MI.
- Chornoby, Z., & Casida, J. M. (2017, October). "VAD Care App: Features and Functions." *Presented at the University of Michigan Third Century Expo*. The University of Michigan, Ann Arbor, MI.
- Casida, J. M. (2017, November). "Mobile Application to Enhance Self-Management Outcomes in LVAD." *Presented at the Monthly Seminar Series D43 Thailand Training Grant/P20 Center for Complexity and Self-Management of Chronic Diseases*, University of Michigan School of Nursing, Ann Arbor, MI.
- Casida, J. M., & Carpenilli, A. (2016, April). "A Self-Care Management App for Patients with a Left-Ventricular Assist Device." *Presented to Mobile Monday Grand Rapids*, Spectrum Health, Grand Rapids, MI.
- Chornoby, Z., & Casida, J. M. (2017, October). "VAD Care App: Features and Functions." *Presented at the University of Michigan Third Century Expo*. The University of Michigan, Ann Arbor, MI.
- Casida, J. M. (2017, November). "Mobile Application to Enhance Self-Management Outcomes in LVAD." *Presented at the Monthly Seminar Series D43 Thailand Training Grant/P20 Center for Complexity and Self-Management of Chronic Diseases*, University of Michigan School of Nursing, Ann Arbor, MI.
- Casida, J. M. (2017, June). "Feasibility of Using a Mobile Phone App as Self-Management Tool for Patients with a Left-Ventricular Assist Device." *Frankel Cardiovascular Center Annual Scientific Symposium and Celebration of Excellence*, Michigan Medicine, University of Michigan, Ann Arbor.

Patents: none

Website(s) or other Internet site(s) (include URL): <https://clinicaltrials.gov/ct2/show/NCT03049748>

Technologies or techniques: none

Grants:

1) in planning stage:

J. Casida (PI); NIH/NHLBI R01

Improving self-management process and outcomes of patients with left-ventricular assist devices: A multi-center RCT

This study will employ a randomized control trial to evaluate the effects of the VAD Care App as self-management tool for patients with LVADs and their caregivers. Outcomes include quality of life, complications, and healthcare utilizations.

Participating Centers: New York Presbyterian Hospital at Columbia University (NY), Michigan Medicine at the University of Michigan (MI), Barnes-Jewish Hospital/Washing University (MO), and Bryan Heart Hospital (NE).

J. Casida (PI); NIH/NHLBI SBIR/STTR

Development and testing of VAD self-management chatbot in advanced heart failure.

This study will develop, beta test, and conduct a feasibility study of a novel interactive self-management tool for advanced heart failure patients living with an LVAD. This relatively high risk and potentially high impact concept is a major departure from the current platform (VAD Care



App[®]) to address obsolescence and further improve LVAD self-management process and outcomes.

2) funded:

Donald and Karin Allen Fund; Awarded March 29, 2018. \$5,000

Optimizing self-management process and outcomes in patients with a left-ventricular assist device. This grant is a supplement of the pilot study aimed at testing the effects of using the “VAD Care App” in the long-term management of LVAD patients.

Janet Gatherer Boyles Research Fund, 2018-2019, \$15,000

Enhancement of mobile application for self-management in implantable left-ventricular assist devices. The purpose of this study is to enhance the design and function of the VAD Care App 1.0 by expanding the current iOs into Android operating system. Specifically, the study will evaluate the usability and acceptability of the new design integrating into the VAD Care App 2.0 fundamental to the conceptual elements of the theoretical model used for a large-scale self-management intervention research.

Pilot Project 2 (PP2, Dr. MinKyoung Song)

An Underutilized Pathway to Reducing Adolescent Obesity: Translating the Results of Adult-oriented Interventions into Their Children’s Obesity-related Behaviors and Outcomes. Awarded September 1, 2014.

Summary: This study examined whether, or to what degree, parent participation and success in a weight-management program (i.e., Weight Watchers) affects the health of adolescent children living in the same household. The project was completed at the end of July 2015 when Dr. Song left the University of Michigan.

Aims:

The specific aims of this study were to: 1) quantitatively assess family functioning, parental behaviors, adolescent children behaviors, and body mass index (BMI)/waist circumference-to-height ratio (WCHt) of Weight Watchers participants and their adolescent children at baseline; and compare with measures taken at 3 months after enrollment. 2) Assess whether changes in family functioning mediate the effect of changes in parental behaviors on changes in adolescent behaviors and BMI/WCHt. 3) Qualitatively assess the perception of parents and their adolescent children regarding the utility and influence of Weight Watchers intervention on family functioning and parental and adolescent behaviors by conducting focus groups at post-3 months. This pilot project directly tested a real world, parent-mediated intervention designed to address the complex interplay among multiple influences on adolescent obesity.

Brief Methods:

Obese parents who are primary caregivers, and their overweight/obese adolescent children (aged 11 to 17 years), were recruited for the study, from among Michigan residents who signed up for Weight Watchers but had not yet started to participate in any Weight Watchers programs.

Progress: Five parent/adolescent child pairs were recruited and completed the study. This project’s final report was submitted on July 31, 2015.

Publications:

- Song M, Corwyn RF, Bradley RH, Lumeng JC. (2017) Temperament and Physical Activity in Childhood. *J Phys Act Health.* Jul 6:1-28. doi: 10.1123/jpah.2016-0633. PMID:28682696
- Song M, Lauseng D, Lee S, Nordstrom M, Katch V. (2016) Enhanced Physical Activity Improves Selected Outcomes in Children With ADHD: Systematic Review. *West J Nurs Res.* 2016 Sep;38(9):1155-84. doi: 10.1177/0193945916649954. Epub 2016 May 24



Pilot Project 3 (PP3, Dr. Cynthia Arslanian-Engoren)

Development and Evaluation of a Computer-based, Nurse-led Cognitive Training and Educational Pilot Intervention to Improve Self-care Management Behaviors in Adults with Heart Failure. Awarded October 1, 2015.

Summary: Acute decompensated heart failure (HF), which usually requires hospitalization for medical management, is a time of important health care decision-making, self-care management education and is associated with new or worsening symptoms, including dyspnea, fatigue, depression and pain. However, cognitive dysfunction impairs the ability of HF patients to focus their attention and remember self-care management information (e.g., medications, diet, symptom management strategies) contributing to their poor learning and impaired self-care management performance. Further adding to the complexity of self-care management for HF patients is the co-occurrence of multiple co-morbid conditions, such as hypertension, diabetes mellitus and hyperlipidemia that also require cognitive function to self-manage, in addition to their HF. This complexity is not limited to the acute phase of HF, but continues as a long-term consequence that contributes to post hospital placements in extended and long-term care facilities. Twenty-six percent of HF patients are discharged to extended care facilities and 21% to long-term care institutions, which may represent, in part, the inability to engage in self-care activities necessary to manage the multiple complexities (medical, environmental, cultural, physical, psychological, and socioeconomic aspects) of their chronic disease. For the remaining majority of HF patients who are discharged home, the need to balance engagement in physical activities, adherence to prescribed medication regimens, self-monitor one's health status and engage in self-care management behaviors to maximize function, independence and quality of life⁹ further adds to the complexity of self-care management.

Approximately 50% of HF hospitalizations are preventable and are commonly caused by poor self-care management practices; the inability to maintain health and manage multiple comorbidities using positive health practices. In a recent study, of hospitalized acute HF patients (n = 53), we showed that symptoms of dyspnea, pain and depressed mood were associated with reduced attention and working memory speed, while pain and fatigue were associated with reduced accuracy of attention and working memory. Research is needed to determine if a nurse-led virtual cognitive training intervention can maintain or improve self-care management of HF, thereby reducing the burden of living with HF and its associated comorbid illnesses, reduce hospital readmission and improve quality of life.

To this end, the proposed study will examine the feasibility of developing and pilot testing a promising nurse-led, home-based cognitive remediation training intervention designed to maintain or improve cognitive function and thereby improve self-care management of HF. This approach includes the development of an electronic platform to deliver a nurse-led cognitive assessment and self-care educational (CASE) intervention along with a nurse enhanced cognitive remediation training (CRT) via the BlueJeans Network. Once developed, the feasibility of delivering the intervention, via computer will be piloted tested in 30 adults who were hospitalized for acute HF and recently discharged home. If effective this intervention has the potential to improve self-care management and to decrease 30 day hospital readmission rates for people with HF.

Aims:

Specific Aim 1: To develop the computer interface to deliver a nurse-led CASE and nurse-enhanced CRT and to evaluate feasibility and acceptability in 30 adults with HF.

Specific Aim 1a. To evaluate the feasibility and acceptability of this approach by HF patients and the study nurse.



Specific Aim 2: (Exploratory) To conduct an exploratory evaluation of the relationship between (a) improvements in self-care management behaviors as measured by the Self Care Heart Failure Index (e.g., symptom management, taking medications as prescribed, daily weights, dietary restrictions, recognizing and responding to changes in signs and symptoms, evaluating effectiveness of self-care management strategy) (b) fidelity of the nurse enhanced CRT and (c) change in cognitive status in 30 adults with HF.

Specific Aim 2a. To evaluate if improvements in self-care management behaviors are affected by fidelity of CRT as measured by subjects' progress through the CRT program and by changes in cognitive state as measured by the Telephone Interview of Cognitive Status (TICS-M).

Specific Aim 3: (Exploratory) To describe 30-day hospital readmission rates for HF patients and compare to existing benchmarks.

Progress/Products:

The computer interface has been developed and we are in the process of evaluating the feasibility and acceptability of this approach by HF patients and the study nurse. Over 100 potentially eligible participants have refused citing the lack of a computer and/or high-speed internet. To address this issue, we are currently converting the computer based cognitive training program to an iPad tablet computer. Participants will be given the iPad tablet computer to use during the study and will keep upon completion of all data collection sessions.

To date (April 8, 2018) eight participants have been enrolled; four of whom completed the 10 sessions and the 2-month follow-up. However 2 did not keep scheduled {multiple} data collection sessions, despite reminders and rescheduling multiple times to be convenient for participant; 1 hospitalized for heart transplant did not complete 2 month follow-up and called from ICU to indicate why unavailable; 1 withdrew indicating 'overcommitted.'

