Center for Complexity and Management of Chronic Disease 2019 External Advisory Committee (EAC) Report

This document includes a 2019 EAC report outlining progress, challenges, accomplishments, and plans for the CSCD Center

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CSCD Activities (2014-2019)

Pilots

The Center has supported nine (9) pilot studies (past and currently ongoing) since its founding in 2014. As of January 2019, all planned pilot study awards have 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; expected to complete by May 1, 2019.

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. Specific aims are:

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 as of January 15, 2019:

Aim 1 is completed.

Aim # 2: A total of 40 patients and 40 caregivers were enrolled (20 patient-caregiver pairs [intervention] and 20 patient-caregiver pairs [control]). There were 4 deaths (patients) in the control and no deaths in the intervention group. Three remaining patient-caregiver pair will complete the 6-month follow-up in April. The study will close on May 1, 2019.

Next Step:

• Full report of the study.

Products:

Presentations:

- Casida, J. M. (December, 2018). App-directed LVAD self-management may improve outcomes further, 9th Annual Meeting on Mechanical Circulatory Support, Hospital Newcastle upon Tyne Hospitals NHS Foundation Trust, UK, [Invited, paper/oral presentation].
- Casida, J. M. (November, 2018). Using mobile app to empower care and self-management in post-LVAD patients, 2nd Asia Pacific Advanced Heart Failure Forum, Hong Kong, [Invited, paper/oral presentation].
- 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.S
- 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.
- Casida, J. M. (2018, November). Using mobile app to empower care and self-management in post-LVAD patients, 2nd Asia Pacific Advanced Heart Failure Forum, Hong Kong, [Invited, paper/oral presentation].
- Casida, J. M. 2018, December). App-directed LVAD self-management may improve outcomes further, 9th Annual Meeting on Mechanical Circulatory Support, Hospital Newcastle upon Tyne Hospitals NHS Foundation Trust, UK, [Invited, paper/oral presentation].

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

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 selfmanagement 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. Final report submitted July 31, 2015. Nothing new to report.

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; expected completion by Fall 2019.

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 cooccurrence 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 life further adds to the complexity of self-care management.

Approximately 50% of HF hospitalizations are preventable and are commonly caused by poor selfcare 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 as of January 15, 2019:

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.

This project evaluated the feasibility and acceptability of a newly developed computer interface for delivering a nurse-led cognitive assessment and self-care intervention along with a nurse enhanced cognitive remediation training via Blue Jeans Network.

20 participants enrolled; 7 completed all 10 sessions and two-month follow-up. One participant who completed all 10 sessions will still need to complete the two-month follow-up. During 2018, the Maze Cognitive training program was converted to an iPad tablet format. This was done to address reasons for refusals (lack of computer and lack of high speed internet). To this end, we provided high-speed internet for using on the iPad tablet computers. Given the remaining monies available

and approval of a carry forward request—12 more participants would be able to be recruited using iPad tablet computers. To date, 12 of the 12 iPad participants have been recruited. The final two participants are currently in the process of completing the sessions 3 of the iPad participants were not able to complete all 10 sessions or the two-month follow-up because of deteriorating physical health and frequent hospitalizations.

For those who completed all 10 sessions, feedback has been 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 has been noticeably improved using the iPad tablet computer that provides high-speed internet.

Preliminary Results:

Preliminary findings from this pilot study provided the basis for a mHealth R01 proposal submission being prepared for February 2019. The study team composition has been expanded to include a kinesiologist, two cardiologists and a health economist. The proposal will include high-speed internet access, along with an honorarium to participants and will extend this work to include the current intervention, the addition of biological markers, two data collections sites and an attention control group to compare outcomes.

Poster Presentation: Arslanian-Engoren C, Giordani B, Moser Debra K, Nelson K, "Evaluation of a computer-based, nurse-led cognitive training and educational pilot intervention to improve self-care management decisions in adults with heart failure", 43*rd Annual Midwest Nursing Research Conference,* March 2019, Kansas City, MO.

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

Patient and Family Engagement in the ICU: A Mixed Methods Study. Awarded March 23, 2016; expected completion in Fall 2019.

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 as of January 15, 2019:

Recruitment

Site 1 recruitment is 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:

- Presentations:
 - 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
 - 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." Dr. Costa will be sharing data collected from Site 1 data

• Publications:

- Costa DK, Moss M. (in press). *The cost of caring: Emotion, burnout and psychological distress in critical care clinicians.* Annals of American Thoracic Society.
- Papers
 - Invited perspective in Annals of ATS on emotion and burnout in critical care clinicians entitled: The cost of caring: Emotion, burnout and psychological distress in critical care clinicians (2018)
 - 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.
 - Unintended consequences of patient and family engagement in the ICU: Clinician burnout (early stages of development)
 - Conceptual model of patient and family engagement in the adult ICU (upon completion of site 2 data)
- Other
 - Annals of American Thoracic Society Doctor-to-Doctor podcast interview on "The problem of burnout in critical care" with Dr. Greg Tino, Dr. Marc Moss and Jennifer Leckie.
- Other Dissemination:
 - In addition to poster presentations and papers, we have presented the preliminary results to the site 1's unit-based council (May 1st, 2018) in a 10-minute PowerPoint presentation. This information will be provided to the nursing bedside staff during daily huddles on the unit as well.

