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TITLE: Risk of Hepatocellular Cancer After Virological Cure with Direct Acting Antiviral Agents in Individuals with Hepatitis C

PRINCIPAL INVESTIGATOR: Fasiha Kanwal, MD, MSHS

CONTRACTING ORGANIZATION: Baylor College of Medicine, Houston, TX

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

Purpose: The overarching goal of this project is to reduce HCC-related morbidity and mortality in persons with chronic hepatitis C (CHC) who have been virologically cured by direct acting antivirals (DAAs).
Aims: 1) Examine determinants of HCC in virologically cured patients and develop a risk prediction model for HCC; 2) Conduct a virtual clinical trial using a mathematical model of the natural history of HCC to evaluate benefits vs harms of HCC surveillance; 3) Develop an online HCC Simulator.
Design: Using cause-specific Cox proportional hazard models for competing risks, we will identify risk factors in a retrospective cohort study of >100,000 patients with DAA-induced SVR. For dynamic risk prediction of HCC, we will use the landmark Cox model. We will use a mathematical model to simulate a virtual trial comparing long-term effectiveness of no surveillance vs routine surveillance. Finally, we will develop an interactive decision support tool.
Progress: The project is on target to be completed by 09/30/2022.
Findings: 19 predictors for HCC were identified, with the nature of predictor variables changing over time. Metabolic traits predicted HCC; however, viral factors (HCV genotype) was no longer predictive at 24 months after cure.
A Mathematical model of the natural history of HCC in DAA-cured CHC patients was developed that led the team to conclude that the burden of HCC will shift from viremic to virologically cured CHC patients, and to older populations. These findings are reported in a manuscript that was accepted by JAMA Network Open and is currently in press.

15. SUBJECT TERMS: Hepatocellular carcinoma; Chronic hepatitis C (CHC); Direct-acting antivirals (DAAs); Sustained viral response (SVR); Risk stratification; Protective factors; Risk factors; Risk prediction models; Benefits and harms; Decision support tool; Simulator tool; Cancer surveillance

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TABLE OF CONTENTS

1.INTRODUCTION: Hepatocellular carcinoma (HCC) is the fastest growing cause of cancer deaths in Americans. HCC incidence has increased 3-fold between 1975–2009 and the trend is still upwards. Despite moderate advances in treatment, most HCC patients present with advanced stage and have low survival (5-year <15%). Chronic hepatitis C (CHC) infection is the leading cause of HCC. The direct-acting antiviral (DAA) treatments offer cure from chronic infection. However, the subsequent risk of HCC persists in patients with CHC after virological cure. In fact, virologically-cured CHC is one of the most important emerging risk factors for HCC. While patients with advanced HCC have a median survival of less than 1 year, patients with early HCC who receive potentially curative therapy achieve 5-year survival rates near 70%. Early diagnosis, therefore, is critical to improved survival. However, the long-term harms and benefits of routine HCC surveillance in virologically cured CHC patients have not been evaluated. Furthermore, instead of using a one-size-fits-all approach, surveillance recommendations based on individualized risk factors could be more efficient — such an approach could detect HCC in early stages in high-risk patients and spare many non-HCC patients who do not need surveillance. The goals of this study are to: (1) identify the most salient protective and risk factors, and combine these factors in predictive models that differentiate high from low risk patients; (2) provide data on long-term benefits and harms of HCC surveillance tailored to individualized risk factors; and (3) develop a first publicly available decision support tool, HCC Simulator, for individualized surveillance recommendations.

2.KEYWORDS:

Hepatocellular carcinoma

Chronic hepatitis C

Direct-acting antivirals

Sustained viral response

Risk stratification

Protective factors

Risk factors

Risk prediction models

Benefits and harms

Decision support tool

Simulator tool

Cancer surveillance

3.ACCOMPLISHMENTS:

◦**What were the major goals of the project?**

The Statement of Work includes the following major goals:

Specific Aim 1 (Kanwal Lead): To examine determinants of HCC in virologically cured patients and develop a risk prediction model for HCC in these patients

Major Task 1: Examine determinants of HCC in patients virologically cured with direct acting antiviral (DAA) agents

Subtask 1: Data acquisition from VA Corporate Data Warehouse, data cleaning, variable creation, and cohort identification (Target date 2/28/2020) – completed 2/28/2020

Subtask 2: EMR chart abstractions to confirm HCC (Target date 2/28/2020) – completed 2/28/2020

Subtask 3: Data analysis of HCC predictors (Target date 4/30/2020) – completed 06/30/20

Major Task 2: Develop & optimize HCC risk prediction model

Subtask 1: Model fitting/Variable selection (Target date 06/30/20) – completed 09/30/2020

Subtask 2: Risk stratification (Target date 07/31/20) – Delayed. 30% complete. Expected to be complete 12/31/2020.

Subtask 3: Subgroup sensitivity analysis (Target date 08/31/20) – Delayed. Expected to be complete by 03/31/2021.

Specific Aim 2 (Chhatwal Lead, Kanwal Team Participating): To evaluate the benefits vs harms of HCC surveillance in virologically cured patients

Major Task 3: Develop a mathematical model simulating the natural history of HCC that incorporates risk estimates and key factors identified in Aim 1

Subtask 1: Model description – Develop a simulation model (individual-level state-transition model) of the natural history of HCC in virologically cured hepatitis C patients (Target date 08/31/20) – completed 08/31/20

Subtask 2: Add modules to the simulation model: surveillance and diagnosis, treatment options based on the BCLC stage at diagnosis (Target date 11/30/2021) – 25% complete

Subtask 3: Liver transplantation - Extend simLT module to simulate the life course of HCC patients on the UNOS waiting list and after the transplant; we will also incorporate HCC recurrence (Target date 11/30/2021) – 0% complete

Subtask 4: Costs and quality of life – Using published studies, estimate costs associated with the mathematical model's (simHCC's) states (Target date 12/31/2021) – 25% complete

Major Task 4: Use simHCC to compare long-term effectiveness of no surveillance versus routine surveillance

Subtask 1: Generate a set of outcomes for surveillance vs no surveillance strategies for each risk group (Target date 02/28/21) – 0% complete

Subtask 2: Conduct probabilistic sensitivity analysis (Target date 03/31/21) – 0% complete

Subtask 3: Conduct value of information analysis (Target date 05/31/21) – 0% complete