For those who completed all 10 sessions (n = 4), feedback was positive: all were very comfortable with the virtual education intervention, to ask questions of the study nurse and indicated it allowed them to obtain timely and trusted responses from the study nurse. Similarly, the study nurse indicated the interactive platform allowed the delivery of timely responses to participant questions, to establish a professional relationship with the study participants and allowed the study nurse to comfortably answer participant questions. The ease of delivering the intervention via the interactive computer platform was more difficult when the participant had a slow processing computer and/or a slow internet connection.

During the next reporting period, we will have converted the computer-based cognitive training program to an iPad computer tablet, which participants will be given and can keep upon completion of all 10 sessions. (We are working with the consultant from Michigan State University to make the conversion). The iPad will be WI-FI enabled and we will provide internet access for two months during data collection. We believe this will significantly reduce the barrier to participation. We plan to recruit total of 12 participants- on average, three/month for the remaining four months [May-August 2018].

In April 2018, results to date will be presented at the Midwest Nursing Research Conference. Poster Presentation: Arslanian-Engoren C, Giordani B, Nelson K, Moser DK. "The feasibility and acceptability of a nurse-led cognitive training and educational intervention to improve self-care management behaviors in older adults with heart failure" *42nd Annual Midwest Nursing Research Conference*, April 2018, Cleveland, OH.

Pilot Project 4 (PP4, Dr. Deena K. Costa)



Patient and Family Engagement in the ICU: A Mixed Methods Study. Awarded March 23, 2016.

Summary: Yearly, about 400,000 mechanically ventilated patients in U.S. Intensive care units (ICUs) have at least 1 comorbid chronic condition. Those who survive experience significant persisting morbidity. As a way to minimize ICU-related morbidity, the Critical Care Societies encourage integrating ICU patients and their families with the ICU team – known as patient and family engagement (PFE). The central hypothesis of this work is that patient and family engagement in ICU care facilitates increased patient activation, predisposing the patient for greater self-management and leading to improved outcomes for mechanically ventilated patients. As a test of concept and feasibility, we propose a mixed methods study in 2 ICUs with the following aims, which are the major goals of this project:

Describe patient and family engagement in the ICU to identify who, how, when and in what ways patients and families are engaged in care using a three-step qualitative approach of observation, shadowing and interviews, for mechanically ventilated patients.

Explore how variation in PFE in the ICU may be associated with differences in patient activation prior to ICU discharge.

Aims:

Aim 1: Describe patient and family engagement in the ICU to identify who, how, when and in what ways patients and families are engaged in care using a three-step qualitative approach of observation, shadowing and interviews, for mechanically ventilated patients.

Aim 2: Explore how variation in PFE in the ICU may be associated with differences in patient activation prior to ICU discharge.

Progress:

We are currently in the process of recruiting in our second site. IRB delays impacted our ability to begin data collection in our second site.

Recruitment

Site 1 recruitment complete. This includes:

Aim 1:

- 18 hours of observation
- 6 clinicians shadowed
- 12 interviews (8 clinician and 4 family interviews)
- Preliminary analysis from Aim 1 indicated that we reached data saturation for Site 1.
- Site 1 qualitative data analysis is complete

Aim 2:

- Patient survey recruitment in Site 1 was deemed infeasible. In over 7 months of attempts, 43 potentially eligible patients were identified but only 4 have been enrolled to date. The majority of patients are not meeting all of our inclusion criteria, specifically many of these patients are delirious (CAM (+)) and ineligible to participate. The reported reasons patients decline to participate are due to fatigue, too lethargic to complete survey or not available (off unit at procedure).
- For site 2, a site PI has been identified and will be conducting the patient surveys which may assist with feasibility.

Site 2 recruitment is ongoing:

- Conducted 10 hours of direct observation.
- Upon execution of DUA, we will transition to shadowing and interviews and Aim 2 patient survey recruitment



Based on the results from both site 1 and site 2, I intend to move forward with a project to examine how to improve patient and family engagement in the adult ICU. This project might involve a national survey to assess penetration of patient and family engagement in adult ICUs or it might focus on ways to improve PFE by leveraging approaches that have worked well in pediatrics and neonatal ICUs. Further, the results of this study also shed light on an important and understudied topic in critical care – clinician burnout. Given these interesting findings, we anticipate moving forward with a line of research to examine how PFE in the ICU can appropriately address or protect clinicians from burnout and other psychological distress. Definitive aims and projects will be formed after completion of data analysis across both sites.

Products:

Upon completion of data collection in both sites, we anticipate publishing several papers from this work (of which two are described below).

Papers:

- Paper #1: *Information sharing in the ICU: An opportunity for meaningful engagement?* This paper will be presented at American Thoracic Society in May 2018 in a Rapid Poster Discussion Session. We are in the process of writing this paper up for publication.
- Paper #2: Invited perspective in *Annals of ATS* on emotion and burnout in critical care clinicians
- Paper #3: *Unintended consequences of patient and family engagement in the ICU: Clinician burnout*

Presentations

2017:

- Invited presentation, American Thoracic Society May 2017 “Engaging families in decision-making: Leveraging behavioral economics and the ICU interprofessional team” in a scientific symposium entitled “Nudges in the ICU: When and how should intensivists guide surrogates’ decisions?” on May 24th, 2017
- Poster presentation “All I want is information: The role of information sharing in patient and family engagement in the ICU” presented at University of Michigan Health System Nursing Research Day on October 9th, 2017

2018:

- Invited presentation “Fallout on the front: How burnout affects nurses” in an American Thoracic Society symposium entitled “Battling Burnout: Overcoming the biggest threat to health care quality and safety”. I will be sharing data collected from the site 1 data

Pilot Project 5 (PP5, Dr. Donna J. Marvicsin)

Family Routines – Healthy Families. Awarded March 23, 2016.

Summary: The purpose of the study, Family Routines – Healthy Families, is to examine the feasibility and acceptability of a parenting/family routine intervention program for parents of young children, ages 2-5, with type 1 diabetes. The intervention, Family Routines – Healthy Families, contains an established and effective parent skills training curriculum, *The Incredible Years*, uniquely integrated with a newly developed family evening routine component e.g., family dinner time and evening routine, to promote improved metabolic control. The evening routine component was developed by Dr. Marvicsin based on her more than 20 years of clinical experience in working with these families. The team includes Dr. Peter Gerrits MD, Section Head, Pediatric Endocrinology & Metabolism at Beaumont Children’s Hospital and Dr. Ruth Anan PhD, BCBA-D, Licensed



Psychologist and Board Certified Behavior Analyst. Dr. Anan is specifically trained to deliver The Incredible Years curriculum.

Aims:

Aim 1. Examine the feasibility of a six session parenting skills and family evening routine intervention delivered in a group format. Post intervention interviews and attendance will determine suitability/preferences for mode of delivery and realism of behavioral expectations.

Aim 2. To develop preliminary evidence regarding the impact of a six-session family intervention on child evening routine and glucose control as measured by four indicators:

- a) time between dinner and bedtime glucose readings
- b) difference between bedtime blood glucose reading and morning fasting blood glucose reading
- c) parent decision making and response to bedtime snack/insulin questionnaire
- d) difference between child A1C pre- and 3 months post- intervention through chart review

Aim 3. Determine impact of Family Routines – Healthy Families intervention on parental quality of life for parents of young children with type 1 diabetes.

Progress/Products:

Results: Five caregivers completed the program. Two families had improved bedtime and morning blood glucose. Four families maintained greater than two hours between dinnertime and the bedtime blood glucose reading. Two families had fewer issues with decision-making at bedtime. Although glucose averages improved between bedtime and morning, the only child who demonstrated a decrease in A1C was the youngest. I was not able to perform statistical analysis; the data will be organized as 5 case studies.

Conclusions: Data demonstrated that caregivers of young children with diabetes already had a goal of providing an evening routine for their child. This feasibility study suggests that a parent program such as this may be a useful tool for parents of young children who need assistance with establishing routines. Further research is suggested to test this intervention in a broader sample.

Clinical Implications: A simple program such as Family-Routines-Health Families may facilitate accurate monitoring of time intervals between dinner and bedtime glucose checks for the benefit of patients and parents. In the course of glucose screening, nurse educators may identify families who would most benefit from a parent guidance program such as this.

Pilot Project 6 (PP6, Dr. Yun Jiang)

Self-Management of Oral Oncolytic Agents and Side Effects among Patients with Cancer. Awarded September 21, 2016.

Summary: With the increasing use of oral oncolytic agents, patients with cancer now assume responsibility to self-administer oral agents in their home instead of receiving intermittent intravenous (IV) therapy in a supervised healthcare environment. As oncolytic agents usually have complex regimens, a low therapeutic index and narrow safety margins, and significant variations in toxicities by individuals, the paradigm shift in cancer treatment can pose huge challenges to patients and families in self-management of oral oncolytics and medication side effects. An emerging literature has raised concerns of patients' non-adherence to oral oncolytics, self-administration safety, and their effects on treatment outcomes and patient quality of life. However, there is a lack of understanding of patients' self-management of oral oncolytics and side effects, and relationships of self-management with medication adherence. The oncology community has focused on cancer



symptom management, but not patient self-management. Medication adherence research highlights patients' compliance with medication administration, but self-management of medication side effects in relation to medication adherence has not been a focus in such studies. This pilot study proposes a conceptual model to explore the complex relationships among side effects of oral oncolytic agents, self-management of side effects, and adherence to oral oncolytics. Also, it intends to lend insight into the feasibility of proposed methods, including the adaptation of self-management measures, for use in future research. The pilot study narrowly focuses on one oral oncolytic agent, capecitabine, and its use as monotherapy or in combination with other chemotherapeutic agents in the treatment of colorectal cancer (CRC) for two consecutive cycles.

Self-management often refers to the tasks that a person undertakes to manage medical, physical and psychosocial issues associated with a chronic condition. Taking medication and dealing with medication side effects are usually included in these tasks. While self-management of several chronic diseases (e.g., diabetes and heart diseases) has been widely addressed in literature, cancer self-management is less studied. Existing cancer self-management programs predominantly focus on breast cancer. There are gaps in the research suggesting effective self-management interventions for patients with other types of cancer, such as CRC patients. Capecitabine monotherapy or in combination with oxaliplatin has been approved for first-line treatment of advanced and/or metastatic CRC (Note: oxaliplatin is administered by IV infusion in clinic, as a covariate in this study). Non-adherence to capecitabine has been reported in the literature, including over-adherence and missing doses. Adherence to capecitabine is adversely affected by its side effects. The most troubling side effects are hand-foot syndrome (HFS), diarrhea, fatigue, nausea, and vomiting. Of concern, patients are reported to have problems identifying and reporting important signs of severe side effects to clinicians.