Next Steps:

To further accomplish the goals of the project the following activities are planned in site 2:

- Complete Site 2 data collection and complete preliminary analysis for site 2
- Conduct qualitative analysis from data across both sites and summarize results in a main findings paper (conceptual model of PFE)
- Move forward with manuscripts in progress

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.

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

Family Routines – Healthy Families. Awarded March 23, 2016; Completed in Spring 2018. Nothing new to report since the 2018 EAC report.

Pilot Project 6 (PP6, Dr. Yun Jiang)

Self-Management of Oral Oncolytic Agents and Side Effects among Patients with Cancer. Awarded September 21, 2016. Completed September 22, 2017.

Progress as of January 15, 2019:

- a. 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 to the NCI in June 2018, but was not discussed in October 2018. I am going to resubmit it in March 16, 2019. I am planning to submit an R01 grant proposal in October 2019.
- b. I am working on two papers from the project:
 - 1. The first paper, titled *Personalized Patient Side Effect Experiences and Self-Management Actions Related to Adherence to Oral Anticancer Agents*, was supposed to be submitted during the summer but it was delayed due to other projects. This paper will be modified and submitted by the end of January 2019.
 - 2. Another paper, with a tentative title of *Correlates of Side Effect Experience and Self-Management among Patients Taking Oral Anticancer Agents*, is expected to be submitted by May 2019.
- c. Recent Abstracts: An abstract, titled *Relationships among Self-Efficacy, Side Effects, and Self-Management of Oral Chemotherapy*, was accepted as the poster presentation at the Society of Behavioral Medicine on March 9, 2019 and paper presentation at the MNRS on March 28, 2019.

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; expected completion Spring 2019, Dr. Visovatti left the University of Michigan in Fall 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.

Primary Aim

• Aim 1: To determine whether identifiable patterns of function exist early in the disease trajectory in individuals newly diagnosed with HNC.

Exploratory Aims

- Aim 2: To evaluate whether changes in function are associated with changes in symptom distress and quality of life in individuals newly diagnosed with HNC.
- Aim 3. Evaluate the feasibility of collecting step data using the Fitbit Zip[™] in individuals newly diagnosed with HNC.

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 rumor 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, noneligible 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 ZipTM Physical Activity Monitor is a questionnaire that asks respondents to describe acceptability of the Fitbit ZipTM 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 ZipTM 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 ZipTM 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.

Progress as of January 9, 2019: This pilot project was approved for funding on June 13, 2017. 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. Forty-one individuals were contacted to assess eligibility.

From mid-October to mid-December we doubled the number of patients we contacted for eligibility and enrolled five more patients.

The number of patients contacted increased from 22 to 41. This increase was secondary to an amendment to broaden eligibility criteria and include individuals receiving adjuvant and palliative therapy.

Recruitment rate for this period was 39%. This is a drop from 50 % at the last report. The drop in the recruitment rate was secondary to more individuals being contacted who were not eligible and likely the inclusion of a sicker population.

We had no further withdrawals from the study after the amendment which increased the window of time for Time 1 data collection (before and on day 1 treatment).

NOTE: Dr. Visovatti has left the University of Michigan School of Nursing as of December 24, 2018, but continues with this pilot study.

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; expected completion by Spring 2020.

Project 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 are 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 selfmanagement 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.

Progress as of January 15, 2019:

- I. Study Status:
 - a. Recruiting 18 women that meet initial screening eligibility criteria
 - b. IRB approved; 90-day reminder
 - c. Met with MADC board first participant by the end of this month
 - d. Developed a registry over 200 potentially eligible women who shared their contact information, currently verifying eligibility
- II. Grants
 - a. fMRI pilot
 - b. K01 awarded
- III. Publications
 - a. JASIST pub
 - b. 2 submitted
 - c. 2 in progress
- IV. Presentations
 - a. ICBM presentation
 - b. MNRS competitive symposium

V. Challenges - hiring and training staff – currently seeking a project manager

- VI. Help with to succeed
 - a. Suggestions for a project manager
 - b. *just received MCUAAAR funds, purchasing i-Pads, obtaining incentives, ...
- VII. Brief summary of aims and outcomes:

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.

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 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 MCUAAAR pilot program, as well as the goals of the National Institute on Aging.

- VIII. Intended Next Steps after this pilot:
 - K01 (original and revised applications under review) Submit applications to design and test health information behavior (information sharing) intervention on blood pressure control
 - R21 Submit application to test the influence of the SAUCY intervention on multiple health outcomes (blood pressure, dietary patterns, exercise behaviors, and medication adherence)
 - 3. R01 Submit application to refine intervention, then conduct multisite trial to test intervention
 - 4. R01 Submit application to explore neurocognitive underpinnings of selfmanagement interventions

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; IRB approval has been received; expected completion by Spring 2020.