Specific Aim 3 (Chhatwal Lead, Kanwal Team Participating): To develop HCC Simulator, an online interactive tool for physicians and patients that provides the short- and long-term value of HCC surveillance in different risk groups

Major Task 5: Create a large dataset of hypothetical virologically cured patients

Subtask 1: Using simHCC model, simulate the life course of 1 million patients having different profiles (Target date 06/30/21) – 0% complete

Subtask 2: Generate a set of graphical outcomes for each patient profile with and without HCC surveillance (Target date 07/31/21) – 0% complete

Major Task 6: Create an online tool, HCC Simulator

Subtask 1: Create an online platform using RShiny (Target date 10/31/21) – 0% complete

Subtask 2: Create a homepage for HCC Simulator (Target date 11/30/21) – 0% complete

Subtask 3: Make the HCC Simulator available on the internet (Target date 12/31/21) – 0% complete

Major Task 7: Conduct a feasibility to assess the usability of the HCC Simulator in a clinical setting

Subtask 1 (Chhatwal & Kanwal Teams Combined): Develop focus group and patient interview guides (Target date 01/31/22) – 0% complete

Subtask 2: Provider and patient recruitment for focus groups and individual patient interviews (Kanwal Team); Conduct focus groups and individual patient interviews (Chhatwal Team Lead; Kanwal Team Supporting) (target date 03/31/22) – 0% complete

Team A (Fasiha Kanwal Team): Dr. Kanwal's team will recruit all providers and patients for focus group sessions and individual patient interviews and will record the sessions and interviews.

Recruit, consent, and enroll 30 patients/human subjects for participating in 6 focus groups

Recruit, consent and enroll 20 providers for individual interviews

Team B (Chhatwal Team): Dr. Chhatwal's team will conduct the focus groups and individual patient interviews

Subtask 3 (Kanwal Team): Transcription services (Target date 04/30/22) – 0% complete

Subtask 4: Coding and analysis of transcripts (Target date 05/31/22) – 0% complete

Team A (Kanwal Team): Dr. Kanwal's team will review coding and analysis results

Team B (Chhatwal Team): Dr. Chhatwal's team will code and analyze transcripts

Major Task 8: Incorporate results from focus group and individual patient feedback into the HCC Simulator

Subtask 1: Re-design relevant components of the HCC Simulator based on the feedback (Target date 07/31/22) – 0% complete

Team A (Kanwal Team): Dr. Kanwal's team will review results

Team B (Chhatwal Team): Dr. Chhatwal's team will modify the HCC Simulator

Subtask 2: Launch the HCC Simulator (Target date 08/31/22) – 0% complete

Team A (Kanwal Team): Dr. Kanwal's team will serve as in a supporting/consulting role

Team B (Chhatwal Team): Dr. Chhatwal's team will launch the HCC Simulator

Major Task 9: Manuscripts and dissemination of results

Subtask 1: Organize a Webinar on use of the HCC Simulator (Target date 08/31/22) – 0% complete

Team A (Kanwal Team): Dr. Kanwal's team will participate in the development of the Webinar contents

Team B (Chhatwal Team): Dr. Chhatwal's team take the lead to organize a Webinar on its use

Subtask 2: Report project results through manuscripts in peer-reviewed journals (Target date 09/30/22) – 0% complete

1. Predictors of HCC in CHC patients with virologically induced cure
2. Risk prediction model to identify patients at high risk for HCC after DAA induced virological cure
3. Cost-effectiveness of personalized HCC surveillance in virologically cured CHC patients
4. When to stop HCC surveillance after virological cure with CHC
5. A brief report on HCC Simulator

Both Team A and Team B will participate collaboratively and equally in manuscript writing

◦**What was accomplished under these goals?** The following was accomplished under these goals:

Specific Aim 1: To examine determinants of HCC in virologically cured patients and develop a risk prediction model for HCC in these patients.

The major activities undertaken by the Kanwal Team in Year 1 included receiving IRB approval, data acquisition from VA Corporate Data Warehouse, data cleaning, variable creation, cohort identification, and data analysis of HCC predictors, model building and results.

We included patients 18 years or older who achieved sustained virological response (SVR) with DAA treatment in any of the 129 VHA hospitals. We defined DAA treatment as ≥ 1 filled prescription of sofosbuvir, simeprevir, ledipasvir, combination **of paritaprevir/ritonavir, ombitasvir and dasabuvir, and daclatasvir** between 1/1/2014-12/31/2018 and followed up for HCC through 12/31/2019. This timeframe allowed a minimum of 9 months of follow up after treatment completion for all patients. We used the date of first filled prescription as treatment initiation and the last date covered by the final prescription as treatment completion date. We classified patients as having achieved SVR if all HCV RNA tests were negative after end of DAA treatment, with one HCV RNA test recorded at least 12 weeks after treatment completion. Because our objective is to examine the risk of incident HCC in patients virologically cured of HCV, we excluded patients who failed to achieve SVR. We also excluded patients with evidence of HCC prior to or during DAA treatment course.

The study **outcome** was new cases of HCC after the date of completing DAA. HCC was defined based on 2 or more instances of ICD-9 (155.0) or ICD-10 codes (C22.0, C22.8, C22.9, D01.5) in CDW or any instance of HCC recorded in the CCR. We also reviewed electronic medical records of cases that had ICD codes but not included in CCR.

Predictor variables. These include age, gender, race/ethnicity, socioeconomic status, marital status, place of residence (rural vs. urban), cirrhosis, HCV genotype, previous HCV treatment status, HIV, diabetes, hypertension, dyslipidemia, body mass index (BMI), alcohol use, other medical comorbidity, HIV, hepatitis B status, and healthcare utilization. We also derived 11 laboratory variables including values of bilirubin, AST, ALT, international normalized ratio, platelet tests, white cell count, hemoglobin, lymphocytes, neutrophils, creatinine, and sodium values. All variables were longitudinal and time updating over time.

Statistical analysis. We used the date of DAA completion as the index date and followed patients to the development of HCC, death, or 09/30/2019, whichever was earlier. We examined the associations between each predictor variable, HCC and competing risk of death. We also examined collinearity between the predictor variables; we used landmark Fine-Gray models, each defined at a different landmark time (baseline T0, 12, and 24 months) after the index date. The prediction at a landmark time was based on the regression model at that time. The outcome was the time from the landmark to HCC. At each landmark, the data only included the at-risk patients at that time (*e.g.*, those who are alive without HCC). We examined all predictors at the time of each landmark, predictors at baseline, and any change in these values overtime. We used a stepwise selection process to identify predictors to be included in the prediction model at each landmark time.