Findings from this study will contribute to the refinement of the conceptual framework, measurement tools, and the specific aims that will be addressed in future studies to develop effective interventions for self-management of oral oncolytic agents and their side effects.

Brief Methods:

This pilot study used two measurement tools, adapted from the Measure of Drug Self-Management (MeDS) and Self-Care Diary (SCD), to assess CRC patients' self-management of capecitabine and capecitabine side effects. The original tools have established reliability and validity, but have not been tested in CRC patients on capecitabine. The original SCD assesses the incidence and frequency of 18 general chemotherapy side effects and self-care activities for each side effect. The modified SCD removed side effects that do not apply for capecitabine and added specific capecitabine side effects, such as HFS, including self-care activities that were derived from the literature.

Aims:

Aim 1: Assess the reliability and validity of the MeDS and the modified SCD in CRC patients under oral oncolytic treatment.

Aim 2: Explore the complex relationships among side effects of oral oncolytics, self-management of oral oncolytics side effects, and adherence to oral oncolytics.

- a. Examine the potential mediation effect of oral oncolytics side effects on the relationship between self-management of oral oncolytics side effects and adherence to oral oncolytics.
- b. Examine the potential moderation effect of self-management of oral oncolytics side effects on the relationship between adherence of oral oncolytics and oral oncolytics side effects.

Aim 3: Test the feasibility of design and conduction of the methods.

- a. Test the feasibility of recruitment and retention of colorectal cancer patient participants who are taking oral oncolytics in the study.



- b. Test the feasibility of weekly telephone based data collection from colorectal cancer patient participants for two consecutive cycles of treatment.

Progress:

Recruitment started on March 7, 2017 and ended on September 22, 2017. Fifty GI cancer patients were recruited. Baseline and follow-up data collection was completed on November 17, 2018. An abstract for a prospective study (n=50) was submitted and accepted by the Society of Behavioral Medicine in January 2018. An abstract was submitted to MNRS in mid-December 2017. I am seeking additional funding support from the UMCCCC and the School of Nursing (submitted December 2017). An R21 application (Oral oncolytic adverse effect self-reporting) was submitted in June 2017, reviewed in October 2017, and received an unfundable score. Resubmission (or a new submission) is planned. One more abstract and at least two papers are in the planning stages.

Pilot Project 7 (PP7, Dr. Moira Visovatti)

Physical and Cognitive Function, Symptom Distress and Quality of Life in Head and Neck Cancer. Awarded June 13, 2017

Progress: This pilot project was approved for funding on June 13, 2017. The project is just beginning. IRB approval was received. The Research Assistant was hired. Study logistics and materials have been worked out; incentive payment protocol established; study mBox and shared drive have been created and tools uploaded. Partnerships with clinicians in the Head and Neck Cancer Program and Physical Medicine and Rehabilitation have been established. Extensive staff training using NIH Toolbox has taken place. One participant has been recruited as of April 8, 2018.

Summary: Head and Neck cancers (HNC) include cancers of the oral cavity, pharynx, salivary glands, and larynx. In 2016, approximately 61,760 new cases of HNC were diagnosed in the US. Mortality rates have been declining and the five year survival rate is now estimated to be greater than 64%. Given the prevalence of the disease and current survival rates, understanding HNC-related changes in function and quality of life is critical to developing targeted self-management interventions to optimize function and reduce distress. Head and neck cancer and its treatments has been associated with functional changes and a high symptom burden including pain, decreased head and neck mobility, dysphagia, lymphedema, fatigue, loss of taste, loss of hearing, vertigo, alterations in speech, dry mouth, dental caries, gingival disease, sleep disturbances, cognitive changes, and emotional distress. A growing number of studies suggest that physical activity or exercise training may be a promising intervention to improve function, reduce symptom distress, and maintain quality of life in individuals with HNC. Additionally, restorative activities or exposure to the natural environment may reduce mental fatigue and improve attention in individuals with cancer. The first step to developing targeted approaches to optimize function and preventing disability in individuals with HNC is to examine functional abilities, symptom distress, and quality of life early in the disease trajectory. At this time, only two studies have examined physical function and one study examined cognitive function pre-treatment in individuals with HNC. No studies were found that examined the relationship between function, symptom distress, and quality of life in individuals newly diagnosed with HNC.

The purpose of this study is to assess physical function, cognitive function (attention and cognitive control domains), symptom distress, and quality of life patterns from pre-treatment to 3-months after treatment initiation. Additionally, this study will assess the feasibility and acceptability of wearing an activity tracker, a novel method of measuring physical function in HNC. Knowledge gained from this study will contribute to the scientific base for the development of timely self-management interventions directed toward maintaining optimal functioning and reducing distress in individuals with cancer. This study will 1) contribute to the scientific knowledge of physical and cognitive



function, symptom distress, and quality of life in HNC, and 2) provide the foundation for developing targeted self-management interventions to optimize function and prevent disability in individuals with HNC. Cancer-related symptoms and preventing disability in individuals with cancer is a research priority of the Oncology Nursing Society and the National Cancer Institute. Developing targeted interventions to improve self-management in individuals with chronic illnesses is a research priority of the National Institute of Nursing Research.

Aims: The specific aims and corresponding hypotheses are:

Aim 1. To determine the feasibility and acceptability of wearing an activity tracker. **Hypothesis 1a:** Wearing an activity tracker will be feasible and acceptable as demonstrated by the recruitment of individuals with HNC who are willing to participate (achieve 100% recruitment of target goal of 40 subjects), adhere to (<15 % attrition) and complete (>75% of pedometer and self-report measures collected) the study. Additionally, acceptability of wearing an activity tracker will be demonstrated by self-report (positive comments).

Aim 2. To determine whether identifiable patterns of physical and cognitive function exist early in the disease trajectory in individuals newly diagnosed with HNC.

Hypothesis 2a: Compared to pretreatment, individuals with HNC at 3-months post initiation of chemoradiotherapy will show lower physical function on measures of performance. **Hypothesis 2b:** Compared to pre-treatment, individuals with HNC at 3-months post initiation post initiation of chemotherapy will show lower attention and cognitive control on measures of performance and self-report 3-months post initiation of CRT.

Aim 3. To determine whether a relationship exists between physical and cognitive function, symptom distress, and quality of life in individuals new diagnosed with HNC. **Hypothesis 3a:** Physical and cognitive performance will be negatively associated with symptom distress and positively associated with quality of life in individuals newly diagnosed with HNC. **Hypothesis 3b:** Pretreatment symptom distress (MDASI-HN) and global quality of health will be associated with function 3-months after initiating of CRT.

Methods: Research Design

The proposed study will use a prospective descriptive design with a total of 40 men and women newly diagnosed with HNC who will begin concurrent platinum-based chemotherapy and radiation therapy for the disease. Overall the incidence of HNC is significantly higher in men than women (3:1 ratio). As such, we aim to recruit 30 men and 10 women. Participants will be assessed at two time points: at diagnosis and before any treatment (time 1) and approximately 3-months following initiation of treatment at a standard follow up visit (time 2).

Participants and Setting

Participants with HNC will be recruited from the University of Michigan Comprehensive Cancer Center (UMCCC) in Ann Arbor, Michigan. In 2016, the UMCCC tumor registry reported that 308 individuals were seen at UMCC for a new diagnosis of Squamous Cell Carcinoma of the Head and Neck providing a sufficient pool.

The sample will reflect the ethnic and racial composition of Washtenaw County and the State of Michigan 1) primarily Non-Hispanic 82.4%; and 2) White 77.1%, Black/African American 13.3%, Asia 5.6%, and 1.2 % Native American (Source: 2015 Census, US Census Bureau). Current UMCCC head and neck oncology clinic population estimates based on race include: primarily Non-Hispanic 98.1%; and White 96.8%, Black/African American 1.3 %, Asian 1.0%, 0.3 % Native American, and other 0.7% (Source 2014 Cancer Registry, University of Michigan Comprehensive Cancer Center



Cancer). Inclusion criteria: 1) a new diagnosis of squamous cell carcinoma of the Head and Neck (American Joint Commission on Cancer stage I-IV), 2) beginning first line concurrent chemoradiotherapy treatment, 3) age at least 18 years, 4) have sufficient command of English to permit testing, and 5) a Mini-Mental State Exam Score of at least 26.

Exclusion criteria: 1) medical history of cancer other than Head and Neck cancer or non-melanoma skin cancer, and 2) debilitating medical disorder such as advanced cardiac, respiratory or renal disease.

Measures

The following measures have been carefully selected based on previous research findings.

Screening Measure

1. The Mini Mental State Exam (MMSE) has been used in studies in individual with cancer to ensure participants have no serious cognitive impairment. It is a standardized test that assesses orientation, memory, attention, and language. The MMSE is scored from 0 to 30 and a score of > 26 generally indicates no serious impairment. It takes 5 minutes to complete.

Feasibility Measures

1. The recruitment log will record the number of screened participants, eligible participants, non-eligible participants, and reasons for ineligibility as well as eligible participants who declined and reasons for decline.
2. The enrollment log will record any reasons for not attending research visits and/or attrition.
3. The Utility of the Fitbit Zip™ Physical Activity Monitor is a questionnaire that asks respondents to describe acceptability of the Fitbit Zip™ and ease of integration into daily life from 0 to 10 on four items. Additionally, the questionnaire asks whether the participant would wear a Fitbit Zip™ again as part of a research study and if he/she have used a physical activity monitor in the past. The Utility of the Fitbit Zip™ Physical Activity Monitor has been used in a healthy adult population and individuals with cognitive changes. It takes 5 minutes to complete.

Demographic and Medical Characteristics

1. Demographic and Medical Information Questionnaires will be completed by participants and used to describe sample characteristics including: age, education, gender, race, marital status, employment status, stage of disease, cancer treatment history, other health problems, smoking history, height, weight, and menopausal status. Additionally, a medical chart audit will be conducted for cancer stage, cancer treatments received, and other health problems.
2. The National Cancer Institute (NCI) Automated Self-Administered 24-Hour (ASA24) Dietary Assessment Tool will be used to assess calorie intake. Participants will be complete one recall at each research visit.