Study Summary

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. This study 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.

Study Status, as of January 15, 2019:

Study recruitment has concluded for the related study (n=30) and preliminary analysis has begun. Present study findings indicate that the sample on average is educated, with at least an associated degree. Similar to national trends, the vast majority of caregivers (90%) in the study were women with a body mass index of 25 or greater (overweight and obese). Unsurprisingly, more than 60% reported high blood pressure and about 20% reported diabetes. About half also reported daily moderate pain with an average intensity of 5. Most caregivers were over 60 and caring for their parents or spouse. A surprising finding was the number of women caring for ex-spouses (n=3), anecdotally, their children played a significant role in their decision to become engaged in care. The average time for study visits, including completion of consent forms and completing assessment measures was about 45 minutes. There was little participant burden identified and just a few survey directions noted that need to be clarified better participant understanding.

Recruitment for the present study continues with 3 enrolled to-date. Though there was a lag in recruitment due to the holiday season. We also have a listing of approximately 11 individuals that have expressed interest in participating in the study and need to be contacted for screening and scheduling of a visit. Further recruitment will continue to take place through community education events. We are also exploring other recruitment strategies.

Next steps:

- Continue with study enrollment
- Hiring a full-time shared project manager
- Continuing with publication development
- Development of related qualitative study

Publication Update

The following publications have been published, are in review, or are in development.

- 1. S.G. Robinson-Lane. (In Review). Adapting to chronic pain: The experiences of Black older adults.
- R.P. McGrath, S.G. Robinson-Lane, S. Cook, B. Clark, S. Herrmann, M.L. O'Connor, & Hackney K. (In Review). The Association between Handgrip Strength and Cognitive Impairment in Older Adults.
- S.G. Robinson-Lane & A.H. Vallerand. (2019). Nursing care of patients in pain. In L.S. Williams & P.D. Hopper (Eds.), Understanding Medical Surgical Nursing, (6th ed, chapter 10). Philadelphia: FA Davis Co. ISBN-13:978-0-8036-6898-0
- S. Robinson-Lane & X. Zhang. (2018). Adaptive coping among Black family caregivers of persons with dementia: A pilot study. Innovation in Aging 2 (suppl 1), 892. DOI: <u>https://doi.org/10.1093/geroni/igy031.3325</u> (abstract).
- 5. S.G. Robinson-Lane, X. Zhang, A. Patel, & M. Dreger. (In Development). Coping with Caregiving: Assessing the Feasibility of Engaging Black Family Caregivers in Dementia Related Research.

Abstract Update

Abstracts are being developed to submit to the following conferences:

- 1. Midwest Nursing Research Society
- 2. Roy Adaptation Association Annual Meeting
- 3. Alzheimer's Association International Conference

Grant Submission Update

UM Geriatric Center

This related award is in the process of development for a January 14th deadline. It tests the feasibility of adding 2 biological measures to the present study and increases the sample size by 20. The proposed measures include grip strength, a biological measure that has been used to predict cognitive decline in other studies, and a cognitive measure-the Montreal Cognitive Assessment (MOCA). My Co-Investigator for this study is an exercise physiologist, Ryan McGrath, from the North Dakota State University.

<u>K01</u>

A related K01 award application is in development and will be submitted by the February 12th 2019 deadline. Mentor team members include Bruno Giordani (primary), Marita Titler, and Ivo Dinov. In addition, statistician Mark Zhang will be working as a consultant on this project.

Alzheimer's Association

An application was submitted in the fall for an Alzheimer's Association award. Funding notifications will be announced in February. Should this grant be awarded (\$150,000), it will be used to expand the current work nationally and include a more age diverse sample of African American/ Black caregivers of persons with dementia.

Midwest Nursing Research Society

Due to the timing/ close proximity of the Alzheimer's Association application, this award was not submitted.

NIH Loan Repayment Program (09/2018 - 06/2020)

Funded through NIMHD for \$70,000.

Center Publications (2014-2019)

