Approved Data Requests

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Impact of a Maryland Law Requiring Jails to Provide Medications for Opioid Use Disorder on Recently Incarcerated People

Approval Date: June 18, 2024

Principal Investigator: Brendan Saloner, PhD

Organizational Sponsor: John Hopkins University

Use Case: Linking and Enhancing Multiple External Data Sets Using CRISP IDs and Geocodes for Research

Summary: This study evaluates the impact of Maryland's 2019 law (HB 116), which requires local detention facilities to provide access to medications for opioid use disorder (MOUD), on post-release outcomes and racial/ethnic disparities. It examines whether jail-based MOUD improves post-release treatment use, reduces overdoses, hospital use, and recidivism, and whether these benefits differ across racial and ethnic groups. Using linked statewide health, criminal justice, and jail data from 2019–2026, the study analyzes cohorts of adults released from jail with comparative interrupted time series methods to assess overall effects and disparities. The analysis draws on eight linked datasets spanning 2019–2026. These include statewide all-payer hospital records to capture inpatient and emergency department utilization; the Prescription Drug Monitoring Program to track MOUD prescriptions after release; medical examiner records to identify fatal overdoses; and emergency medical services data to measure non-fatal overdose events. Criminal justice information system data are obtained from individual jails as well as statewide systems, including CJIS, OCMS, and MDEC, to capture incarceration histories and recidivism. Jail-level datasets identifying individuals treated under HB 116 are provided through the Governor's Office of Crime Control & Prevention.

Novel Approaches in the Investigation of Kidney Disease (NAIKiD)

Approval Date: November 14, 2023

Principal Investigator: Chirag Parikh, MD, PhD

Organizational Sponsor: John Hopkins University

Use Case: IRB approved, patient consented

Patient Opt-out Application: Patient Consented

CRISP Data Requested: HSCRC Case Mix and CRISP participant data

Summary: Kidney injury continues to be a significant and growing problem in part due to limited diagnostic tools. The objective of this project is to create a biorepository of kidney tissue, blood, and urine at the time of kidney biopsy. The sample biorepository along with the biopsy registry that captures longitudinal follow-up of patients will foster future research aimed at improving precision in the diagnosis and management of various kidney diseases. Integrating biomarkers measured in blood and urine samples (linked directly to kidney tissue) with long-term kidney outcomes, we hope

to develop new diagnostic and predictive tools of both short and long-term kidney function, integrating multiple determinants of kidney damage.

The Home Environment and Re-hospitalization in COPD study (HEAR COPD)

Approval Date: January 21, 2020

Principal Investigator: Nirupama Putcha, MD

Organizational Sponsor: John Hopkins University

Use Case: IRB approved, patient consented

Patient Opt-out Application: Patient Consented

CRISP Data Requested: CEND Data and CRISP Query Portal access

Summary: The study objective is to identify modifiable risk factors in the home environment that explain COPD re-hospitalization risk. The central hypothesis is that the indoor environment, including air pollution and allergen exposure are associated with re-hospitalization risk among recently-hospitalized COPD patients. This study will provide much needed information about the contribution of indoor air pollution and allergen sensitization with exposure to re- hospitalizations in the high-risk population of individuals with COPD recently hospitalized for exacerbation. Study results can provide valuable information which can ultimately be utilized to design interventions to modify the home environment post-hospital discharge with the goal to improve outcomes including re- hospitalization risk in COPD.

Alzheimer's Study

Approval Date: July 13, 2023

Principal Investigator: Michelle Carolson Ph. D.

Organizational Sponsor: John Hopkins University

Use Case: IRB approved, patient consented

Patient Opt-out Application: Patient Consented

CRISP Data Requested: HSCRC Case Mix and CEND data

Summary: Initiated in 2006, the Baltimore Experience Corps Trial (BECT) examined whether multi-modal social, cognitive, and physical engagement enhanced cognitive functions in cognitively healthy older adults. The BECT was novel among intervention trials in its appeal to economically disadvantaged adults at elevated risk for Alzheimer's disease. Results from the trial showed the productive social engagement as volunteers in elementary schools increased lifestyle activity and generative purpose and improved cognition and brain biomarkers for Alzheimer's disease over two years of exposure (Carlson, 2015; Gruenewald, 2016; Parisi, 2015). The goal is to determine whether increased social, physical and cognitive engagement in Experience Corps, examined in the BECT among participants enrolled from 2006-2009, led to long-term lower risk for Alzheimer's disease,

reductions in healthcare expenditures, maintained functional independence, improved quality of life, less disability, and lower mortality up to approximately 10+ years later. To achieve these goals, the study requested CRISP data to augment fee-for-service Medicare claims data because it is particularly important to capturing healthcare usage among Medicare Advantage recipients.