Pilot Project 8 (PP8, Dr. Lenette Jones)

Evaluating Relationships Among Health Information Behavior, Neuroprocessing, and Self-Management: Creating a Foundation to Improve Blood Pressure and Glucose Control Among African American Women. Awarded December 7, 2017.

Progress: This pilot project was approved for funding on December 7, 2017. The project is just beginning. IRB approval is pending.

Summary:



Poorly controlled blood pressure and glucose levels increase the risk of stroke, end-stage renal disease, and premature death. Forty-seven percent of African American women are living with hypertension and are twice as likely to be diagnosed with type 2 diabetes than White women. Hypertension and type 2 diabetes frequently co-occur. In fact, the prevalence of hypertension is 71% among adults diagnosed with diabetes. Although previous studies have outlined strategies to improve self-management behaviors among African-American women, no studies to our knowledge explore the neurobiological mechanisms of self-management interventions. We need to know both *if* and *how* self-management interventions for this population work. Uncovering these basic neurobiological mechanisms is an important step in designing more precise and effective interventions to produce behavior change. This pilot study will be one of the first to incorporate psychosocial and cognitive factors (executive function and self-management processes) with neurobiological factors (neuroprocessing, or brain activity in response to analytic/empathetic prompts) associated with health information behavior (seeking, sharing, use) and the performance of self-management diet behaviors.

Our review of the neuroscience literature suggests that interventions can “rewire” our brains to change behavior. Researchers have examined brain activity in response to health messaging and were able to predict ability to abstain from smoking and use of sunscreen. A better understanding of the brain-behavior interaction is needed to deepen our knowledge of how health information rewires the brain and enhances self-management behaviors in patients with chronic illness. Examining the relationships between health information behavior and neuroprocessing will help scientists and practitioners to better understand why messaging leads to behavior change. Integrating knowledge of how our brains differ in processing information is an important step forward to affect behavior change and chronic illness self-management.

Exploring the brain-behavior mechanisms underlying the health information behavior will help to clarify some of the behavior translation pathways that currently are unclear. Additional knowledge of brain-behavior translation will help researchers and practitioners to transform clinical practice. Designing interventions based on neural activity and response will enhance current self-management regimens. Current evidence suggests that health education strategies that incorporate *both* analytic (knowledge and skills) and empathetic (social and emotional prompts) information have the potential further to increase participation in self-management behaviors (i.e. improved dietary patterns) and to improve health outcomes, such as blood pressure and glucose control and decrease the incidence of negative sequelae (i.e. stroke and myocardial infarction).

In a recent study, we found associations among health information behavior, neuroprocessing (using functional magnetic resonance imaging, or fMRI), and self-management processes in (n=26) African Americans *with prehypertension* (SBP 120-139 and/or DBP 80-89 mmHg). We have also found that information seeking and sharing explained improved blood pressure self-management in African American women $\beta = -.17$ ($p = .05$) & $\beta = .46$ ($p < .001$), respectively). The purpose of this descriptive study is to examine the neurobiological mechanisms associated with health information behavior and



self-management in African American women *with comorbid hypertension and type 2 diabetes*. A convenience sample of 45 community-dwelling African American women who have been clinically diagnosed with hypertension and type 2 diabetes will be recruited.

Aims

1. Characterize the relationships among health information behavior (seeking, sharing, use), neuroprocessing (ability to differentiate between analytic/empathy tasks) and executive function, self-management processes (self-efficacy, self-regulation, patient activation), and outcomes (diet self-management, blood pressure, hemoglobin A1C, hsC-reactive protein, quality of life) in African American women with hypertension and type 2 diabetes.
2. Evaluate the shared and independent variance contributions of health information behavior, neuroprocessing and executive function, self-management processes on diet self-management, blood pressure, hemoglobin A1C, hsC-reactive protein, and quality of life outcomes.

In line with the Precision Medicine initiative, identification of brain-behavior phenotypes relating to health information behavior and self-management will assist in designing and testing of targeted and tailored interventions for African American women that potentially are more effective than current self-management interventions. This work will contribute to the reduction of health disparities affecting this population by exploring culturally driven self-management processes. It will also establish a foundation of additional findings to support our next project, an R01 application to examine the effects of our information sharing intervention in a sample of African American women with hypertension. These goals are in line with the goals of the CSCD pilot program, as well as the goals of the National Institute of Nursing Research.

This study will be conducted by the applicant, Dr. Lenette Jones, with the support of her co-investigators: Drs. Laura Saslow (*psychologist*), Tiffany Veinot (*information scientist*), and Robert J. Ploutz-Snyder (*statistician*) and consultants: Drs. Bruno Giordani (*neuropsychologist*), Douglas Noll (*neuroimaging expert*), and Heather Johnson (*preventative cardiologist and researcher*). The study will be performed within the science and research infrastructure of the P20 Center for Complexity and Self-Management of Chronic Disease (CSCD) Center at the University of Michigan School of Nursing that is focused on the discovery of brain mechanisms associated with self-management behaviors. Collaborations among investigators at the University of Michigan provide a rich set of resources and mentorship. Other resources include the University of Michigan hospital, Michigan Clinical Research Unit, and Nutritional Assessment Laboratory.

We must address health disparities affecting African American women. African American women are a vulnerable population, as they are disproportionately affected by both hypertension and diabetes. The rates of hypertension in the general population is one



in three, yet almost one in two African-American women have high blood pressure. Although many Americans are affected, the prevalence of hypertension is highest among African American women. African American women are also disproportionately affected by type 2 diabetes. In fact, the prevalence of diabetes among African American women is twice as high compared to rates among White American women. African American women are diagnosed earlier, live with chronic illness longer, and die at an earlier age from complications of diabetes. African American women have higher blood pressure readings when compared to other women and studies have shown that there are hypertension knowledge deficits among this group. Additional research is needed about ways to eliminate health disparities affecting African American women with these chronic illnesses.

We must study self-management of hypertension and diabetes within the context of each other. Patients must manage these chronic illnesses in tandem, so we must design interventions that are effective in addressing both. There are evidenced based recommendations available to assist patients to successfully self-manage their blood pressure and blood glucose levels, but additional studies are needed to assist patients in making lifestyle changes. Self-management of hypertension and type 2 diabetes requires that patients understand and use health information to complete specific actions: taking medications, making dietary changes, or exercising. Finding ways to assist African American women to enhance self-management strategies, such as goal setting and problem-solving, to improve blood pressure and glucose control is important and needed as well as understanding neurobiological mechanisms of these interventions.

We have the opportunity to understand what changes in the brain subsequent to our interventions. Studies that advance the science related to brain-behavior connections related to self-management of chronic illness are especially important. One tool that can be used to examine cognitive and behavior mechanisms is fMRI. In our previous work, we used fMRI to examine the extent to which two distinctly anti-correlated (analytic and empathetic) networks influenced self-management behaviors. The Task Positive Network (TPN) or **analytic network**, is involved with using skills, knowledge and self-monitoring for problem solving and goal-directed action. It is located in the prefrontal and parietal areas of the brain, is activated during attention-demanding tasks (skills, knowledge, and self-monitoring). The Default Mode Network (DMN), or **empathetic network**, focuses on emotion-management and self-awareness. It is located posterior cingulate and medial prefrontal cortices, is activated during wakeful rest (emotion management, social cognition, and self-awareness). As the activation of the analytic network increases, activity in the empathy network decreases. This neural network activity is consistently observable on fMRI. Prior work has shown that people who have greater balance in analytic processing and emotional processing are more likely to formulate and act on their plans.

Therefore, we hypothesize that those who were better able to differentiate between analytic and socio-emotional tasks will likely be better at setting goals and acting on them (better self-managers). This proposed study extends that work in examining brain mechanisms associated with health information behavior and self-management behaviors in individuals diagnosed with hypertension and diabetes. Findings from studies that include



neurocognitive underpinnings of behavior have the potential to inform theory, help scientists develop interventions that are specific and effective, and tailor interventions to specific populations; therefore improving clinical practice and reducing disparities in chronic illness.

Studies of health information behavior to support self-management of chronic illnesses are innovative. Information is the basic component of the self-management process. Although knowledge alone does not lead to behavior change, having accurate information about hypertension is the first step in managing blood pressure. In our previous work, we've found that both seeking and sharing led to improved self-management behavior and improved blood pressure control. The findings from this study will serve as a foundation for building more tailored interventions to support effective information seeking, sharing, and use to improve self-management of chronic illnesses. Not only is research needed about the patterns and roles of health information behavior in self-management of hypertension, but knowledge about the underlying mechanisms of informational behavior change are needed.

Sample. A convenience sample of 45 community-dwelling African American women with hypertension and type 2 diabetes will be recruited from primary care practices and community organizations. The principal investigator is currently establishing relationships within a large community organization and a large primary care practice. The majority of the clients served are African American. Potential participants will be recruited via flyers posted within the organization and practice buildings. The flyers will include a number for individuals to call to contact study personnel to be screened. If we struggle with recruitment, we can recruit participants the day they attend an appointment at Michigan Medicine, as well as recruit through other approaches, such as posting notices online at sites such as Facebook as well as use online research recruitment sites such as ResearchMatch. Inclusion criteria are (a) diagnosed with hypertension and type 2 diabetes, (b) aged 21-64 years, and (c) right-handed (to control for the differences in handedness on cognition). Exclusion criteria are (a) blood pressure >160/110; (b) cognitively impaired as evidenced by a score <20 on the Montreal Cognitive Assessment (MOCA); (c) those in active treatment for major depressive disorder; and (d) having one of the following contraindications for fMRI: heart pacemaker, heart defibrillator, metal in the eye, and some types of metal elsewhere within the body such as certain surgical clips for aneurysms in the head, heart valve prostheses, electrodes, and some other implanted devices, women who are pregnant.

Research Design. A cross sectional, experimental design will be used. In this pilot study, measures of health information behavior, neuroprocessing (using fMRI), self-management processes, and outcomes (diet, blood pressure, hemoglobin A1C, hsC-reactive protein, and quality of life) will be collected.