- 1. Amiri S, Dinov ID. <u>Comparison of genomic data via statistical distribution.</u> J Theor Biol. 2016 Oct 21;407:318-327. doi: 10.1016/j.jtbi.2016.07.032. Epub 2016 Jul 25. PMID: 27460589
- Casida JM, Aikens JE, Craddock H, Aldrich MVV, Pagani FD. <u>Development and Feasibility of</u> <u>Self-management Application in Left-Ventricular Assist Devices</u>. ASAIO J. 2018 Mar/Apr;64(2):159-167, doi: 10.1097/MAT.0000000000000673. PMID: 28937409.
- 3. Casida JM, Craddock H, Hoff-Nygard D, Kay C, Pierzynski A, Manker D, Cooley L. <u>Construction and evaluation of a VAD Care App© as self-management tool for patients with</u> <u>ventricular assist devices (VADs)</u>. ASAIO.2017;63(3), 48. Accessed June 8, 2017.
- 4. Dinov ID. Volume and Value of Big Healthcare Data. J Med Stat Inform. 2016;4. pii: 3. PMID: 26998309
- 5. Dinov ID. <u>Methodological challenges and analytic opportunities for modeling and interpreting</u> <u>Big Healthcare Data.</u> Gigascience. 2016 Feb 25;5:12. doi: 10.1186/s13742-016-0117-6. eCollection 2016. Review. PMID: 26918190
- Dinov ID, Heavner B, Tang M, Glusman G, Chard K, Darcy M, Madduri R, Pa J, Spino C, Kesselman C, Foster I, Deutsch EW, Price ND, Van Horn JD, Ames J, Clark K, Hood L, Hampstead BM, Dauer W, Toga AW. <u>Predictive Big Data Analytics: A Study of Parkinson's</u> <u>Disease Using Large, Complex, Heterogeneous, Incongruent, Multi-Source and Incomplete</u> <u>Observations.</u> PLoS One. 2016 Aug 5;11(8):e0157077. doi: 10.1371/journal.pone.0157077. eCollection 2016. PMID: 27494614
- Dinov ID, Palanimalai S, Khare A, Christou N<u>Randomization-Based Statistical Inference: A</u> <u>Resampling and Simulation Infrastructure.</u> Teach Stat. 2018 Summer;40(2):64-73. doi: 10.1111/test.12156. Epub 2018 Apr 11. PMID: 30270947
- Dinov ID, Siegrist K, Pearl DK, Kalinin A, Christou N. <u>Probability Distributome: A Web</u> <u>Computational Infrastructure for Exploring the Properties, Interrelations, and Applications of</u> <u>Probability Distributions.</u> Comput Stat. 2016 Jun;31(2):559-577. Epub 2015 Jun 26. PMID: 27158191
- Fu KA, Nathan R, Dinov ID, Li J, Toga AW. <u>T2-Imaging Changes in the Nigrosome-1 Relate</u> to Clinical Measures of Parkinson's Disease. Front Neurol. 2016 Oct 20;7:174. eCollection 2016. PMID: 27812347
- Huang Z, Shang H, Boss J, Goutman SA, Mukherjee B, Dinov ID, Guan Y. Complete hazard ranking to analyze right-censored data: An ALS survival study. Pooled Resource Open-Access ALS Clinical Trials Consortium. PLoS Comput Biol. 2017 Dec 18;13(12):e1005887. doi: 10.1371/journal.pcbi.1005887. eCollection 2017 Dec. PMID: 29253881.
- Husain SS, Kalinin A, Truong A, Dinov ID. <u>SOCR data dashboard: an integrated big data</u> <u>archive mashing medicare, labor, census and econometric information.</u> J Big Data. 2015;2. pii: 13. PMID: 26236573

- Jiang Y, West BT, Barton D, Harris M. Acceptance and Use of eHealth/mHealth Technologies for Self-Management among Cancer Survivors. Studies in Health Technology and Informatics. 2017; 245:131-135. PMID: 29295067.
- Kalinin AA, Allyn-Feuer A, Ade A, Fon GV, Meixner W, Dilworth D, Husain SS, de Wet JR, Higgins GA, Zheng G, Creekmore A, Wiley JW, Verdone JE, Veltri RW, Pienta KJ, Coffey DS, Athey BD, Dinov ID. <u>3D Shape Modeling for Cell Nuclear Morphological Analysis and Classification.</u> Sci Rep. 2018 Sep 12;8(1):13658. doi: 10.1038/s41598-018-31924-2. Erratum in: <u>Sci Rep. 2018 Oct 26;8(1):16142</u>. PMID: 30209281
- Kalinin AA, Higgins GA, Reamaroon N, Soroushmehr S, Allyn-Feuer A, Dinov ID, Najarian K, Athey BD. <u>Deep learning in pharmacogenomics: from gene regulation to patient stratification.</u> Pharmacogenomics. 2018 May;19(7):629-650. doi: 10.2217/pgs-2018-0008. Epub 2018 Apr 26. Review. PMID: 29697304
- Kalinin AA, Palanimalai S, Dinov ID. <u>SOCRAT Platform Design: A Web Architecture for</u> <u>Interactive Visual Analytics Applications.</u> Proc 2nd Workshop Hum Loop Data Anal (2017). 2017 Apr;2017. pii: 8. doi: 10.1145/3077257.3077262. PMID: 29630069
- Mandal PK, Mahajan R, Dinov ID. <u>Structural brain atlases: design, rationale, and applications</u> <u>in normal and pathological cohorts.</u> Mandal PK, Mahajan R, Dinov ID. J Alzheimers Dis. 2012;31 Suppl 3:S169-88. Review. PMID: 22647262
- Marino S, Xu J, Zhao Y, Zhou N, Zhou Y, Dinov ID. <u>Controlled feature selection and compressive big data analytics: Applications to biomedical and health studies.</u> PLoS One. 2018 Aug 30;13(8):e0202674. doi: 10.1371/journal.pone.0202674. eCollection 2018. PMID: 30161148
- Moon SW, Dinov ID, Hobel S, Zamanyan A, Choi YC, Shi R, Thompson PM, Toga AW. <u>Structural Brain Changes in Early-Onset Alzheimer's Disease Subjects Using the LONI</u> <u>Pipeline Environment.</u> Alzheimer's Disease Neuroimaging Initiative. J Neuroimaging. 2015 Sep-Oct;25(5):728-37. doi: 10.1111/jon.12252. Epub 2015 May 4. PMID: 25940587
- Moon SW, Dinov ID, Kim J, Zamanyan A, Hobel S, Thompson PM, Toga AW. <u>Structural</u> <u>Neuroimaging Genetics Interactions in Alzheimer's Disease.</u> J Alzheimers Dis. 2015;48(4):1051-63. doi: 10.3233/JAD-150335. PMID: 26444770
- 20. Moon SW, Dinov ID, Zamanyan A, Shi R, Genco A, Hobel S, Thompson PM, Toga AW. <u>Gene interactions and structural brain change in early-onset Alzheimer's disease subjects</u> <u>using the pipeline environment.</u> Alzheimer's Disease Neuroimaging Initiative (ADNI). Psychiatry Investig. 2015 Jan;12(1):125-35. doi: 10.4306/pi.2015.12.1.125. Epub 2015 Jan 12. PMID: 25670955
- Robinson-Lane SG, Vallerand AH. Nursing care of patients in pain. In LS Williams & PD Hopper (eds.), Understanding Medical Surgical Nursing, (6th ed., Chapter 10). Philadelphia: FA Davis Co. ISBN-13: 978-0-8036-6898-0
- 22. Sepehrband F, Lynch KM, Cabeen RP, Gonzalez-Zacarias C, Zhao L, D'Arcy M, Kesselman C, Herting MM, Dinov ID, Toga AW, Clark KA. <u>Neuroanatomical morphometric</u>