Currently the team is developing and optimizing these HCC risk prediction model which involves model fitting and variable selection, as well as conducting subgroup sensitivity analyses.

Specific objectives: Our specific objectives were to acquire data from VA Corporate Data Warehouse and complete data cleaning, variable creation, and cohort identification; abstract EMR to confirm HCC; analyze data to identify predictors of HCC risk; develop and optimize HCC prediction models and perform subgroup analyses. We were on target for all of our objectives before the COVID-19 pandemic. Our work towards the last 2 objectives was delayed due to COVID-19 pandemic.

Significant results: We have identified 97,863 patients who initiated DAA during 1/1/2014-12/31/2018 and achieved SVR; 2298 patients developed HCC and 7903 patients died until 12/31/2019. Mean age was 61.6 years old (sd=7.5); 96.4% were male; 38.5% were Black and 51.2% were white.

The baseline Cox proportional hazards model included 19 significant predictors for HCC. These included male sex, older age at index, current smoker, history of cirrhosis and/or varices, prior treatment with a DAA, infection with HCV genotype 3, and AST, ALT, bilirubin, creatinine, platelet, albumin levels, and interaction. The nature of predictor variables changed over time. Metabolic traits predicted HCC whereas viral factors (HCV genotype) was no longer predictive at 24 months after virological cure.

Table. Predictors selected in the models at 3 clinically important timepoints.

Model at Landmark T0 (treatment completion)		Model at Landmark T12 (12 months following treatment completion)		Model at Landmark T24 (23 months treatment completion)	
Variables	p-values	Variables	p-values	Variables	p-values
Cirrhosis	<0.001	Cirrhosis	<0.001	Cirrhosis	<0.001
Age	<0.001	Varices	<0.001	Varices	<0.001
Gender	<0.001	Platelet count	<0.001	Platelet count (baseline)	<0.001
Varices	<0.001	Albumin	<0.001	Albumin (baseline)	<0.001
Platelet count	<0.001	Age	<0.001	Age	<0.001
Albumin	<0.001	Smoking	<0.001	Smoking	0.0006
Age	<0.001	ALT value	<0.001	ALT value (change from baseline	0.03
Smoking	<0.001	AST value	<0.001	AST (baseline)	0.002
ALT value	<0.001	HCV genotype	0.0005	Dyslipidemia	0.002
AST value	<0.001	Prior treatment	0.0007	HBV core	0.014
Bilirubin	<0.001	Platelet count	0.0012	Hemoglobin	0.018
AST/ALT ratio	<0.001	Creatinine	0.0014	Hemoglobin (baseline)	0.01
HCV genotype	<0.001	INR	0.0084	Albumin (change from baseline)	0.008
Prior treatment	<0.001	Sodium	0.016		
Platelet count	0.014	Hemoglobin	0.014		
Creatinine	<0.001	Albumin	0.03		
Platelet*hemoglobin	<0.001				
Hemoglobin	<0.75				
Albumin	<0.001				

Currently the team is refining and optimizing these HCC risk prediction model which involves model fitting and further variable selection, as well as conducting subgroup sensitivity analyses.

Stated goals not met. We were not able to fully meet the last 2 objectives that were planned for March 2020 onwards. Our team experienced delays due to the COVID-19 emergency. Despite extraordinary efforts by the VA to expand network capabilities to accommodate the sudden and dramatic increase in the number of employees working remotely from home, all team members regularly experienced connection problems and slow response time on all platforms (VINCI, VA secure servers, Outlook Email, Skype, etc.) from March through July. The team currently has completed 50% of Major Task 2 and is increasing the data analyst effort to full-time for Year 2 in an effort to complete the project on time.

Specific Aim 2: To evaluate the benefits vs harms of HCC surveillance in virologically cured patients

For Specific Aim 2 , **the major activities** undertaken by the Chhatwal Team, with participation from the Kanwal Team, in Year 1 included developing a mathematical model simulating the natural history of HCC incorporating risk estimates and key factors identified in Aim 1, as well as developing a simulation model (individual-level state-transition model) of the natural history of HCC in virologically cured hepatitis C patients. The team met all stated goals for this aim. The following key findings are reported in a manuscript accepted by JAMA Network Open in August 2020:

Methods: The team used an individual-level state-transition simulation model to examine changes in the incidence rate and surveillance burden of HCC in the era of DAA treatment for hepatitis C. The model simulated disease progression, screening, and different waves of antiviral treatments for hepatitis C in the US from 2012 to 2040. Using simulated hepatitis C patients at risk of developing HCC, the team applied current clinical management interventions for chronic hepatitis C infection, producing model-projected temporal trends and age distribution of incident HCC cases and candidates for HCC surveillance among viremic and virologically cured hepatitis C patients.

Significant results: The resulting simulation model projected that the annual incidence of HCC among hepatitis C patients (viremic and virologically cured) will continue increasing to 24,000 (95% Uncertainty Interval: 18,000-31,000) cases until 2021. In virologically cured patients, incident HCC cases are projected to increase from 1000 (500-2,100) in 2012 to the peak of 7,000 (5,000-9,600) in 2031 with a subsequent decline to 6,000 (4,300-8,300) by 2040. The proportion of incident HCC cases that occur in virologically cured individuals will increase from 5.3% in 2012 to 45.8% in 2040. The number of candidates for HCC surveillance in virologically cured population is projected to increase from 106,000 (70,000-178,000) in 2012 to the peak of 649,000 (512,000-824,000) in 2030 and decline to 539,000 (421,000-687,000) by 2040, while the proportion of all surveillance candidates who are virologically cured would increase from 8.5% to 64.6% during the same period. The average age of HCC incidence and surveillance candidates will increase from 55 in 2012 to 72 and 71, respectively, by 2040.

The team concluded 1) that the burden of HCC will shift from viremic to virologically cured hepatitis C patients, and to older populations, and 2) that appropriate management are needed for early detection of HCC in patients who may no longer be under liver specialty care.

These findings are reported in a manuscript that was accepted by JAMA Network Open and is currently in press.