Variables and Measures

Health Information Behavior (seeking, sharing, and use) will be measured using the Modes of Health Information Acquisition, Sharing, and Use Scale. This is a 21-item survey with three subscales and can be adapted to a specific chronic illness. The first scale measures how the participant finds information (8 items). The second scale measures how the participant shares information (5 items). The third scale measures how the participant



uses information to make self-management decisions (8 items). Each item is on Likert-type scale, ranging from 0 (“never”) to 5 (“very often”). Internal consistency for this measure is $\alpha = 0.77$. Scores are calculated by scoring the items, with higher scores indicating greater use of a particular information behavior.

Neuroprocessing (or brain activity in response to prompts) will be measured by fMRI to identify responses associated with the analytic and empathetic networks described previously. In a previous study, we designed a paradigm that would allow us to examine brain activity in response to different types of health information. There were two types of stimuli that were examined responses to: analytic (video clips describing anatomy and physiological processes, such as how blood flows through the heart) and empathetic (individuals describing how emotional salient aspects of self-management, like how they overcame difficulty of managing a chronic illness). These content categories were selected, by hypothesis, to elicit activation and deactivation in the analytic and empathetic networks. In addition to the two conditions, we will include periods of rest with similar frequency and duration to the videos. This will allow us to establish a resting baseline, so that we can assess both activations (brain activity greater than resting baseline) and deactivations (brain activity suppressed below resting baseline). **Magnetic resonance imaging (MRI) acquisition.** Imaging data will be acquired with a GE 3T MR750 scanner at the University of Michigan Functional MRI Laboratory using either an 8- or 32-channel array receiver coil. Participants will undergo a T1-weighted magnetization-prepared rapid-acquisition gradient-echo structural sequence (MP-RAGE), followed by four T2*-weighted functional task runs (230 volumes each). Functional runs will use a gradient echo spiral-in acquisition with 43 contiguous 3.0 mm slices, 3.4 X 3.4 mm in-plane resolution, TE = 30ms, flip angle = 80°, TR = 2.00 s. Diffusor tensor imaging (DTI) will also be conducted to map the white matter of the brain. **Stimulus presentation.** Stimuli will be presented using Eprime software. Videos will be projected onto an MRI-compatible LCD display, viewed by subjects through a mirror and sound will be presented through pneumatic Avotech headphones. An integrated microphone will allow for two-way communication, to establish that participants can clearly see and hear the videos.

Executive Function will be measured using the Flanker Inhibitory Control and Attention Test and the Dimensional Change Card Sort (DCCS) Test. The Flanker test measures both a participant’s attention and inhibitory control. The test requires the participant to focus on a given stimulus (arrows) while inhibiting attention to stimuli flanking it. Scoring (0 -10) is based on a combination of accuracy and reaction time. Test-retest reliability is $\alpha = 0.94$. The DCCS test measures cognitive flexibility in detecting and using rules that guide behavior. Scoring (0-3) is based on correctly sorting nine or more of the 12 test cards. Both measures are part of the NIH Toolbox and are administered by computer.

Self-Management Processes

Self-efficacy will be measured using the Chronic Disease Management Self-efficacy Scale. This scale measures how confident the participant is in doing activities to self-manage chronic disease. This is a 6-item scale with responses that range from 1 (“not confident at



all”) to 10 (“confident”). Internal consistency is $\alpha = 0.91$. Scores are calculated by summing the items; higher scores indicate higher self-efficacy.

Self-regulation will be measured using the Index of Self-regulation. This 9-item, Likert-type scale measures self-regulation in the maintenance of health behavior change. It ranges from 1 (“strongly disagree”) to 6 (“strongly agree”). Internal consistency is $\alpha = 0.87$. Scores are calculated by summing the items; higher scores indicate increased motivation.

Patient activation will be measured using the Patient Activation Measure. This 13-item scale assesses patient knowledge, skill, and confidence for self-management. It contains Guttman-like scale with responses ranging from 1 (“strongly disagree”) to 4 (“strongly agree”). Internal consistency is $\alpha = 0.89-0.94$. Scores are calculated by summing the items; higher scores indicate increased knowledge, skill, and confidence.

Outcomes of Interest

Self-management diet behaviors. Fruit, vegetable, and sodium intake will be measured using the 24-hour dietary recall collected using Nutrition Data System for Research (NDSR), a computer-based software application that facilitates the collection of recalls in a standardized fashion. This measure is considered to be the gold standard approach to dietary assessment and is known to be valid and precise in assessing the diets of patients with chronic illness. We will use this data to calculate a healthy eating index (HEI) score for each participant.

Blood pressure (systolic and diastolic) will be measured with an automated sphygmomanometer using a standardized protocol. We will report the average of three, consecutive measures.

Serum samples will be obtained to measure hemoglobin A1C, hsC-reactive protein, and lipids.

Quality of Life will be measured with the PROMIS Global Scale. This 10-item measure has two subscales that assess global perceptions of physical and mood. Items range from 1 (“never”) to 5 (“always”) on a Likert-type scale. Internal consistency for the subscales range from $\alpha = 0.81-0.86$.

Other

Demographic factors such as age and prescribed medications will be measured using a demographic and medical history survey.

Cognitive impairment will be screened for using the 11-item Montreal Cognitive Assessment (MOCA). It assesses the cognitive domains: attention and concentration, executive functions, memory, language, visuoconstructional skills, conceptual thinking, calculations, and orientation. Internal consistency is $\alpha = 0.88$. The total possible score is 30 points; 20 will be used as our screening threshold.



Sample Size & Power. Correlations from in our prior work on prehypertensive African American women helped to inform our sample size determination. Specifically, we found correlations between VMPFC task differentiation and information sharing ($r=.53$), DMN task differentiation and information sharing ($r=.43$), hsCRP and information sharing ($r=-.44$), and self-regulation with information use ($r=.42$), all of which are variables proposed here. We anticipate effects of this magnitude or greater from Aim 1 in the proposed study. Our proposed sample size of $n=42$ exceeds 80% power to detect effects of similar magnitude, and enables reasonable precision for characterizing the shared and independent variance contributions (with 95% CI's) proposed in Aim 2.

Data Analysis Plan. Statistical analyses will use two-tail alpha to reject null hypotheses at 0.05. Statistical reports will emphasize our desire to characterize the evidence with 95% confidence intervals, in addition to reporting significance levels. Prior to final analyses, we will screen the data, consulting with the PI as needed. To address Aim 1, pairwise correlational analyses will be used to determine statistical associations among health information behavior, brain activity, cognitive factors, and self-management behaviors. We will employ Bonferroni adjustments to correct for inflated Type I error risks on these significance tests, though our primary goals here are to characterize the strength of associations with 95% Confidence Intervals. To address Aim 2, we will use hierarchical-regression techniques augmented with squared semi-partial correlation coefficients designed to assess the combined variance contributions of contextual factors (ex. age, number of medications, depressed mood), health information behavior measures (seeking, sharing, use, submitted as a block), and measures of self-management behaviors (self-efficacy, decision-making, self-regulation, patient activation, submitted as a block) on outcomes including diet self-management, blood pressure, HbA1C, hsC-reactive protein and quality of life. Variance contributions of blocks of predictors will be evaluated by comparing model R^2 s of the nested vs. fuller models. If the larger models account for significantly greater proportions of the variance in outcomes as we expect, we will adopt the more complete models. Squared semi-partial correlation coefficients will then be used to evaluate the *independent* variance attributable to *individual* predictors in the resulting model(s).

Pilot Project 9 (PP9, Dr. Sheria Robinson-Lane)

Self-Efficacy in Chronic Disease Management among Black Dementia Caregivers: A Feasibility Study. Awarded January 3, 2018

Progress: This pilot project was approved for funding on January 3, 2018. The project is just beginning. IRB approval has been received.



Specific Aims

Familial caregivers of Black older adults with Alzheimer's disease and/or related dementias (ADRD) are a vulnerable population with multiple risk factors associated with new onset ADRD and premature death. Specific stress-related risk factors with a higher prevalence among Black caregivers, such as high blood pressure and obesity, may be reduced through targeted caregiver interventions that improve caregiving self-efficacy, or perceived ability to provide care, and self-management of chronic disease. Though evidence suggests that culture plays an important role in caregiver outcomes, few interventions are specifically designed to meet the needs of underserved racial and ethnic populations. Programs like REACH II and Savvy Caregiver that have included Black caregivers, have not had significant effects on chronic health outcomes, or have focused exclusively on cognitive behavioral therapy (CBT) with limited inclusion of other domains of care. Furthermore, access to caregiver support programs is often limited by specific health system membership, geography, or care recipient disease state. There is a need for targeted, community-based health interventions to help Black caregivers effectively manage their own health and use personally relevant ways of coping, or cognitive and behavioral efforts to manage stress. By studying the adaptive coping strategies most prominent amongst caregivers and understanding both their personal health needs and caregiving responsibilities, appropriate participant informed interventions may be developed. Pilot funding from the Center for Complexity and Self-management of Chronic Disease at the University of Michigan School of Nursing, will facilitate the intervention development process by allowing for initial feasibility testing of a questionnaire and self-assessment techniques designed to evaluate caregiver outcomes including: physical functioning, available social supports, coping, psychological distress, self-efficacy in both chronic disease self-management and caregiving, as well as positive aspects of caregiving. In particular, the questionnaire and self-assessments will be evaluated for response burden. The preliminary data provided by this study will allow for the completion of a power analysis to determine the necessary sample size for future study and is a first step towards clinical trial development.

The central hypothesis of this work is that the shared values, beliefs, and customs that create communities extend to ways of coping. Identifying and reinforcing the adaptive coping strategies communities prefer to use, strengthens the health of both the community and the individual. This hypothesis has been formulated on the basis of a previous study in which a community of Black older adults with chronic severe pain used adaptive coping strategies inclusive of positive reappraisal, social supports, and spirituality to maintain function and independence. As a result of adaptive coping, the older adults had the ability to care for others, found satisfaction in their caregiving work, and experienced spiritual well-being and decreased psychological distress. The work of Dunn, McIntosh and Rosselli, and Lee and Mason support this hypothesis.