characterization of sex differences in youth using statistical learning. Neuroimage. 2018 May 15;172:217-227. doi: 10.1016/j.neuroimage.2018.01.065. Epub 2018 Feb 3. PMID: 29414494

- 23. Song M, Corwyn RF, Bradley RH, Lumeng JC. Temperament and Physical Activity in Childhood. J Phys Act Health. 2017 Jul 6:1-28. doi: 10.1123/jpah.2016-0633. PMID:28682696.
- 24. Song M, Lauseng D, Lee S, Nordstrom M, Katch V. 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.
- 25. Stelmokas J, Yassay L, Giordani B, Dodge HH, Dinov ID, Bhaumik A, Sathian K, Hampstead BM.<u>Translational MRI Volumetry with NeuroQuant: Effects of Version and Normative Data on Relationships with Memory Performance in Healthy Older Adults and Patients with Mild Cognitive Impairment. J Alzheimers Dis. 2017;60(4):1499-1510. doi: 10.3233/JAD-170306. PMID: 29060939</u>
- 26. Tang M, Gao C, Goutman SA, Kalinin A, Mukherjee B, Guan Y, Dinov ID. <u>Model-Based and Model-Free Techniques for Amyotrophic Lateral Sclerosis Diagnostic Prediction and Patient Clustering.</u> Neuroinformatics. 2018 Nov 20. doi: 10.1007/s12021-018-9406-9. [Epub ahead of print] PMID: 30460455
- 27. Toga AW, Dinov ID. <u>Sharing big biomedical data.</u> J Big Data. 2015;2. pii: 7. Epub 2015 Jun 27. PMID: 26929900
- 28. Zhang H, Boss J, Goutman SA, Mukherjee B, Dinov ID, Guan Y; Pooled Resource Open-Access ALS Clinical Trials Consortium. <u>Complete hazard ranking to analyze right-censored</u> <u>data: An ALS survival study.</u> PLoS Comput Biol. 2017 Dec 18;13(12):e1005887. doi: 10.1371/journal.pcbi.1005887. eCollection 2017 Dec. PMID: 29253881
- 29. Zheng G, Kalinin AA, Dinov ID, Meixner W, Zhu S, Wiley JW. <u>Hypothesis: Caco-2 cell</u> <u>rotational 3D mechanogenomic turing patterns have clinical implications to colon crypts.</u> J Cell Mol Med. 2018 Dec;22(12):6380-6385. doi: 10.1111/jcmm.13853. Epub 2018 Sep 25. PMID: 30255651

Seminars

The table below shows the Center seminar series during Year 5, to date. The full breadth and depth of research expertise and presentations for Years 1-4 can be found in the 2018 EAC report.

Date	Seminar	Details

- Mar. 13, Dr. Sheria G. Robinson-Lane, PhD, RN, Assistant Professor, Department of systems, Populations and Leadership, School of Nursing, University of Michigan. "Pain, Stress, and Complex Health: Considering the Needs of Black Family Caregivers."
- Dec. 5, Dr. <u>Ben Hampstead, PhD</u>, Associate Professor, Department of Psychiatry, University of Michigan. "Non-pharmacologic interventions in aging and dementia."
- Oct. 24,Dr. Massy Mutumba, PhD, MPH, BSN, Assistant Professor, School of2018Nursing, University of Michigan. "Self-management of HIV among
perinatally HIV-infected Uganda adolescents."
- Sept. 19, Dr. <u>Cynthia Arslanian-Engoren, PhD, RN, ACNS-BC, FAHA, FAAN,</u>
 2018 Associate Professor, School of Nursing, University of Michigan,
 "Computer-based, cognitive training and educational intervention to improve self-care management in adults with health failure."