Medstar COVID Emergency Department Returns

Approval Date: August 8, 2022

Principal Investigator: Jessical Galarraga

Organizational Sponsor: Medstar

Use Case: Patient Consented, IRB

Patient Opt-out Application: Patient Consented

CRISP Data Requested: HSCRC Case mix and ADT Encounter Data

Summary: The research developed and validated a COVID-19 emergency department (ED) return screening tool that provided ED clinicians a risk assessment to guide admissions and discharges to reduce morbidity and mortality associated with acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection.

Demonstration of Person Driven Outcome Measures (MedStar PDO)

Approval Date: June 26th, 2020

Principal Investigator: George Hennawi

Organizational Sponsor: Medstar Health Research Institute

Use Case: Combining CRISP Patient Identifiers and Geocoding Data with HSCRC Case Mix Data for Research

CRISP Data Requested: HSCRC Case Mix Data (Pre-Post Report)

Summary: For this study, investigators at MedStar Health Research Institute are collaborating with the National Committee for Quality Assurance (NCQA) to evaluate an intervention focused on improving care to adults with complex conditions in care management. This intervention involves eliciting, documenting, and tracking person-centered goals of care. The study investigators hypothesize that providing goal-based care will result in improved outcomes for patients including reduced utilization of acute care. The Center for Successful Aging (CSA) is one of four study sites and is the only site located in Maryland. This study will compare change over time between the intervention group to a comparison group of patients from the same practice.

DACOR (COVID 19 Analytics)

Approval Date: March 25, 2020

Principal Investigator: Christopher Chute, MD, DrPH

Organizational Sponsor: John Hopkins University on behalf of its School of Medicine

Use Case: Linking and Enhancing Multiple External Data Sets using CRISP Geocodes

Patient Opt-out Application: CRISP opt out policy applies

CRISP Data Requested: Non-PII HSCRC Case Mix and CRISP Encounter Data

Summary: Requested case mix data in a limited data set of patient data on a cohort of patients identified by CRISP as having been tested for SARS-CoV-2, the virus that causes the COVID-19 disease. The primary purpose of including the case mix data in this project is to establish a past medical history of existing co-morbidities that can help understand the risk factors for patients who experience more severe forms of the COVID-19 disease and to help predict disease progression among COVID-19 patients. The case mix data was combined with encounter data from CRISP.

UMD Prescription Drug Monitoring Program

Approval Date: March 18, 2020

Principal Investigator: Marianne Cloeren, Associate Professor

Organizational Sponsor: University of Maryland, Baltimore

Use Case: Administrative Data Only

Patient Opt-out Application: NA – no PHI provided

CRISP Data Requested: Non-PHI Prescriber Data

Summary: The University of Maryland Division of Occupational and Environmental Medicine worked with the Maryland State Department of Health, under a grant from the National Institute for Occupational Safety and Health to evaluate the effectiveness of a brief educational intervention on opioid prescribing attitudes and POMP use behaviors of Maryland medical providers. The study objectives were to measure changes in baseline and post training attitudes about the POMP; baselines self-reported POMP use and post training planned POMP use; differences based on workers' compensation care experience; effect of the module on clinical decision making in fictional cases; and, changes between baseline and post training POMP use patterns in participants as compared to other Maryland providers. CRISP data was used to measure changes between baseline and post training POMP use patterns in participants as compared to other Maryland providers.

Addressing Suicide Research Gaps: Understanding Mortality Outcomes

Approval Date: April 29th, 2019

Principal Investigator: Erica Shelton

Organizational Sponsor: Johns Hopkins University on behalf of its School of Medicine

Use Case: Linking and Enhancing Multiple External Data Sets Using CRISP IDs and Geocodes

CRISP Data Requested: Master Patient Index to link data sets

Summary: The proposed study will conduct population-level analysis on data from multiple sources to address suicide research gaps by understanding the risk factors for, and the burden of, suicide among those seen in structured healthcare settings. The analysis will link clinical data such as hospital discharges, insurance claims, and electronic Health Records to discover the type, severity, and timing of suicide predictors in the Mid-Atlantic region. The project will also offer essential benchmarks and measures for providers and payers to reduce suicide events in their systems. The project will seek data from the following sources, including population-level HSCRC Case Mix data, MHCC claims data, and Medicaid data from Hilltop; as well as individual data including data on completed suicides from Maryland Examiner's Office, EMR data from Johns Hopkins, Sheppard Pratt hospitals, VHA, Anne Arundel Medical Center, and Peninsula Regional Medical Center.