The rationale for the proposed research is that completing feasibility testing prior to initiating the full study will provide the opportunity to test recruitment methods and determine participant burden in completing the survey tools and self-assessment measures. Furthermore, we will be able to evaluate our ability to measure study variables as expected and determine effect size for future studies. Ultimately, this pilot work will help to identify feasibility concerns that may be modified and will result in a larger study in the future. It is anticipated that the following Specific Aims will be achieved with this work:

Aim 1: To conduct a pilot, descriptive study to evaluate the feasibility of recruiting Black caregivers of persons with ADRD, and their ability to complete a battery of assessments that measure function, social support, coping, caregiving self-efficacy, self-efficacy for managing caregivers' chronic disease, psychological distress, positive aspects of caregiving, blood pressure, and weight (year 1). Participant recruitment will take place primarily through participant registries that target minority older adults. Process outcomes to be evaluated, include recruitment success and ease of assessment completion.

Aim 2: To evaluate the effects of physical function, social supports, coping, caregiving self-efficacy, self-efficacy in managing personal health, psychological distress, and positive aspects of caregiving (year 2). Preliminary effects may be evaluated and used for power analysis.

Aim 3: To develop the necessary skills and experiences that will lead to a successfully funded R34 planning grant to continue clinical trial develop of the intervention. This aim will be accomplished through effective collaboration and mentorship provided by senior researchers affiliated with CSCD, and the experiential training that will occur with the completion of the prior aims.

This work addresses a clinical void in culturally responsive health interventions developed for Black ADRD caregivers. Few studies have examined how stress-related modifiable health risks may be reduced through participant informed community-based support programs that encourage self-management of health.

Alzheimer's disease is one of the top ten leading causes of death in the United States and is a key contributor to cognitive and functional disability among older adults. In recent years, Alzheimer's disease related mortality rates have significantly increased among Black Americans, despite overall population declines in prevalence. Difficulty in clinical distinction between Alzheimer's disease and related dementias (ADRD), such as frontotemporal, Lewy



body, mixed, and vascular dementia has led to the expansion of Alzheimer's disease focused policy, health prevention, and promotion efforts to be more inclusive of the related disorders and the framing of these conditions collectively as Alzheimer's disease and/ or related dementias (ADRD). This is particularly important in beginning to address health disparities between Blacks and Whites as Black older adults with Alzheimer's disease are 20 percent more likely than Whites to have mixed forms of dementia. Reducing ADRD disparities for ethnic and racial minority populations is also one of the aims of National Alzheimer's Project Act (NAPA) (Public Law 111-375) enacted in 2011. The expansion of supports for family caregivers of persons with ADRD is a key outcome.

Familial caregiving allows Black older adults with ADRD to remain in the community and achieve optimal health despite progressive, debilitating disease that causes both cognitive and physical disability.

Unfortunately, family caregivers of Black older adults with ADRD are at risk for developing dementia themselves due to hereditary risk factors, such as the presence of the Apolipoprotein E (APOE) genotype and common stress related risk factors such as obesity, hypertension, and cardiovascular disease. Furthermore, Black caregivers of persons with ADRD often experience significant emotional, financial, and physical health challenges that can increase stress, diminish satisfaction with caregiving, and reduce their ability to assist with care. Empowering Black ADRD caregivers to proactively manage their own complex health needs and provide optimal care for their family members with ADRD increases the likelihood that these caregivers can 1) maintain their caregiving responsibilities; 2) reduce their own ADRD risks; and 3) have a high quality of life. Supporting caregiver health facilitates aging in place for older adults with a disability and sustains the ability of caregivers to continue contributing to the estimated \$230.1 billion in health system cost savings from the uncompensated care they provide. An effective and culturally relevant intervention for Black ADRD caregivers may be developed by identifying the preferred adaptive coping strategies of Black caregivers of persons with ADRD and encouraging caregivers to engage in these strategies as they work to improve their own personal health and self-efficacy in caregiving.

The overall scientific premise of this work is that cultural values influence the coping strategies that individuals use when managing stress. Common Black American community values such as spirituality and social engagement are hypothesized to be predominant coping strategies used by the community that may be associated with particular health outcomes and perceptions of caregiving. By identifying the specific coping strategies most commonly used by Black caregivers and recognizing these strategies as group strengths that may be emphasized in a positive way, a strength-based approach to community health is encouraged. Interestingly, community-based health interventions are usually developed from deficit-based frameworks that emphasize community failures and needs rather than



community strengths. These deficit-based approaches are more likely to lead to increased dependency on outside resources and solutions, and in the long-term result in poor program sustainability. On the other hand, positive mental health approaches that are not inclusive of physical domains of care have little effect on health outcomes. Identifying and reinforcing multifaceted community assets and strengths supports intersectional health system frameworks that can improve population health. One of the guiding principles of the National Alzheimer's Project Act, is to optimize existing community resources. Encouraging communities to maximize adaptive coping strategies is a way of optimizing existing resources. This project aims to identify a culturally responsive conceptual model that will guide the development of an effective and sustainable community-based intervention that improves the health of Black ADRD caregivers. The model may be identified through the descriptive study of Black ADRD caregivers and effective evaluation of coping strategy use along with related health and quality of life outcomes. This pilot study will provide an effective means of evaluating study process outcomes and determining the feasibility of the proposed work in a larger study.

Very few studies have been designed to engage Black caregivers with ADRD in the intervention development process or have had a primary goal of improving caregiver health outcomes. Furthermore, unlike other caregiver studies, this study posits that a caregiver's physical health, a key of measure quality of life, is a contextual concern that influences the caregiver's ability to adaptively cope with the cognitively impaired patients increasing support needs, and is an outcome of effective coping. This varies from the commonly used Pearlin stress process model, and the model presented by Knight and colleagues, which do not recognize the antecedent role of physical health on caregiver outcomes. Finally, this study is innovative in its conceptualization of coping.

While most stress and coping frameworks measure and evaluate coping as either a situational/ problem-solving response to environmental stressors, or a cognitive/ emotion-focused response, here, coping is recognized as being a function of both personality and the internal/ external environment. Aldwin and Werner note that both situational and cognitive coping are used in coping efforts, and there is no hierarchy of adaptation. The proposed study integrates a validated and internationally tested tool, the Coping and Adaptation Processing Scale (CAPS), which is designed to measure the ability of a person, or community, to respond, or adapt, to changes in the environment (which is often variable). By identifying the coping strategies most commonly used by Black ADRD caregivers, an intervention may be developed that will teach caregivers how to maximize their preferred ways of coping. The CAPS tool, which has not been yet been used in a Black adult population, will be central in the work of identifying and testing a culturally responsive and strength-based support program for caregivers of persons with Alzheimer's disease and/or related dementias. The innovative aspects of this project will culminate in a thorough and comprehensive understanding of the factors that influence adaptive coping among Black ADRD caregivers.



Ethnic and cultural identity effects coping and subsequent health outcomes across the lifespan. It is hypothesized that use of spirituality and social supports will be the predominant coping preference of Black ADRD caregivers. It is further hypothesized that an ADRD caregivers' ability to cope with and effectively adapt to stress is dependent upon their own physical health, their confidence in their own caregiving abilities, and the benefits they perceive occur with caregiving. The proposed pilot study (n=30) will evaluate recruitment effectiveness, questionnaire burden, and process outcomes. In addition, this preliminary work will provide information on effect size for future studies. The study and its dissemination will be completed within two years.



Center Publications (2014-2018)

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- Casida JM, Craddock H, Hoff-Nygaard D, Kay C, Pierzynski A, Manker D, Cooley L. Construction and evaluation of a VAD Care App[®] as self-management tool for patients with ventricular assist devices (VADs). *ASAIO.*2017;63(3), 48. Accessed June 8, 2017.
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Seminars

The table below shows the breadth and depth of research expertise and presentations presented at the Center seminar series (in reverse chronological order).

Date	Seminar Details
Apr. 5, 2018	Dr. Joanne McPeake, PhD, MSc, BN, RGN, FHEA , Nurse Consultant, Clinical Research and Innovation, NHS Greater Glasgow and Clyde; Honorary Clinical Senior Lecturer, School of Medicine, Dentistry & Nursing, University of Glasgow. “InSpire: A Program to Improve Patient Recovery After Critical Illness by increasing Self-efficacy.”
Mar. 14, 2018	Dr. George C. Alter, PhD , Research Professor, Population Studies Center. Research Professor, Inter-University Consortium for Political and Social Research, Institute for Social Research; Professor, Department of History, University of Michigan. “Promise and Problems of Common Data Elements.”
Mar. 7, 2018	Dr. Gerald Bloomfield, MD, MPH , Assistant Professor of Medicine, Assistant Research Professor of Global Health, Member in the Duke Clinical Research Institute, School of Medicine, Duke University. “A Systems Approach to Tackling Cardiovascular Non-Communicable Diseases in Western Kenya.”
Dec. 11, 2017	Dr. Katherine W. Bauer, PhD, MS , Assistant Professor, Department of Nutritional Sciences, School of Public Health, University of Michigan. “Promoting Parents’ Self-Regulation to Address Childhood Obesity.”
Nov. 14, 2017	Dr. Jesus (Jessie) Casida, PhD, RN, APN-C , Assistant Professor, Department of Health Behavior and Biological Sciences, School of Nursing, University of Michigan. “Mobile Application to Enhance Self-management of Left-Ventricular Assist Device in Advanced Heart Failure.”
Oct. 17, 2017	Dr. Donna J. Marvicsin, PhD, PNP-BC, CDE , Clinical Associate Professor, Department of Health Behavior and Biological Sciences, School of Nursing, University of Michigan. “Evening Routines in Families of Young Children with Diabetes: Lessons Learned and Next Steps.”
Mar. 22, 2017	Dr. Lee F. Schroeder, MD, PhD , Assistant Professor, Chemical Pathology, Director of Point of Care Testing, Associated Director, Chemical Pathology, Clinical Pathology, Department of Pathology, Michigan Medicine, University of Michigan, presented on “Essential NCD Diagnostics for Non-Communicable Disease in Resource-Poor Settings.”
Jan. 18, 2017	Dr. Matt Davis, PhD, MPH , University of Michigan School of Nursing, Department of Systems, Populations, and Leadership, presented on “Using Big Data for Healthcare Research.”
Nov. 30, 2016	Dr. Brad Zebrack, PhD, MSW, MPH, FAPOS , Professor, University of Michigan School of Social Work; and Comprehensive Cancer Center, presented on “Psychosocial Distress Screening and Medical Service



Utilization: A Report from the Association of Oncology Social Work's Project to Assure Quality Cancer Care."