◦**What opportunities for training and professional development has the project provided?**

Nothing to Report

◦**How were the results disseminated to communities of interest?**

Nothing to Report

◦**What do you plan to do during the next reporting period to accomplish the goals?**

In Year 2, Dr. Kanwal's team will refine and optimize the HCC risk prediction model which involves model fitting and further variable selection, as well as conducting subgroup sensitivity analyses.

In Year 2, Dr. Chhatwal's team with participation from Dr. Kanwal's team will extend our mathematical model to include the following modules: surveillance and diagnosis, and treatment options based on the BCLC stage at diagnosis. We will further extend the model to simulate the life course of HCC patients on the UNOS waiting list and after the transplant. Next, we will add costs associated with HCC surveillance, hepatitis C sequelae, liver transplant and other HCC treatments. We will also extract quality of life associated with all health states in the model. Using this extended framework, we will evaluate the cost effectiveness of HCC surveillance in hepatitis C cured patients. We will evaluate the optimal time to start and stop surveillance in different subgroups identified in Aim 1. We will conduct probabilistic sensitivity analysis and value of information analysis to evaluate the impact of uncertainty of HCC surveillance recommendations. We will also initiate the first subtask of Aim 3. Using the mathematical model, we will simulate the life course of hypothetical patients with different risk profiles and store them in a database.

4.IMPACT: Nothing to Report.

5.CHANGES/PROBLEMS:

◦**Changes in approach and reasons for change**

Nothing to Report.

◦**Actual or anticipated problems or delays and actions or plans to resolve them**

Chhatwal Team – Nothing to report.

Kanwal Team – The team experienced delays due to the COVID-19 emergency. Despite extraordinary efforts by the VA to expand network capabilities to accommodate the sudden and dramatic increase in the number of employees working remotely from home, all team members regularly experienced connection problems and slow response time on all platforms (VINCI, VA secure servers, Outlook Email, Skype, etc.) from March through July. Mondays after IT system and program changes over the weekend were especially difficult. The team currently has completed 50% of Major Task 2 and is increasing the data analyst effort to full-time for Year 2 in an effort to complete the project on time.

◦**Changes that had a significant impact on expenditures**

Chhatwal Team – Nothing to report.

Kanwal Team – Due to the problems described above, the team experienced delays in completing Major Task 2 Develop & optimize HCC risk prediction model. To accelerate progress and meet Year 2 target dates, we plan to use the carryforward funds from Year 1 to increase the data analyst effort to full-time during Year 2. No change in the scope of work is planned.

◦**Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**

Nothing to Report.

6.PRODUCTS:

◦**Publications, conference papers, and presentations**

Nothing to Report.

▪**Books or other non-periodical, one-time publications.**

Nothing to report.

▪**Other publications, conference papers, and presentations.**

Nothing to report.

◦**Website(s) or other Internet site(s)**

Nothing to report.

◦**Technologies or techniques**

Nothing to report.

◦**Inventions, patent applications, and/or licenses**

Nothing to report.

◦**Other Products**

Nothing to report.

7.PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

◦**What individuals have worked on the project?**

Name: Fasiha Kanwal, MD, MSHS
Project Role: Principal Investigator
Researcher Identifier (e.g. ORCID ID): 0000-0001-6715-3966

Nearest person month worked: 2
Contribution to Project: As the Principal Investigator, Dr. Kanwal oversees all aspects of the project and has primary responsibility for supervising Aim 1 activities: 1) Data acquisition, data cleaning, variable creation, cohort identification, 2) EMR chart abstractions to confirm HCC, 3) data analysis of HCC predictors, 4) develop and optimize HCC risk prediction model.
Funding Support:

Name: Jennifer R. Kramer, PhD
Project Role: co-Investigator
Researcher Identifier (e.g. ORCID ID): https://orcid.org/0000-0003-2953-4949
Nearest person month worked: 2
Contribution to Project: Dr. Kramer is leading the Data Analysis Team based at the VA (Aim 1 to examine determinants of HCC in virologically cured patients and develop a risk prediction model for HCC in these patients). She works closely with the PI, the biostatistician, and the data analyst on data acquisition, and operationalizing study variables. She supervises chart abstractors, oversees data analysis, and interprets results.
Funding Support:

Name: Roxanne Desiderio, BS
Project Role: Research Assistant
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 6
Contribution to Project: Ms. Desiderio conducted electronic medical record (EMR) chart reviews and assisted with administrative tasks, such as meeting scheduling, reporting, and maintaining regulatory documentation.
Funding Support:

Name: Yumei Cao, MS
Project Role: Data Analyst
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 12
Contribution to Project: Ms. Cao is the data analyst for Aim 1 of the project, responsible for the build and upkeep of the study databases, quality control measures, and conducting statistical analyses with the guidance of Drs. Kramer, Richardson, and Kanwal. She performed the programming required to identify the cohort, define the study variables, and construct analytic datasets. Ms. Cao provided weekly summary reports on the state of data analysis at the weekly project meeting headed by Dr. Kanwal (PI).
Funding Support:

Name: Donna Smith, MEd
Project Role: Project Coordinator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 3
Contribution to Project: Ms. Smith is responsible for all administrative and regulatory tasks of the project, including IRB protocol approvals, renewals, and amendments; organizing project team meetings; maintaining study binders; and managing the budget. She coordinates data acquisition requests and data use agreement renewal updates. She will work closely with the core research investigators to coordinate writing and editing of progress reports and will assist with the development and publication of dissemination products.
Funding Support:

Name: Jagpreet Chhatwal, PhD
Project Role: Principal investigator
Researcher Identifier (e.g. ORCID ID): https://orcid.org/0000-0001-8741-4430
Nearest person month worked: 2
Contribution to Project: As the Principal Investigator, Dr. Chhatwal has primary responsibility for supervising Aim 2 activities: development of the mathematical model to simulate the natural history of HCC in hepatitis C cured patients, literature review, validation and analysis of the proposed model.
Funding Support:

Name: Asmae Toumi, BS
Project Role: Data Analyst
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 3
Contribution to Project: Ms. Toumi is a data analyst who worked with Dr. Chhatwal to conduct literature review and assist development of the mathematical model of the natural history of HCC.
Funding Support:

Name: Mary Ann Ladd, BS
Project Role: Data Manager
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1
Contribution to Project: Ms. Ladd is the Systems Manager of the MGH Institute for Technology Assessment. She was responsible for overseeing the integration and day-to-day management of computer systems at the Institute for Technology Assessment, and for facilitating electronic communications among collaborators. She worked with the other team members to facilitate data extraction and storage, and ensure that all study data are secure, adequately stored and backed up.
Funding Support:

◦**Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**

PREVIOUS, CURRENT, AND PENDING SUPPORT (PCPS)

KANWAL, FASIHA

PREVIOUS

Title: CPRIT RP150587 Risk Factors of Hepatocellular Cancer in Non-Alcoholic Fatty Liver Disease
Role on project: PI Project #1 (Overall PI: El-Serag)
AIMS: 1) To examine the risk of hepatocellular cancer (HCC) in patients with non-alcoholic fatty liver disease (NAFLD); 2) To identify predictors of HCC in patients with NAFLD; 3) To develop and validate an HCC risk stratification algorithm.
Time Commitment (Level of Effort): 1.5 calendar months
Supporting Agency: Cancer Prevention and Research Institute of Texas (CPRIT)
Name and address of funding agency's Grant's Officer:
Patty Moore
CPRIT
1701 N Congress Ave
Austin, TX 78701
Phone:
Fax:
Email: pmoore@cprit.texas.gov
Performance Period: 09/2015-05/2020
Level of funding:
Brief description of project's goals: The overarching goal of this study is to examine risk of hepatocellular cancer in a broad spectrum of Texas-based NAFLD patients receiving care in the Veterans Health Administration.
% Overlap: None

CURRENT

Title: NIDDK P30 DK 56338-10/15 Center for Gastrointestinal Development, Infection and Injury
Role on project: Co-director (Overall PI: El-Serag)
AIMS: 1) To serve clinical and basic science investigators in digestive diseases with comprehensive study design consultation and support; 2) To assist DDC investigators in all aspects of the acquisition of clinical

specimens required for their research in digestive diseases; 3) To support comprehensive data analyses and interpretation of basic, translation, clinical and epidemiological studies.
Time Commitment (Level of Effort): 0.6 calendar months
Supporting Agency: NIH/National Institute of Diabetes and Digestive and Kidney Diseases
Name and address of funding agency's Grant's Officer:
Peter J Perrin
Program Official
Division of Digestive Diseases and Nutrition, NIDDK, NIH
6707 Democracy Blvd., Room 6015
Bethesda, MD 20892-5450
Email: Peter.Perrin@nih.hhs.gov
Phone:
Fax:
Performance Period: 12/1999-02/2023
Level of funding:
Brief description of project's goals: This Center supports four scientific cores, conferences and a pilot project program to facilitate on-going Digestive Disease research of center members, promote interactions and translational research between basic and clinical areas, develop new projects, nurture new investigators, and provide GI educational activities.
% Overlap: None

Title: HSR&D Project # IIR 16-075 (Application # 1 I01 HX002204-01A2) Patient Centered Care for Individuals with Advanced Liver Disease
Role on project: MPI
AIMS: 1) To develop risk stratification models of advanced liver disease (AdvLD) prognosis; 2) To describe patients' experiences and goals of AdvLD care; 3) To identify clinicians' perceptions of opportunities and barriers to patient-centered AdvLD care.
Time Commitment (Level of Effort): 4.2 calendar months
Supporting Agency: VA HSR&D
Name and address of funding agency's Grant's Officer:
Cathie Plouzek, PhD, PMP
Health Services Research and Development (10P9H)
Office of Research and Development, VA Central Office
Department of Veterans Affairs
810 Vermont Avenue NW
Washington, DC 20420
Phone:
Cell:
E-mail: cathie.plouzek@va.gov
Performance Period: 05/2018-04/2021
Level of funding:
Brief description of project's goals: The main goal of the project is to develop a patient-centered care model for advanced liver disease, including risk-prediction models and clinician-patient collaborative treatment planning guides that focus on addressing patient unmet needs and expectations about illness course and care preferences for curative, supportive, and palliative care. The study findings will have direct impacts on current advanced liver disease care, as well as provide evidence for developing innovative care models for other serious chronic illnesses.
% Overlap: None

Title: 1 U01 CA230997-01 Risk Stratification for and Early Detection of Liver Cancer
Role on project: PI
AIMS: 1) Develop and test novel personalized risk stratification indices for predicting future HCC development in cirrhosis from diverse etiologies; 2) Develop and evaluate an algorithm combining existing HCC blood based biomarkers (AFP, AFPL3, DCP), their longitudinal changes and host features (e.g., cirrhosis etiology) to improve early HCC detection; 3) Evaluate novel plasma-based methylation markers for cell-free DNA (MDMs) as an independent surveillance biomarker for early HCC detection. Using the PRoBE design, we will test 12 individuals MDMs identified in Phase 2 study.

Time Commitment (Level of Effort): 2.4 calendar months
Supporting Agency: NIH Consortium on Translational Research in Early Detection of Liver Cancer: Translational Research Centers (U01)
Name and address of funding agency's Grant's Officer:
Viviana Knowles
National Cancer Institute
Office of Grants Administration
9609 Medical Center Drive
West Tower, 2nd floor
Rockville MD 20850
Phone
viviana.knowles@nih.gov
Tel.
Performance Period: 09/2018-08/2023
Level of funding:
Brief description of project's goals: The overarching goal of our Translational Research Center (TRC) is to reduce the mortality of hepatocellular cancer (HCC) by developing personalized indices that combine novel and existing biomarkers with clinical, behavioral and genetic data to improve clinical risk stratification and increase early detection of HCC.
% Overlap: None

Title: RSG-17-022-01 A Personalized Surveillance Program for Hepatocellular Carcinoma
Role on project: co-PI (Lead PI: Chhatwal)
AIMS: 1) Develop an effective and cost-effective surveillance program in hepatitis C patients who have – and have not – been cured of their infection, by incorporating individual's risk factors including age, sex, genotype and biomarkers; 2) Evaluate personalized HCC surveillance in patients with HBV, NASH, and ALD stratified by their risk factors; 3) Project the impact of personalized HCC surveillance on population-level cancer control, and identify future research priorities that will reduce HCC mortality and burden.
Time Commitment (Level of Effort): 0.2 calendar months
Supporting Agency: American Cancer Society
Name and address of funding agency's Grant's Officer:
Elvan Daniels
Extramural Grants Department
American Cancer Society
250 Williams Street
Atlanta, GA 30303-1002
E-mail: ellie.daniels@cancer.org
Phone:
Performance Period: 07/2017-06/2021
Level of funding:
Brief description of project's goals: The goal of this proposal is to reduce the burden of hepatocellular carcinoma by identifying effective surveillance programs that improve early detection.
% Overlap: None