Collaborative Commitment to Emergency Department Follow-Up Care: A Community-Based Approach to Patient Engagement

Approval Date: February 19th, 2019

Principal Investigator: Erica Shelton

Organizational Sponsor: Johns Hopkins University on behalf of its School of Medicine

Use Case: IRB-Approved, Patient-Consented Research

CRISP Data Requested: CRISP Query Portal access

Summary: Barriers associated with linkage to care for patients at high risk for frequent emergency department (ED) utilization have previously been defined, and include limited health literacy, knowledge deficits of where to seek care or what services to request, as well as transportation, and insurance status, each important for navigating a complex healthcare system. The goal of our study is to adopt a proven community health worker (CHW) patient partnership model, previously used in the hospital setting, for use in a novel application in an ED setting: We will enroll patients at high risk for frequent ED re-utilization in this patient partnership model in order to empower them to overcome barriers they experience in linkage to care post ED visit. In our study, the linkage is defined as completing a second post-ED follow-up care visit. In the setting of the Johns Hopkins Hospital (JHH) ED, we will conduct a randomized clinical trial to test the effectiveness of a CHW intervention, compared to an enhanced standard of care, in 1) improving the attainment of post-ED follow-up care, 2) decreasing repeat ED visits, and 3) reducing costs associated with ED visits, among patients at high risk for frequent ED re-utilization. Ultimately, our proposed outcomes are improved health, improved patient experiences with care, and lower healthcare costs.

Comparing Effectiveness of Self-Management and Peer Support Communication Programs Amongst Chronic Obstructive Pulmonary Disease Patients and Family Caregivers (BREATHE2)

Approval Date: December 11th, 2018

Principal Investigator: Hanan Aboumatar

Organizational Sponsor: Johns Hopkins University on behalf of its School of Medicine

Use Case: IRB-Approved, Patient-Consented Research

CRISP Data Requested: Encounter notifications and CRISP Query Portal access

Summary: The overall goal of this study is to compare the effectiveness of two health communication and dissemination strategies that are designed to engage patients and family caregivers in successfully managing COPD in "real-world" settings. One strategy relies on the healthcare professional (HCP) as the primary communicator about COPD self-management (HCP Arm), whereas the other uses a dual approach that involves both healthcare professionals and peer mentors delivering such communication (HCP PLUS Peer Support Arm). Peer mentors are COPD patients and caregivers who have successfully managed COPD and have received foundational training on peer mentoring. The proposed study will answer the research question: amongst COPD patients and their caregivers, would a dual strategy that combines healthcare professional and peer mentor delivery of COPD self-management education and support result in greater improvements in health status and quality of life, and reductions in acute healthcare services' utilization, compared to relying on healthcare professionals alone in these communications?

BREATHE2 - Additional Data Request

Approval Date: December 11th, 2018

Principal Investigator: Nisha Gilotra, Diane Lepley

Organizational Sponsor: Johns Hopkins University on behalf of its School of Medicine

Use Case: Combining CRISP Patient Identifiers and Geocoding Data with HSCRC Case Mix Data

CRISP Data Requested: HSCRC Case Mix Data (Pre-Post Report)

Summary: Heart failure hospitalizations contribute to a tremendous health care expenditure, and the post-discharge heart failure patient population is highly vulnerable to early readmission. In 2012, we established a Heart Failure Bridge Clinic at Johns Hopkins Hospital, which provides guideline-directed HF care, intravenous diuretic administration, laboratory testing, education, pharmacy visits, and palliative care. The concept of such a clinic is still fairly novel and literature is sparse. We maintain a database of patients followed in the Heart Failure clinic, that is used clinically, for quality improvement initiatives and is also Johns Hopkins IRB approved. The clinic has about 2500 patient visits per year. We have demonstrated a significant reduction in 30-day readmission rates for those patients that are cared for in the clinic. Our next aim is to demonstrate decreased healthcare utilization by comparing pre-and post-clinic intervention healthcare visits and costs by leveraging CRISP and HSCRC Case Mix data. Our group already has access to this data and utilizes the same analyses requested in this application for hospital QI initiatives. We are formally requesting the use of this de-identified data for publications to further support justification for similar Care Redesign efforts. Our group already uses CRISP and HSCRC Case mix data to analyze our patients' healthcare utilization trends. This request is to allow the use of de-identified data in manuscripts.