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
P20NR018081	Gardner, Sue E (Contact); Rakel, Barbara	Center for Advancing Multimorbidity Science: Profiling Risk and Symptom Expression to Develop Customized Therapies for Adults with Multiple Chronic Conditions (CAMS)	University of Iowa
P20NR018075	Melkus, Gail (Contact); Taylor, Jacquelyn Y	Exploratory Center for Precision Health in Diverse Populations	New York University
P20NR018072	Stone, Patricia (Contact); Shang, Jingjing	Center for Improving Palliative Care for Vulnerable Adults with MCC (CIPC)	Columbia University Health Sciences
P20NR015331	Barton, Debra (Contact) Dinov, Ivo	Center for Complexity and Self- Management of Chronic Disease (CSCD)	University of Michigan
P20NR015320	Guthrie, Barbara	Northeastern Center for Technology in Support of Self Management and Health	Northeastern University
P20NR015339	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
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
P30NR018090	Corwin, Elizabeth	Center for the Study of Symptom Science, Metabolomics and Multiple Chronic Conditions	Emory University
P30NR018093	Szanton, Sarah	Hopkins Center to Promote Resilience in Persons and Families Living with Multiple Chronic Conditions (the PROMOTE Center)	Johns Hopkins University
P30NR015326	Moore, Shirley	SMART Center II Brain Behavior Connections in Self Management Science	Case Western Reserve University
P30NR015339	Kim Miyong	Center for Transdisciplinary Collaborative Research in Self-Management Science	University of Texas, Austin
P30NR016579	Dorsey, Susan (Contact), Renn, Cynthia & Resnick, Barbara	Omics Associated with Self- Management Intervensions for Symptoms (OASIS) Center	University of Maryland, Baltimore
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

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
May 7, 2019	Washington, DC	Leveraging Complexity to Improve Health Outcomes Through Self-management

CSCD actively participates in the annual NINR Center directors meetings:

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

	PROMIS SF v1.0 - Fatigue 6a Participant Version					
PROMIS SF v1.0-Sleep Disturbance 6a	PROMIS SF v1.0-Sleep Disturbance 6a PROMIS Item Bank v1.0 – Sleep Disturbance – Short Sleep Disturbance – Short Form 6a	PROMIS / Neuro- QOL	PROMIS / Neuro-QOL, NINR	Qualified	Assessment Center: EFB1133D- 429E-4C9D- B322- 32C614CB3C9D	6
Positive Affect and Well-Being - Short Form	Positive Affect and Well-Being - Short Form Neuro-QOL Item Bank v1.0 - Positive Affect and Wel	PROMIS / Neuro- QOL	PROMIS / Neuro-QOL, NINR	Qualified	Assessment Center: 38DF2C87-0858- 4C1B-A0A1- D48EC4100D66	9
PROMIS SF v1.0 - Applied Cog General Concerns 6a	PROMIS SF v1.0 - Applied Cog General Concerns 6a Applied Cognition- General Concerns-Short Form 6a PROMIS v1.0- Applied Cognition- General Concerns	PROMIS / Neuro- QOL	PROMIS / Neuro-QOL, NINR	Qualified	Assessment Center: A09CDF4E- E70C-40DC- 849D- 756A7C60C454	6
PROMIS SF v.1.0 – Pain Intensity 3a	PROMIS SF v.1.0 – Pain Intensity 3a Pain Intensity – Short Form 3a	PROMIS / Neuro- QOL	PROMIS / Neuro-QOL, NINR	Qualified	Assessment Center: 7224FB55-81D7- 4131-A136- 8C89907CDFBB	3
<u>Depression –</u> <u>Short Form 6a</u>	Depression – Short Form 6a PROMIS Item Bank v1.0 – Emotional Distress – Depresion	PROMIS / Neuro- QOL	PROMIS / Neuro-QOL, NINR	Qualified	Assessment Center: 7B1EF457-E187- 4E47-8179- FFF821A72584	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 four annual progress reports submitted so far:

2018-2019 Progress Summary (to be submitted to NIH/NINR, May 31, 2019)

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

The most substantive accomplishment in this aim over the past year has been a working definition of "Complex Health Systems", which is adopted by the NINR community & center directors. Over 30 investigators have contributed to this discussion (<u>https://docs.google.com/document/d/1_-</u> <u>QU8iDC8GxLQhiypVhMUmHULZk_p1RIVsCSOxdFeVE/</u>).</u>

General definition: A *complex (health) system* is a phenomenon consisting of multiple parts that individually are weak descriptors of a natural process of interest, but collectively may explain deeply the entire phenomenon (all phenotypic states). The constituent parts are dynamic and may be independent or interdependent and interact with one another. The most interesting complex systems are difficult to model, their behavior is multiplex, and it is challenging to holistically forecast their states in the past, present or future. Complex systems are not generally completely tractable or observable, however evidence-based inference is still possible using data as a proxy of the phenomenon. Complex systems may or may not be closed, which implies that they may be influenced by outside effects of their ambient environment.