Title: PR181562 Risk of hepatocellular cancer after virological cure with direct acting antiviral agents in individuals with hepatitis C (subject grant)
Role on project: MPI
AIMS: 1) To examine determinants of HCC in virologically cured patients and develop a risk prediction model for HCC in these patients; 2) To evaluate benefits versus harms of HCC surveillance in virologically cured patients; 3) To develop HCC Simulator, an online interactive tool for physicians and patients that provides the short- and long-term value of HCC surveillance in different risk groups.
Time Commitment (Level of Effort): 2.4 calendar months
Supporting Agency: Department of Defense Office of Congressionally Directed medical Research Programs (CDMRP)
Name and address of funding agency's Grant's Officer:
Annmarie Gersch, Ph.D.
Science Officer

Congressionally Directed Medical Research Programs (CDMRP)
US Army Medical Research Materiel Command (USAMRMC)
1054 Patchel Street
Ft. Detrick, MD 21702-5024
PH:
Email: annmarie.gersch.ctr@mail.mil
Performance Period: 07/2019-06/2022
Level of funding:
Brief description of project's goals: The goal of this study is to examine the risk and determinants of hepatocellular carcinoma (HCC) in patients with chronic hepatitis C (CHC) virologically cured with new direct acting antiviral agent (DAA) regimens and to identify cost-effective strategies for early detection of HCC in those patients.
% Overlap: None

Title: Cirrhosis Quality Collaborative
Role on project: co-PI (Corresponding co-PI: Volk)
AIMS: Phase 1: Design phase and network development. Aim 1a: Design a collaborative chronic care network that involves stakeholders at all levels in the design process. Aim 1b: Engage clinician, patient and policy stakeholders to refine a parsimonious set of quality measures – including patient-reported outcomes (PRO's). Phase 2: Software build and network pilot. Aim 2a: Work with ArborMetrix to build the data registry. Aim 2b: Prospectively collect data on the set of quality measures across 10 sites, to identify variation in process, outcome, and patient reported measures of cirrhosis care. Aim 2c: Pilot test a rapid-cycle quality improvement project on a single focused target.
Time Commitment (Level of Effort): 0.6 calendar months
Supporting Agency: American Association for the Study of Liver Diseases
Name and address of funding agency's Grant's Officer:
Julie Deal
Interim CEO, American Association for the Study of Liver Diseases
1001 N. Fairfax Street, #400
Alexandria, VA 22314
Phone:
Performance Period: 09/2018-08/2021
Level of funding:
Brief description of project's goals: This is the first large-scale quality improvement project targeting patients with advanced and chronic liver diseases. It will pilot test a collaborative chronic care network, including necessary technology infrastructure.
% Overlap: None

PENDING
Title: CPRIT RP200633 Reducing disparities in the risk of hepatocellular cancer
Role on project: MPI
AIMS: 1) Examine the role of individual, inter-personal and community level factors in explaining racial/ethnic disparities in cirrhosis progression to HCC (prevention); 2) Examine the role of individual, inter-personal and community level factors in explaining racial/ethnic disparities in HCC tumor stage at diagnosis (early detection); 3) Identify specific targets for future interventions to reduce racial/ethnic HCC disparities.
Time Commitment (Level of Effort): 1.5 calendar months
Supporting Agency: Cancer Prevention & Research Institute of Texas (CPRIT)
Name and address of funding agency's Grant's Officer:
General CPRIT Contact Information:
Email: cprit@cprit.state.tx.us
Cancer Prevention and Research Institute of Texas
1701 North Congress Avenue, Suite 6-127
Austin, TX 78701
Phone:
Fax:
Performance Period: 08/2020-08/2025
Level of funding: (in JIT)

Brief description of project's goals: The primary objective of this study is to identify in a large racial/ethnically and socioeconomically diverse cohort of patients with cirrhosis the multi-level factors that explain racial and ethnic disparities in HCC risk/incidence and tumor stage at diagnosis, as well as a set of potentially actionable (identifiable, preventable or treatable) determinants of HCC disparities in Texas.
% Overlap: None

Title: R01 PAR-20-088 Multi-level Evaluation of Racial/Ethnic and Socioeconomic Disparities in Liver Disease Outcomes
Role on project: MPI
AIMS: 1) Examine the contribution of individual-, interpersonal-, and community-level factors to racial/ethnic and socioeconomic disparities in cirrhosis progression to hepatic decompensation, including HCC; 2) Identify individual-, interpersonal-, and community-level determinants of racial/ethnic and socioeconomic disparities in liver-related hospitalization; 3) Characterize the contribution of individual-, interpersonal-, and community-level factors to racial/ethnic and socioeconomic disparities in overall survival of patients with cirrhosis.
Time Commitment (Level of Effort): 1.8 calendar months
Supporting Agency: National Institutes of Health
Name and address of funding agency's Grant's Officer:
Rina Das, PhD
National Institute on Minority Health and Health Disparities (NIMHD (https://www.nimhd.nih.gov/))

Telephone:
Email: dasr2@mail.nih.gov (mailto:dasr2@mail.nih.gov)
Performance Period: 12/2020-11/2025
Level of funding:
Brief description of project's goals: To conduct a comprehensive evaluation of multilevel factors hypothesized to play important roles in causing racial/ethnic and SES disparities in three key measures of cirrhosis prognosis: a) hepatic decompensation, including HCC, b) liver-related hospitalization, and c) overall survival.
% Overlap: None

OVERLAP
There is no overlap between current projects and this application. If the pending R01 application "Multi-level Evaluation of Racial/Ethnic and Socioeconomic Disparities in Liver Disease Outcomes" is funded, we will adjust the scope and effort from the R01 project to avoid overlap with the pending CPRIT grant.