Study to Help the AIDS Research Effort (SHARE)

Approval Date: November 13th, 2018

Principal Investigator: Joseph Margolick, Todd Brown

Organizational Sponsor: Johns Hopkins University on behalf of its School of Medicine

Use Case: IRB-Approved, Patient-Consented Research

CRISP Data Requested: CEND Notifications, CRISP Query Portal access

Summary: The Study to Help the AIDS Research Effort (SHARE) is the Baltimore site of the Multicenter AIDS Cohort Study (MACS). MACS is an ongoing prospective study of the natural history of HIV infection in homosexual and bisexual men. SHARE has played an integral role in accomplishing the MACS-specific Aims. In addition, SHARE provided critical leadership and intellectual input in MACS studies and sub-studies through participation in the MACS Executive Committee and the 14 MACS Working Groups. During the past year, there were 978 individual SHARE study visits. Study participants are followed up at six-month intervals at two locations, the SHARE study at Johns Hopkins in Baltimore, MD, and the Whitman-Walker Clinic in Washington, DC. Study visits include a behavioral interview which includes questions about general health, history of selected symptoms, signs, and diseases, particularly sexually transmitted diseases and immunologic disorders, sexual practices, drug use, treatment history, and demographic characteristics. Interviews are conducted by trained study staff and via Audio Computer-Assisted Self-Interview (ACASI). Other diagnostic tools include a physical examination and neuropsychological testing. Lastly, study participants are asked to donate approximately 140 ccs of blood for testing (CBC with differential, CD4/CD8 T-cell testing by flow cytometry, HIV serostatus, hepatitis status, HIV viral load, RPR), and storage.

Action for Health in Diabetes (Look AHEAD – Extension)

Approval Date: September 28th, 2018

Principal Investigator: Jodi Segal

Organizational Sponsor: Johns Hopkins University on behalf of its School of Medicine

Use Case: IRB-Approved, Patient-Consented Research

CRISP Data Requested: CRISP Query Portal access

Summary: The Look AHEAD Study began in 2002 as a randomized trial comparing the effects of an intensive lifestyle intervention (ILI) focused on weight loss achieved through healthy eating and increased physical activity versus a control group given Diabetes Support and Education (DSE) in overweight and obese individuals with type 2 diabetes. In September 2012 the intervention was halted because the ILI did not produce beneficial effects on the primary and secondary outcomes related to cardiovascular disease. Because it did produce beneficial effects on a broad spectrum of health parameters during the period of the intervention, the study is continuing to follow the original Look AHEAD cohort through January 2021. The LA Extension (LA-E) will examine whether ILI,

provided for 10 years during mid-life, has enduring benefits that persist beyond the period of the intervention for older individuals with diabetes. Nationwide, approximately 3,800 participants (current ages 58-89 years), 230 at Johns Hopkins, are being followed with biennial clinic visits and 6-month outcomes phone calls. The primary aims of LA-E are to test whether ILI relative to DSE has long-term legacy effects on 1) increased lifespan and 2) reduced health care costs. Secondary aims test whether ILI relative to DSE has long-term effects on key dimensions of healthy aging: less frailty, reduced diabetic microvascular complications, and improved quality of life. LA-E will also compare long-term trajectories of weight, physical activity, fat and lean mass, and bone density and examine how these are related to outcomes. LA-E focuses on the clinical outcomes that are most relevant to healthy aging and resilience and will provide the long-term data needed to frame guidelines related to lifestyle intervention in the care of older overweight or obese individuals with type 2 diabetes.