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 selfmanagement study designs, data processing, and analytical protocols.

In 2018-2019, the CSCD Methods and Analytics Core (MACORE) made significant progress in three complementary directions. The first one developed a powerful protocol enabling data sharing and aggregation via statistical obfuscation. The second achievement was introducing a new compressive big data analytics (CBDA) framework for analyzing biomedical and health studies. The last important development involves the deployment of an advanced visualization webapp for interrogating extremely-high dimensional data.

I. Open Data-Sharing Technique

In support of open-science, we developed a novel statistical approach that enables the harmonization, merging, and sharing of complex datasets without compromising sensitive information like person identifiable elements (NIHMSID 1012970, DOI:

10.1080/00949655.2018.1545228). The DataSifter provides on-the-fly de-identification of structured and unstructured sensitive high-dimensional data such as clinical data from electronic health records (EHR). The technique provides complete administrative control over the balance between risk of data re-identification and preservation of the data information. Our simulation results suggest that the DataSifter can provide privacy protection while maintaining data utility for different types of outcomes of interest. The application of DataSifter on a large autism dataset provides a realistic demonstration of its promise practical applications.

II. Application of Compressive Big Data Analytics (CBDA) in Biomedical and Health Studies

We introduced a scalable computational statistics method for addressing some of the challenges associated with handling complex, incongruent, incomplete and multi-source data and analytics challenges. The CBDA mathematical framework enables the study of the ergodic properties and the asymptotics of the specific statistical inference approaches. We implemented and validated the high-throughput CBDA method using pure R and several simulated datasets as well as a real neuroimaging-genetics of Alzheimer's disease case-study (PMCID: PMC6116997, DOI: 10.1371/journal.pone.0202674).

III. Visualization of Extremely High-dimensional Data

We developed a distributed webapp for visually interrogating complex data archives. It allows all users to address health questions like: *Do patient phenotypes (e.g., race, gender, and age), clinical settings (e.g., admission type, time in hospital, medical specialty of admitting physician), and treatment regiments (e.g., number of lab test performed, HbA1c test result, diagnosis, number of medication, diabetes medications, number of outpatient, inpatient, and emergency visits in the year before the hospitalization) affect diabetes treatment outcomes?*

We demonstrate the capability of the web-resource by examining a diabetes case-study including a 10-year span (1999-2008) of clinical care observations of 130 US hospitals and integrated delivery networks. There are over 50 features representing patient phenotypes and hospital outcomes related to diabetes care. The data includes over 24,084 encounters with 45 features.

We developed an interactive learning module that illustrates:

- Data science and predictive analytics (DSPA) data wrangling methods to preprocess the data and generate a computable data object.
- The use of linear (PCA) and non-linear (t-SNE) dimensionality reduction methods to project the high-dimensional data into 2D or 3D space.
- Visual and exploratory data analytics to interrogate the low-dimensional projection, identify clusters of patients, and explore the intrinsic lower-dimensional structure of the data.

This open-science project provides a low-cost solution for interactive visual analytics, hypothesis generation, and pattern identification for complex biomedical and healthcare case-studies. It does not require any special software or licensing and supports evidence-

based discovery science and provides semi-automated clinical decision support for health practitioners.



Figure: Visualization of the high-dimensional Diabetes data into 3D, using t-SNE.

This CSCD TensorBoard application provides a tutorial and a high-end visualization protocol for interrogating extremely high-dimensional data (<u>http://www.socr.umich.edu/CSCD/html/Cores/Macore2/CSCD_SOCR_Diabetes_CaseStudy</u>). Users

may upload and interrogate their own data into the webapp.

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

- March 26, 2019: Ivo Dinov is presenting Challenges and Opportunities in Predictive Big Data Analytics at the Ann Arbor Chapter of ASA.
- February 23, 2019 (9:30AM 5 PM): Alex Kalinin is organizing the 4-th annual 2019 Ann Arbor Deep Learning Event (a2-dlearn4), UM College of Engineering, Ann Arbor, MI.
- November 2, 2018: Ivo Dinov presented on Open Data Science and Predictive Health Analytics at the 2018 Society for Neuroscience, San Diego, CA.
- Oct 25, 2018: Ivo Dinov presented DataSifter: Sharing of sensitive information via statistical obfuscation (Video) at the 14th annual cyber security conference on Security at University of Michigan IT (SUMIT).
- Oct 15-16, 2018: Ivo Dinov presented the Michigan Institute of Data Science: Computational Challenges and Research Opportunities at the 2018 Center for Network and Storage-Enabled Collaborative Computational Science (CNSECCS) Symposium, Ann Arbor, Michigan.
- Oct 12, 2018: Offered a day-long Health Data Analytics Workshop (University of Michigan).
- Sept 21, 2018: Ivo Dinov presented The Enigmatic Kime: Time Complexity in Data Science at the University of Michigan Institute for Data Science (MIDAS) Seminar Series.