- Nov. 3, 2016** Dr. [Andrea Barsevick, PhD, RN, FAAN, AOCN](#), Thomas Jefferson University presented on "Energy Conservation as a Strategy to Manage Cancer-related Fatigue."
- October 19, 2016** Dr. [Sarah Stoddard, PhD.](#), University of Michigan School of Nursing, presented on "Mixed Methods Research Design."
- April 6, 2016** Dr. [Siriorn Sindhu, DNSc](#), Department of Surgical Nursing, Faculty of Nursing, Mahidol University, Thailand, presented at the CSCD Seminar series "An Integrated Approach to Coordination of Community Resources to Improve Health Outcomes and Satisfaction in Care of Thai Patients with NCDs."
- March 23, 2016** Dr. [James E. Aikens](#), University of Michigan Medical School, presented at the CSCD Seminar series [Diabetes Self-management Support Delivered via mHealth](#).
- January 20, 2016** Dr. [Donna L. Berry](#), PhD, RN, OACN, FAAN, Phyllis F. Cantor Center for Research in Nursing & Patient Care Services, Dana-Farber Cancer Institute, presented at the CSCD Seminar series "Patient-centered Technologies: Making a Difference in Cancer Care."
- November 22-23, 2015** Dr. Ivo Dinov gave a keynote lecture [Predictive Big Data Analytics: Using Large, Complex, Heterogeneous, Incongruent, Multi-source and Incomplete Observations to Study Neurodegenerative Disorders](#) at the [2015 Big Data Analytics Experience Conference, Tecnológico de Monterrey \(Monterrey Tech\), Santa Fe, Mexico](#).
- November 04, 2015** Dr. [Denise Saint Arnault](#), PhD, RN, FAAN, presented "Mixing Methods to Capture Complex Phenomena."
- Sept 23, 2015** Dr. [Ivo Dinov](#), PhD presented on "Exploratory Big Data Analytics".
- August 8–13, 2015** Dr. [Ivo Dinov organized a special session on Big Data: Modeling, Tools, Analytics, and Training](#) at the 2015 Joint Statistical Meeting, Seattle, WA.
- April 21, 2015** [The CSCD Presents: Dr. Saeid Amiri \(University of Nebraska\)](#)

NINR P20/P30 Center Director meetings

The National Institute for Nursing Research (NINR) organizes annual P20/P30 Center meetings.

Currently [Funded P20 Centers](#)



Grant number	Principal Investigator	Center Name	Institution
P20-NR014126	Redeker, Nancy	Yale Center for Sleep Disturbance in Acute and Chronic Conditions	Yale University
P20-NR015331	Barton, Debra (Contact) Dinov, Ivo	Center for Complexity and Self-Management of Chronic Disease (CSCD)	University of Michigan
P20-NR015320	Guthrie, Barbara	Northeastern Center for Technology in Support of Self Management and Health	Northeastern University
P20-NR015339	Schiffman, Rachel	Self-Management Science Center at UWM	University of Wisconsin, Milwaukee
P20NR016599	Jacelon, Cynthia	UManage Center: UMass Center for Building the Science of Symptom Self-Management	U. Massachusetts Amherst
P20NR016605	Starkweather, Angela	Center for Accelerating Precision Pain Self-Management	U. Connecticut Oct
P20NR016575	Kelechi, Teresa	The Symptoms Self Management Center	Medical U. South Carolina

For more information about NINR Centers please visit [the NINR Research Centers page](#).

Currently [Funded P30 Centers](#)

Grant number	Principal Investigator	Center Name	Institution
P30-NR014129	Dorsey, Susan G.	Center for the Genomics of Pain	University of Maryland, Baltimore
P30-NR014131	Page, Gayle	Center for Sleep-Related Symptom Science	Johns Hopkins University
P30-NR014134	Waldrop-Valverde, Drenna	Center for Neurocognitive Studies	Emory University
P30-NR014139	Docherty, Sharron	Center for Adaptive Leadership in Symptom Science	Duke University
P30-NR015326	Moore, Shirley	SMART Center II Brain Behavior Connections in Self Management Science	Case Western Reserve University
P30-NR015339	Kim Miyong	Center for Transdisciplinary Collaborative Research in Self-Management Science	University of Texas, Austin
P30NR016579	Dorsey, Susan (Contact), Renn, Cynthia & Resnick, Barbara	Center to advance Chronic Pain Research	University of Maryland, Baltimore



Grant number	Principal Investigator	Center Name	Institution
P30NR016585	Ward, Teresa (Contact) & Heitkemper, Margaret	Center for Innovation in Sleep Self-Management	U. Washington
P30NR016587	Bakken, Suzanne (Contact) & Hickey, Kathleen	Precision in Symptom Self-Management (PriSSM)	Columbia University

For more information about NINR Centers please visit [the NINR Research Centers and Program Projects page](#).

NINR Center directors meetings

CSCD actively participates in the annual NINR Center directors meetings:

Date	Location	CSCD Presentations
May 4, 2015	Washington, DC	Leveraging Complexity to Improve Health Outcomes through Self-management
May 3, 2016	Washington, DC	Leveraging Complexity to Improve Health Outcomes through Self-management
May 2, 2017	Washington DC	Embracing Complexity for Successful Self-management of Chronic Disease
May 1, 2018	Washington, DC	Leveraging Complexity to Improve Health Outcomes through Self-management

Common Data Elements

The Center has compiled tables of *core* and *additional* CDEs that we utilize in all CSCD pilot projects and research activities.

CSCD Core CDE Concepts

CDE Concept	Name of the Measure / # Items	Reference
Motivation	Patient Activation Measure (PAM) /10 items (also available in Spanish)	Hibbard JH, Stockard J, Mahoney ER, Tusler M. Development of the Patient Activation Measure (PAM): conceptualizing and measuring activation in patients and consumers. Health Serv Res. 2004 Aug;39(4 Pt 1):1005-26. PMID: 15230939.
Self-regulation	Index of Self-regulation/9 items	Fleury J. The index of self-regulation: development and psychometric analysis. J Nurs Meas. 1998 Summer;6(1):3-17. PMID: 9769608.
Self-efficacy	Self-efficacy for Managing Chronic Disease /6 items	Lorig KR, Sobel DS, Ritter PL, Laurent D, Hobbs M. Effect of a self-management program on patients with chronic disease. Eff Clin Pract. 2001 Nov-Dec;4(6):256-62. PMID: 11769298.
Global health	PROMIS v. 1.1.- Global Health /10 items	Hays RD, Bjorner JB, Revicki DA, Spritzer KL, Cella D. Development of physical and mental health summary scores from the patient-reported outcomes measurement information system (PROMIS) global items. Qual Life Res. 2009 Sep;18(7):873-80. doi: 10.1007/s11136-009-9496-9. Epub 2009 Jun 19. PMID: 19543809.

Other CDE Hierarchies

Name	Other Names	Steward	Used by Organizations	Registration Status	Admin Identifiers Status	Questions
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<u>NINR Demographics</u>	NINR Demographics	NINR	NINR	Qualified		5
<u>Short Form 36-Item Health Survey (SF-36)</u>	Short Form 36-Item Health Survey (SF-36)	NINDS	NINDS, NINR	Qualified		36
<u>PROMIS SF v1.0-Anxiety 6a</u>	<p>PROMIS SF v1.0-Anxiety 6a</p> <p>PROMIS Item Bank v1.0 – Emotional Distress-Anxiety ...</p> <p>Emotional Distress-Anxiety – Short Form 6a</p>	PROMIS / Neuro-QOL	PROMIS / Neuro-QOL, NINR	Qualified	Assessment Center: 32FDB758-FB1B-492D-8C73-F2CF6C8A653B	6
<u>PROMIS SF v1.0-Fatigue 6a</u>	<p>PROMIS SF v1.0-Fatigue 6a</p> <p>PROMIS Item Bank v1.0 – Fatigue – Short Form 6a</p>	PROMIS / Neuro-QOL	PROMIS / Neuro-QOL, NINR	Qualified	Assessment Center: 1C3CC8B7-9F70-46A5-9616-E0A9A3403453	6



	Fatigue – Short Form 6a					
	PROMIS SF v1.0 - Fatigue 6a Investigator Version					
	PROMIS SF v1.0 - Fatigue 6a Participant Version					
<u>PROMIS SF v1.0-Sleep Disturbance 6a</u>	PROMIS SF v1.0-Sleep Disturbance 6a PROMIS Item Bank v1.0 – Sleep Disturbance – Short Sleep Disturbance – Short Form 6a	PROMI S / Neuro- QOL	PROMIS / Neuro- QOL, NINR	Qualified	Assessment Center: EFB1133D- 429E-4C9D- B322- 32C614CB3C9 D	6
<u>Positive Affect and Well-Being - Short Form</u>	Positive Affect and Well-Being - Short Form	PROMI S / Neuro- QOL	PROMIS / Neuro- QOL, NINR	Qualified	Assessment Center: 38DF2C87- 0858-4C1B- A0A1- D48EC4100D6 6	9



	Neuro-QOL Item Bank v1.0 – Positive Affect and Wel ...					
<u>PROMIS SF v1.0 - Applied Cog General Concerns 6a</u>	PROMIS SF v1.0 - Applied Cog General Concerns 6a Applied Cognition- General Concerns- Short Form 6a	PROMI S / Neuro- QOL	PROMIS / Neuro- QOL, NINR	Qualified	Assessment Center: A09CDF4E- E70C-40DC- 849D- 756A7C60C45 4	6
	PROMIS v1.0-Applied Cognition- General Concerns- Sho ...					
<u>PROMIS SF v.1.0 – Pain Intensity 3a</u>	PROMIS SF v.1.0 – Pain Intensity 3a Pain Intensity – Short Form 3a	PROMI S / Neuro- QOL	PROMIS / Neuro- QOL, NINR	Qualified	Assessment Center: 7224FB55- 81D7-4131- A136- 8C89907CDFB B	3
<u>Depression – Short Form 6a</u>	Depression – Short Form 6a PROMIS Item Bank v1.0 – Emotional Distress – Depression	PROMI S / Neuro- QOL	PROMIS / Neuro- QOL, NINR	Qualified	Assessment Center: 7B1EF457- E187-4E47- 8179- FFF821A7258 4	6

CSCD website

The center website provides a portal to all CSCD activities (<http://www.socr.umich.edu/CSCD>).