PREVIOUS, CURRENT, AND PENDING SUPPORT (PCPS)

KRAMER, JENNIFER R., MPH, PhD

PREVIOUS

Title: CPRIT RP150587 Risk Factors of Hepatocellular Cancer in Non-Alcoholic Fatty Liver Disease
Role on project: Co-Investigator
AIMS: 1) To examine the risk of hepatocellular cancer (HCC) in patients with non-alcoholic fatty liver disease (NAFLD); 2) To identify predictors of HCC in patients with NAFLD; 3) To develop and validate an HCC risk stratification algorithm.
Time Commitment (Level of Effort): 1.5 calendar months
Supporting Agency: Cancer Prevention and Research Institute of Texas (CPRIT)
Name and address of funding agency's Grant Officer:
General CPRIT Contact Information:
Email: cprit@cprit.state.tx.us
Cancer Prevention and Research Institute of Texas
1701 North Congress Avenue, Suite 6-127
Austin, TX 78701
Phone:
Fax:
Performance Period: 09/2015-05/2020

Level of funding;
Brief description of project's goals: The overarching goal of this study is to examine risk of hepatocellular cancer in a broad spectrum of Texas-based NAFLD patients receiving care in the Veterans Health Administration.
% Overlap: None

CURRENT

Title: R01 CA206479-01 Identifying Novel Pharmacologic Risk factors for Common Malignancies in Individuals with Well-controlled HIV Infection
Role on project: Co-Investigator
AIMS: 1) a) To measure the effect of the duration of specific classes of cART medications on the risk of each of the 8 NADCs of interest in a cohort of veterans with well-controlled HIV, adjusting for known risk factors for each type of cancer, and b) to assess the extent of cancer risk that is mediated by metabolic disorders; 2) a) To measure the effect of duration of specific classes of common medications used to treat metabolic disorders known to impact cancer risk, utilized by HIV-infected individuals (e.g., statins, metformin, betablockersand ACE-Inhibitors) on the risk of developing the 8 NADCs of interest in a cohort of veterans with well-controlled HIV-infection; and b) to assess the extent that the observed cancer risk association from these common metabolic disorder-related medication is primarily mediated through their impacts on metabolic disorder control.
Time Commitment (Level of Effort): 2.4 calendar months
Supporting Agency: National Institutes of Health; National Cancer Institute
Name and address of funding agency's Grant Officer:
Viviana Knowles
National Cancer Institute
Office of Grants Administration
9609 Medical Center Drive
West Tower, 2nd floor
Rockville MD 20850
Phone
viviana.knowles@nih.gov
Tel.
Performance Period: 06/2016-05/2021 (NCE)
Level of funding;
Brief description of project's goals: This proposal aims to examine the effect of novel pharmacological agents on cancer risk in individuals with well-controlled HIV infection using the VA Corporate Data Warehouse.
% Overlap: None

Title: EPID-001-16S: Sex hormones and HCV-related liver disease progression
Role on project: Co-Investigator
AIMS: 1) To evaluate the association between baseline levels of circulating major sex hormones, including precursors, metabolites, and carrier proteins, and risk of liver disease progression to incident cirrhosis, decompensation, and/or HCC; 2) To evaluate the association between use of androgen altering medications including the anti-androgen finasteride or supplemental testosterone (T) and risk of HCV-related liver disease progression.
Time Commitment (Level of Effort): 0.6 calendar months
Supporting Agency: VA HSR&D
Name and address of funding agency's Grant Officer:
Sara Clark
Department of Veterans Affairs
Office 10P9B
1100 First St. NE
Washington, DC 20002
sara.clark@va.gov
Tel.
Performance Period: 07/2017-06/2021
Level of funding;

Brief description of project's goals: The goals of this proposal are to examine circulating sex hormone levels at baseline and risk of hepatitis C-related liver disease progression in males and to examine use of sex hormone modifying medications on risk of hepatitis C-related liver disease progression.
% Overlap: None

Title: HSR&D Project # IIR 16-075 (Application # 1 I01 HX002204-01A2) Patient Centered Care for Individuals with Advanced Liver Disease
Role on project: Co-Investigator
AIMS: 1) To develop risk stratification models of advanced liver disease (AdvLD) prognosis; 2) To describe patients' experiences and goals of AdvLD care; 3) To identify clinicians' perceptions of opportunities and barriers to patient-centered AdvLD care.
Time Commitment (Level of Effort): 0.6 calendar months
Supporting Agency: VA HSR&D
Name and address of funding agency's Grant Officer:
Cathie Plouzek, PhD, PMP
Health Services Research and Development (10P9H)
Office of Research and Development, VA Central Office
Department of Veterans Affairs
810 Vermont Avenue NW
Washington, DC 20420
Phone:
Cell:
E-mail: cathie.plouzek@va.gov
Performance Period: 05/2018-04/2021
Level of funding;
Brief description of project's goals: The main goal of the project is to develop a patient-centered care model for advanced liver disease, including risk-prediction models and clinician-patient collaborative treatment planning guides that focus on addressing patient unmet needs and expectations about illness course and care preferences for curative, supportive, and palliative care. The study findings will have direct impacts on current advanced liver disease care, as well as provide evidence for developing innovative care models for other serious chronic illnesses.
% Overlap: None

Title: VA IIR 16-025 Less is More: Improving Antimicrobial Stewardship for Asymptomatic Bacteriuria
Role on project: Co-Investigator
AIMS: 1) Conduct formative assessments of context, barriers and facilitators at each of the four VA medical sites to inform intervention implementation; 2) Evaluate implementation of a scalable version of the Kicking CAUTI intervention in four geographically distinct VA medical centers, including acute and long-term care settings, with four contemporaneous controls; 3) Assess the financial implications of the intervention through a budget impact analysis
Time Commitment (Level of Effort): 0.6 calendar months
Supporting Agency: VA HSR&D
Name and address of funding agency's Grant Officer:
Cathie Plouzek, PhD, PMP
Health Services Research and Development (10P9H)
Office of Research and Development, VA Central Office
Department of Veterans Affairs
810 Vermont Avenue NW
Washington, DC 20420
Phone:
Cell:
E-mail: cathie.plouzek@va.gov
Performance Period: 02/2018-01/2021
Level of funding;
Brief description of project's goals: The main goal of this project is to implement the Kicking UTI intervention across four VA sites nationally. Kicking UTI is an intervention to improve management of

Asymptomatic Bacteriuria in Veterans in hospitals and long-term care, to protect Veterans from the harms of unnecessary antibiotic use. It was designed and validated in a previous study.
% Overlap: None