- Sept 6, 2018: Ivo Dinov presented Data Science & Predictive Neuro-Analytics at the 2018 Advanced Computational Neuroscience Network (ACNN) Workshop, Case Western Reserve University, Ohio.
- May 17, 2018, Ivo Dinov presented a day-long series on Big Data & Health Analytics at the Global Sexual Health Summer Institute. Ivo Dinov is presenting an interactive session on Big Healthcare Data: Research Challenges, AI Capabilities, and Educational Opportunities.

SA4 Sustainability

The theme of the CSCD P20 Center revolves around self-management of chronic disease and health science complexity. CSCD investigators develop tools, build skills, and support infrastructure to help nurse and health scholars lead teams and engage in advanced transdisciplinary discovery. As health systems are complex, chronic human health conditions cannot always be distilled down into smaller alterable units. Collecting, aggregating, processing and interpreting evidence is paramount for detecting, monitoring, intervening, and forecasting the progression of many chronic disorders.

We have accomplished several things toward achieving our objective to equip nurse scientists to design studies that embrace the "messiness" that is reality. First, our methods and analytics core has continued to develop advanced algorithms and data visualization techniques to handle millions of data points from different sources. Second, this core has expanded in such a way that a research intensive entity, called the Health Analytics Collabortory (HAC), has been spun off. This collaborator has a number of interdisciplinary faculty as members, all with the interest and expertise to develop research that can utilize large amounts of data from various sources. The School of Nursing has invested in two core resources, two data analytics experts, who are available to help interested faculty get proof of concept pilot data as well as assist with grant application development and implementation.

Other CSCD-driven Research Intensive Entities (RIE) have grown organizationally to address selfmanagement of chronic disease issues. Appropriate personnel are being hired with the identified needed skills to help faculty develop research proposals that can advance the science in critical ways. Currently, a research scientist with expertise in mixed methods is being hired. There are numerous faculty addressing the needs of a diverse number of populations involved in this RIE called the Center for Improving Patient and Population Health. Faculty working the community of Detroit and populations with housing and food insecurities as well as faculty addressing symptom self-management in cancer survivorship are involved in this RIE, facilitating innovative thinking and new collaboration.

CSCD experts provide complex intervention education and training, starting with School of Nursing graduate students, and reaching postdoctoral scholars, research fellows and junior faculty. Complexity is the main theme in the recently funded T32 training program in the School. Complexity plays a key role in pre- and post-doctoral training as well as CSCD-supported seminars and boot camps.

Finally, grant applications to further support the advancement of science in complex selfmanagement in chronic illness are being submitted by large teams of interdisciplinary scientists, with nursing leading the charge. Most notably, a P50 has been submitted to be an advanced center in Implementation Science, where evidence-based symptom management for the community coping with cancer is the target objective.

In summary, the University of Michigan School of Nursing has enhanced core resources for health scientists to allow knowledge generation, sharing and translation into practice. CSCD is an important part of the efforts to harness the power of complex systems with the data revolution to enhance self-management of chronic disease. CSCD investigators have woven these themes into a broader infrastructure organizing hubs of faculty from diverse backgrounds and schools around the common themes to facilitate team science and innovative ideas. The future is both exciting and bright, and we are well-posed to actively drive progress forward.



Challenges

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

Plans and Strategies (2019-2020, and beyond)

Examples of questions CSCD investigators are currently pondering:

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

Key products

Complexity Methods:

- Defined the concept of complex health system
- Leveraged complexity to advance the science of self-management for the promotion of health in chronic illness.
- Provided consultation and mentorship to interdisciplinary teams around innovative methods for analyzing the effects of complex interventions.
- Facilitated development of symposia focused on complex methodology.

Infrastructure:

- Expanded the number and quality of research investigators by funding pilot programs of self-management research.
- Linked novice investigators with resources to facilitate development as independent researchers and to lead interdisciplinary teams (website, computational server).
- Deployed unique and powerful statistical computing infrastructure and a data analytic platform to managing, processing, analyzing and visualizing complex biomedical and health data.

Methods/Data Analytics:

- Developed a range of techniques, with supporting documentation and leaning modules, for selecting appropriate methods to address complexity for self-management study designs, data processing, and analytical protocols.
- Provided methodological and analytic expertise and tools to collaborators and pilot project investigators.
- Develop efficient and reliable end-to-end computational workflow solutions for advanced data analytics.
- Allocated and managed the CSCD shared resources based on availability and demand according to the strategic priorities.

Training Materials:

- Scientific Methods for Health Sciences (SMHS) electronic book: <u>http://www.socr.umich.edu/people/dinov/SMHS_Courses.html</u>
- Data Science and Predictive Analytics MOOC: <u>http://dspa.predictive.space</u>



Vision about the Center's sustainability and future plans

We welcome the feedback of EAC members and the broader scientific community!



Notes

Contact

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