Progress reports

Below we highlight some of the Center's annual accomplishments, taken from the Center's three annual progress reports submitted so far:

2017-2018 Progress Summary, to be submitted to NIH/NINR on June 1, 2018

SA 1 (SM Complexity): To leverage complexity to advance the science of self-management for the promotion of health in chronic illness.

....

SA 2 (Training): To expand the number and quality of research investigators who are successful in independently funded careers in self-management research to improve health outcomes.

....

SA 3 (Methods/Data Analytics): To develop a range of techniques and supporting documentation for selecting appropriate methods to address complexity for self-management study designs, data processing, and analytical protocols.

- a. Provide methodological and analytic expertise and tools to collaborators and pilot project investigators.
- b. Develop the CSCD computational infrastructure, including a distributed NoSQL database for managing and sharing (de-identified) data.
- c. Develop efficient and reliable end-to-end computational workflow solutions for advanced data analytics.

In 2017-2018, the CSCD Methods and Analytics Core (MACORE) made significant progress in three complementary directions. The first one developed a powerful protocol for managing complex data for a devastating chronic neurodegenerative disorder - Amyotrophic Lateral Sclerosis (ALS). The second achievement was developing a statistical computing approach for genomics analysis, and the third one involved a visualization of extremely-high dimensional data via non-linear manifolds.

I. Predictive big data analytics study of Amyotrophic Lateral Sclerosis (ALS)

We developed a [new non-parametric method for estimating the prognosis of ALS patients using survival analysis](#) (PMC5749893). Our survival ranking technique transforms patients' survival data into a linear space of hazard ranks and enables the subsequent machine learning prediction of the neurodegenerative progression. This technique was received the top ranking in the DREAM Amyotrophic Lateral Sclerosis (ALS) Stratification Challenge. As an application, we identified salient features that are important in ALS diagnosis and prognosis.

II. Genomic Data Analysis

We introduced a [new theoretical model for analyzing genetics sequence data](#) (PMC5361063). We compared our technique to other techniques for quantifying sequence distances and variability. Most alignment-free methods rely on counting words, which are



small contiguous fragments of the genome. Our approach considers the locations of nucleotides in the sequences and relies more on appropriate statistical distributions. We reported results of extracting information and comparing matching fidelity and location regularization information to classify mutation sequences.

III. Visualization of Extremely High-dimensional Data

The [CSCD analytics team developed a new demonstration of modeling, simplifying and visualizing extremely high-dimensional data](#). Many datasets have million observations and attributes/features. Datasets with high dimensions/features are subjected to what is colloquially known as the curse of dimensionality. For instance, medical images generate thousands of features and are difficult to integrate with clinical and phenotypic information. We utilized a novel manifold statistical technique, t-distributed stochastic neighbor embedding (t-SNE), to reduce 3,000 dimensional data for 10,000 volunteers into a 3D space, see **Figure**.

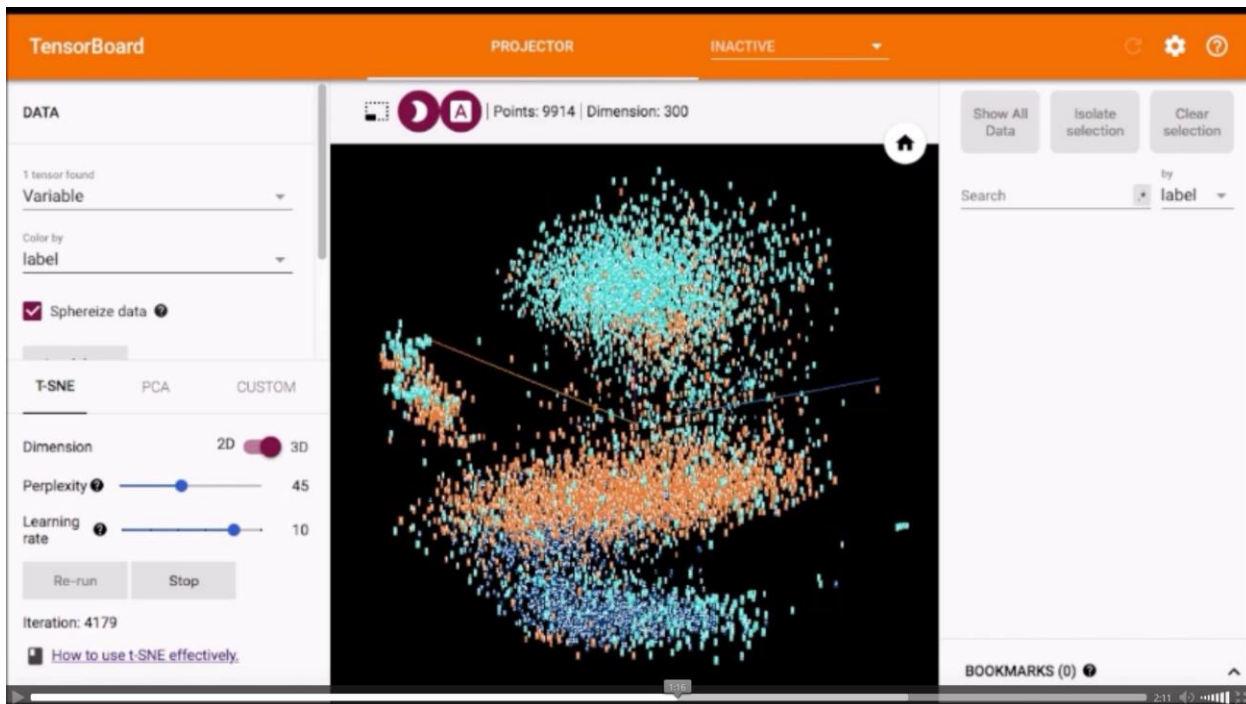


Figure: Visualization of extremely high-dimensional data (3,000 dimensions) into 3D, using t-SNE.

The CSCD TensorBoard application provides a tutorial and a high-end visualization protocol for interrogating extremely high-dimensional data (http://www.socr.umich.edu/CSCD/html/Cores/Macore2/CSCD_tSNE_UKBB_Demo.html). We demonstrated manifold-based statistical dimensionality-reduction technique, t-distributed



stochastic neighbor embedding (t-SNE), to reduce 3,000 dimensional data for 10,000 volunteers into a 3D space.

In the past year, CSCD MACORE investigators organized workshops and bootcamps, offered a MOOC course on Data Science and Predictive Analytics, and presented at national and international conferences:

Dec 08, 2017, "Big Brain Data Science & Predictive Health Analytics" webinar at the BD2K Guide to the Fundamentals of Data Science Series, Webinar ID: 932-094-291.

Nov 05, 2017, A. Sharma (Emory University), W. Hsu (UCLA), E. Siegel (University of Maryland), K. Cheng (Penn State University) and I. Dinov (University of Michigan) organized a half-day workshop at AMIA 2017. The title of the workshop is (W15) Does Integrative Data Analytics on Biomedical Imaging Bring Us Closer to Precision Medicine?, which is sponsored by the AMIA Biomedical Imaging Working Group, Washington Hilton, 1919 Connecticut Ave., NW, Washington, DC 20009. Dr. Dinov's keynote lecture is on Big Brain Data & Predictive Analytics.

Sept 8-9, 2017, "Predictive Big Brain Data Analytics" at the 2017 Advanced Computational Neuroscience Network (ACNN) Big Data Workshop, Indiana University, Bloomington, IN.

Aug 15, 2017, a keynote lecture on "Predictive Data Analytics" at the Malaysia Telemedicine Conference 2017 (August 15-17, 2017, Kuala Lumpur, Malaysia).

Aug 10-18, 2017: Ivo Dinov, Alex Fornito, Andrew Zalesky, Satrajit Ghosh, and Eric Tatt Wei Ho organized an INCF/IBRO Neuroscience Summer School for graduate students and postdoctoral fellows. Dr. Dinov lectured on (1) Statistical Computing, (2) High-Throughput Processing of Big Neuroscience Data, and (3) Neuroimaging-genetics. The Summer Neuroscience School is part of the International Neuroinformatics Coordinating Facility (INCF)/International Brain Research Organization IBRO-APRC School on Neuroinformatics and Brain Network Analysis, Kuala Lumpur, Malaysia.

July-September 2017, Summer 2017: Data Science and Predictive Analytics (UMich HS650), a Massive Open Online Course (MOOC).

SA4 Sustainability

Discussions around using a fee for service model for sustainability have led us to believe this will likely not be sufficient. We reached out to other Centers to collect information about their sustainability and most have leveraged R01's and related equivalent funding mechanisms to keep shared resources going.

Challenges

There are substantial barriers to interdisciplinary involvement and limitations related to funding (e.g., pilot projects, hiring staff, building infrastructure).





Plans and Strategies (2018-2019)

Examples of questions CSCD investigators are currently pondering include:

- How are we operationalizing complexity?
- What should be our strategic priorities in the next year, two years?
- When to start planning P20 renewal (or a P30 expansion)?
- What are some models for Center sustainability?



Key products

Complexity Methods: Leverage complexity to advance the science of self-management for the promotion of health in chronic illness. Provide consultation and mentorship to interdisciplinary teams around innovative methods for analyzing the effects of complex interventions. Facilitate development of symposia focused on complex methodology.

Infrastructure: Expand the number and quality of research investigators successful in funded programs of self-management research. Link novice investigators with resources to facilitate development as independent researchers and to lead interdisciplinary teams (website, computational server).

Methods/Data Analytics: Develop a range of techniques and supporting documentation for selecting appropriate methods to address complexity for self-management study designs, data processing, and analytical protocols. Provide methodological and analytic expertise and tools to collaborators and pilot project investigators. Develop the CSCD computational infrastructure, including databases for managing and sharing (de-identified) data. Develop efficient and reliable end-to-end computational workflow solutions for advanced data analytics. Allocate and manage the CSCD shared resources based on availability and demand according to the strategic priorities.

Training Materials:

Scientific Methods for Health Sciences (SMHS) electronic book:

http://www.socr.umich.edu/people/dinov/SMHS_Courses.html

Data Science and Predictive Analytics MOOC: <http://dspa.predictive.space>



Vision about the Center's sustainability and future plans

...



Notes



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