Evaluation of Walgreens' Meds to Beds Program

Approval Date: July 17th, 2018

Principal Investigator: Jodi Segal

Organizational Sponsor: Johns Hopkins University on behalf of its School of Medicine

Use Case: Combining CRISP Patient Identifiers and Geocoding Data with HSCRC Case Mix Data

CRISP Data Requested: HSCRC Case Mix Data

Summary: We propose to evaluate the intervention conducted by Walgreens Pharmacy at 11 acute care hospitals in Maryland. This was an intervention that Walgreens pilot-tested in 2 hospitals in the southeastern U.S. in 2011. The results were very promising in that there was 90% lower odds of 30-day readmission among patients who received the intervention. The Meds to Beds program aimed to promote medication adherence and reduce unplanned readmissions by expanding the role of the outpatient pharmacy. The two key program components included bedside delivery of post-discharge medications and follow-up telephone calls two to three days after discharge. Briefly, medications were delivered directly to the patient's room by either a pharmacy technician or pharmacist from the community pharmacy on the hospital campus and were given to the patient or caregiver within one to three hours of the scheduled hospital discharge. The pharmacist or technician asked patients if they had questions about their medication. If a patient had questions during a technician delivery, the technician had access to connect the patient and pharmacist via telephone or the pharmacist would come to the room. Furthermore, the pharmacy staff processed insurance verifications and approvals and collected copayments from the patient, just as they would if the patient had arrived at a community pharmacy. Study participants could receive up to two follow-up telephone calls. This program was implemented at 14 acute care hospitals in Maryland and we plan to evaluate the impact in the 11 hospitals from which data will be available. We hypothesize that the intervention reduces the risk of 30-day readmission for the patients who received it relative to comparable patients who did not receive the intervention.

INSITE

Approval Date: February 13, 2018

Principal Investigator: Gregory M. Lucas, MD

Organizational Sponsor: Baltimore City Health Department

Use Case: Patient Consented, IRB Approved

Patient Opt-out Application: Patient Consented

CRISP Data Requested: HSCRC Case Mix, CEND Data, and CRISP Query Portal access

Summary: Study is a cluster-randomized trial assess the impact of a new integrated care van (ICV) that will accompany the Baltimore City Health department needle exchange van. The ICV will provide a range of medical services to relevant people who inject drugs. Study randomizes roll-out of the ICV among 12 existing needle van stops in Baltimore neighborhoods. Objective of study is to determine if the ICV affects utilization of medical resources by PWID who access needle exchange.

Predictive Risk Evaluation to Combat Overdose Grant (PRECOG)

Approval Date: November 21st, 2017

Principal Investigator: Hadi Kharrazi

Organizational Sponsor: Johns Hopkins University / Johns Hopkins Center for Public Health IT

Use Case: Linking and Enhancing Multiple External Data Sets

CPHIT has already requested and received the HSCRC Public Use Data Files for use with this project, including both inpatient and outpatient records. Under the approved request for public use data, we are working with CRISP to link records for individuals across the HSCRC and other data sets using an encrypted study identification number. We are now requesting supplemental confidential data to improve the reliability and validity of our analyses. CRISP will apply the encrypted study ID to a file containing the approved confidential data elements, which will allow linkage with the public use data already at CPHIT.

Summary: Johns Hopkins CPHIT (researcher), The Maryland Department of Health (MDH) Behavioral Health Administration (BHA, prime), and the Chesapeake Regional Information System for our Patients (CRISP, subcontractor) were awarded a Harold Rogers Prescription Drug Monitoring Program by the Department of Justice (DOJ), Office of Justice Programs (OJP), Bureau of Justice Assistance (BJA). The funding was awarded under CATEGORY 2: PDMP PRACTITIONER AND RESEARCH PARNERSHIPS in which the goal is to strengthen prescription drug monitoring program (PDMP) efforts, to develop and test innovative strategies for opioid abuse and addiction, and to implement evidence-based approaches that demonstrate the impact of expanded use of PDMP data to support patient and provider decision-making. The grant, entitled Predictive Risk Evaluation to Combat Overdose Grant (PRECOG), will focus on addressing the opioid addiction and overdose epidemic currently facing Maryland. This project will combine multiple disparate datasets to identify risk factors related to this epidemic through the development of a predictive risk model. Predictive

risk modeling is a scientific methodology used to identify individuals with an elevated probability of experiencing an adverse event. Using quantitative data, patterns of risk may be identified that are not immediately evident to front-line practitioners, allowing for more effective targeting of resources to individuals who would benefit from timely, focused interventions.

Atherosclerosis Risk in Communities (ARIC) Study

Approval Date: October 3rd, 2017

Principal Investigator: Josef Coresh

Organizational Sponsor: Johns Hopkins Hospital (Johns Hopkins School of Medicine)

Use Case: IRB-Approved, Patient-Consented Research

CRISP Data Requested: Query Portal and CEND access for consented patients

Summary: The Atherosclerotic Risk in Communities (ARIC) Study is originally designed to characterize the natural history of cardiovascular disease (e.g., coronary heart disease and stroke) and identify cardiovascular risk factors. ARIC is funded by NIH contracts and grants. ARIC researchers recruited a population-based sample of 15,792 men and women aged 45-64 from four field centers across the United States. Approximately 73% of the recruited participants are white and 27% African American. The first examination took place over two years, from 1987-1989. It was followed by four completed visits, and a sixth visit exam is currently ongoing. At 6- to 12- month intervals, participants or a family member are contacted to inquire about hospital admissions, major clinical procedures/diagnoses, and deaths. Self-reported diagnoses or relevant events identified by active surveillance are verified by a physician panel using medical records. For deaths, interviews with the next of kin and death certificates help to identify the cause of death. There are over 1600 published manuscripts including ARIC data. We are requesting CRISP access for ARIC participants that signed consent at the Johns Hopkins University Field Center to access their data. For more information see https://www2.cscc.unc.edu/aric/desc.

Building on Needle Exchange to Optimize Prevention and Treatment

Approval Date: October 3rd, 2017

Principal Investigator: Gregory Lucas

Organizational Sponsor: Johns Hopkins Hospital (Johns Hopkins School of Medicine)

Use Case: IRB-Approved, Patient-Consented Research

CRISP Data Requested: CEND and CRISP Query Portal access

Summary: This study is a cluster-randomized trial to assess the impact of a new integrated care van (ICV) that will accompany the Baltimore City Health Department needle exchange van. The ICV will provide a range of medical services relevant to people who inject drugs (PWID), including rapid HIV testing, HIV co-management (with a primary clinic), pre-exposure prophylaxis (PrEP), initiation of medication-assisted treatment for opioid dependence with buprenorphine/naloxone, hepatitis C

virus (HCV) testing and referral to treatment, and wound care. We will randomize the roll-out of the ICV among 12 existing needle van stops in Baltimore neighborhoods. During the assessment period, 6 stops will receive the ICV intervention and 6 will not (usual care). To assess outcomes, we will enroll cohorts of 50-60 participants per stop (maximum of 760) prior to intervention roll-out. Participants will complete study visits at baseline, 6 months, and 12 months.

Utilizing the B'FRIEND Data and Platform to Develop and Test a Predictive Risk Model for Falls in Elder Adults

Approval Date: March 8th, 2017

Principal Investigator: Hadi Kharrazi

Organizational Sponsor: Johns Hopkins University / Johns Hopkins Center for Public Health IT

Use Case: Combining CRISP Patient Identifiers and Geocoding Data with HSCRC Case Mix Data for Research

CRISP Data Requested: HSCRC Case Mix Data enhanced with anonymized CRISP IDs and census block group level geocodes

Summary: Using the HSCRC case-mix data, the investigators are developing and validating spatiotemporal risk prediction trajectory models to predict elder falls. The investigators will examine geographical information system (GIS) data sources for completeness, accuracy, and timeliness and develop a hot-spotting algorithm using GIS triangulation and predictive modeling. The analysis will utilize Poisson and Bernoulli distribution models to identify hotspots and we will customize methodology using ArcGIS, SaTScan, and R software packages. They will develop and evaluate a falls risk score with new and external data to improve current methodology and risk prediction scores. The research involves a large anonymized population health dataset. Sample size varies each year depending on the number of Baltimore residents who receive care at a hospital. The average number of inpatient hospital visits for Baltimore in 2013 has been about 103,000 and outpatient visits have been over 1.3 million. The team will validate the identification of falls among older adults comparing information from HSCRC and MHCC using statistical means. They will merge external datasets that are publicly available to include in the development of a risk score. Using the merged data sets, they will develop and validate the risk scores through logistic regression.

Navigation Services to Avoid Rehospitalization (NavSTAR)

Approval Date: February 28th, 2017

Principal Investigator: Christopher Welsh / Jan Gryczynski

Organizational Sponsor: University of Maryland Medical System / Friends Research Institute, Inc.

Use Case: IRB-Approved, Patient-Consented Research

CRISP Data Requested: Query Portal and CEND access for consented patients

Summary: Substance use disorders (SUD) are strongly associated with repeat hospital admissions. A major contributor to rehospitalization for individuals with SUD is a lack of adherence to hospital post-discharge plans for outpatient medical care and substance abuse treatment. Several factors influence such non-adherence for this population. These include difficulty navigating systems of care, concrete barriers to treatment entry (e.g., lack of health insurance and transportation), and low motivation for medical and/or substance abuse treatment. The goal of the Navigation Services To Avoid Rehospitalization (NavSTAR) research project is to assess the value of care navigation services delivered to hospital patients with SUDs. NavSTAR will employ evidence-based patient navigation and motivational intervention strategies initiated during hospitalization and continued for three months post-discharge. Navigators will work closely with patients to increase motivation and resolve barriers to entering appropriate outpatient medical and substance abuse treatment services. This two-arm randomized controlled trial (RCT) will evaluate NavSTAR for patients hospitalized for medical/surgical problems who have a comorbid substance use disorder. Adult hospital patients with a SUD for opiates, cocaine, or alcohol (N=420) will be randomly assigned to NavSTAR or treatment as usual (TAU). Research follow-ups will be conducted at 3-, 6-, and 12-months post-discharge. This RCT will examine the effectiveness, cost-effectiveness, and cost-benefits of NavSTAR for the primary outcome of rehospitalization, as well as other important medical and substance use outcomes.

JHU Alive – AIDS Linked to the IntraVenous Experience

Approval Date: November 28th, 2016

Principal Investigator: Gregory Kirk

Organizational Sponsor: Johns Hopkins University

Use Case: IRB-Approved, Patient-Consented Research

CRISP Data Requested: Access to CEND and Clinical Query Portal for consented participants in the study.

Summary: The AIDS Linked to the IntraVenous Experience (ALIVE) study uses a prospective, observational cohort design to follow persons 18 years of age or older with a history of injecting drugs in Baltimore. Since its inception in 1988, ALIVE has followed participants systematically with study visits every 6 months and with comprehensive evaluation including both nurse and interviewer-administered as well as computerized questionnaires, a focused clinical examination, and collection of blood samples. The primary objectives of the study include characterization of the incidence and risk factors for blood-borne infections, the natural history of injection drug use, the natural and treated course of HIV infection, and the impact of coinfection and comorbidities in the setting of HIV. Since inception, >5000 persons have been enrolled in the study. Currently, in follow-up, we have ~1,100 active participants including both HIV-infected (~30%) and HIV uninfected (70%) persons to allow appropriate comparisons and evaluation of HIV-specific effects. ALIVE is one study supported by two grants from the National Institute on Drug Abuse – ALIVE I and ALIVE II which follows the HIV-infected and HIV-uninfected participants, respectively. All subjects are initially

enrolled into the ALIVE-2 study which covers the basic study protocol. HIV-infected persons also provide informed consent for ALIVE-1.

Multi-Ethnic Study Atherosclerosis

Principal Investigator: Wendy Post

Organizational Sponsor: Johns Hopkins Hospital (Johns Hopkins School of Medicine)

Use Case: IRB-Approved, Patient-Consented Research

CRISP Data Requested: Query Portal and CEND access for consented patients

Summary: The Multi-Ethnic Study of Atherosclerosis (MESA) is a study of the characteristics of subclinical cardiovascular disease (disease detected non-invasively before it has produced clinical signs and symptoms) and the risk factors that predict progression to clinically overt cardiovascular disease or progression of the subclinical disease. MESA is funded by NIH with some additional supplemental funding by EPA and foundations. MESA researchers recruited a diverse, population-based sample of 6,814 asymptomatic men and women aged 45-84 from six field centers across the United States in 2000-2002. Approximately 38% of the recruited participants are white, 28% African American, 22% Hispanic, and 12% Asian. The first examination took place over two years, from July 2000-July 2002. It was followed by four examination periods that were 17-20 months in length, and a sixth exam which started in September 2016. At 9-to-12-month intervals, participants or a family member is contacted to inquire about outpatient visits, hospital admissions, and deaths. Self-reported diagnoses are verified using medical records of outpatient visits and hospitalizations. For deaths, interviews with the next of kin and death certificates help to identify the cause of death. Two physicians from the MESA mortality and morbidity review committee independently adjudicated all events using blind records. There are over 1000 manuscripts published including MESA data. For more information see https://www.mesa-nhlbi.org.