Title: 5R01CA212008-02 Harms of Hepatocellular Carcinoma Screening in Patients with Cirrhosis
Role on project: Co-Investigator
AIMS: 1) Assess the effect of HCC screening on a) physical harms due to follow-up tests, b) financial harms, and c) overdiagnosis in patients with severe liver dysfunction or comorbid illness, through electronic medical record data, manual chart review, and validated survey measures; 2) Assess the effect of HCC screening on screening-related psychosocial harms, e.g. cancer-specific worry, situational anxiety, mood disturbances, and decisional regret, through longitudinal validated measures and qualitative interviews; 3) Create and disseminate a balance sheet of benefits and harms to inform patients, nurses, providers, healthcare organizations, payers, and policymakers about the value of HCC screening in patients with cirrhosis.
Time Commitment (Level of Effort): 0.6 calendar months
Supporting Agency: National Cancer Institute
Name and address of funding agency's Grant Officer:
Crystal Wolfrey
Chief Grants Management Officer
National Cancer Institute
Office of Grants Administration
9609 Medical Center Drive
West Tower, 2nd floor
Rockville MD 20850
wolfreyc@mail.nih.gov,
Tel.
Performance Period: 08/2017-07/2022
Level of funding;
Brief description of project's goals: The purpose of this study is to investigate the harms that may be associated with screening for HCC in patients with cirrhosis recruited from 4 medical centers in Texas.
% Overlap: None

Title: PR181562 Risk of hepatocellular cancer after virological cure with direct acting antiviral agents in individuals with hepatitis C (subject grant)
Role on project: Co-Investigator
AIMS: 1) To examine determinants of HCC in virologically cured patients and develop a risk prediction model for HCC in these patients; 2) To evaluate benefits versus harms of HCC surveillance in virologically cured patients; 3) To develop HCC Simulator, an online interactive tool for physicians and patients that provides the short- and long-term value of HCC surveillance in different risk groups.
Time Commitment (Level of Effort): 2.4 calendar months
Supporting Agency: Department of Defense Office of Congressionally Directed medical Research Programs (CDMRP)
Name and address of funding agency's Grant's Officer:
Annmarie Gersch, Ph.D.
Science Officer
Congressionally Directed Medical Research Programs (CDMRP)
US Army Medical Research Materiel Command (USAMRMC)
1054 Patchel Street
Ft. Detrick, MD 21702-5024
PH:
Email: annmarie.gersch.ctr@mail.mil
Performance Period: 07/2019-06/2022
Level of funding;
Brief description of project's goals: The goal of this study is to examine the risk and determinants of hepatocellular carcinoma (HCC) in patients with chronic hepatitis C (CHC) virologically cured with new direct acting antiviral agent (DAA) regimens and to identify cost-effective strategies for early detection of HCC in those patients.
% Overlap: None

PENDING

Title: 1 I01 BX004183-01A1 Million Veteran Program (MVP); Subaward – Immunogenetic determinants of HPV-related head and neck cancer in Veterans (project in JIT)
Role on project: Co-Investigator
AIMS: 1) To utilize clinical data to phenotype four study cohorts within the MVP: cancer-free controls, HPVOPC, OPC, and non-OPC HNSCC patients; 2) To perform parallel integrative analysis of the association between polymorphism of immune genes and HPVOPC, OPC, and non-OPC HNSCC.
Time Commitment (Level of Effort): 0.6 calendar months
Supporting Agency: VA HSR&D
Name and address of funding agency's Grant Officer:
Jennifer Moser
Department of Veterans Affairs (VACO 10X2)
1100 First Street NE
Washington, DC 20002
Jennifer.moser@va.gov
Tel.
Performance Period: 07/2019-06/2021
Level of funding;
Brief description of project's goals: To determine the clinical predictors, and genotypic variation in immune-related genes is associated with risk of OPC, an HPV-related cancer among Veterans.
% Overlap: None

OVERLAP

None

PREVIOUS, CURRENT, AND PENDING SUPPORT (PCPS)

AANAND D. NAIK, M.D.

PREVIOUS

Title: AHA Mentored Clinical & Population Research Award:*Optimizing Patient-Initiated Post-Discharge Care for Patients with Heart Failure*
Role on project: Primary Mentor (PI: Horstman)
AIMS: 1) Determine how the frequency and distribution of different types of post-discharge care affects unplanned 30-day hospital readmissions for patients with heart failure; 2) Explore the patient and provider experience with patient-initiated post-discharge care following a patient hospital admission for heart failure.
Time Commitment (Level of Effort): 0.1 calendar months
Supporting Agency: AHA AWRP Summer 2016 Career Awards
Name and address of funding agency's Grant's Officer:
Science Officer: April Ciesla
Program Coordinator
American Heart Association Inc.
7272 Greenville Ave.,
Dallas, TX
E-mail: April.ciesla@heart.org
Phone:
HQ Phone:
Performance Period: 01/2017-12/2019
Level of funding: total
Brief description of project's goals:
mentored career development award to understand the communication patterns and team dynamics of patient and caregiver dyads with healthcare professionals at the time of discharge for CHF.
% Overlap: None.

Title: Integrating Patient Priorities Care and Social Work Case Management.

Role on project: PI
AIMS: 1) Partner with VA facility leaders to cultivate the practice changes needed for PPC and promote local champions; 2) Develop a toolkit for reliably conducting PPC in routine VA encounters across sites.
Time Commitment (Level of Effort): 0.3 calendar months
Supporting Agency: VHA Office of Rural Health, VA Office of Social Work
Name and address of funding agency's Grant's Officer:
Laura Taylor, LSCSW
National Director, Social Work
VA Central Office
Office of Academic Affiliations (10A2D)
Department of Veterans Affairs
810 Vermont Ave NW
Washington, DC 20420
E-mail: laura.taylor@va.gov
Phone:
Performance Period: 10/1/17-9/30/2019
Level of funding:
Brief description of project's goals:
Study will develop prognostic models for advanced liver disease predicting mortality, complications, and hospitalizations as well as a mixed methods qualitative exploration of patients, caregivers, and health professionals' values, goals, and expectations of care and outcomes in the setting of advanced liver disease.
% Overlap: None.

Title: Patient Priorities Care Implementation
Role on project: Program Director
AIMS: 1) Evaluate current demonstration projects to inform wider dissemination; 2) Develop Healthcare Improvement (HI) portfolio to guide widespread implementation of PPC in VA local practices; 3) Build a phase 2 training program with the Employee Education Service (EES) to focus on advanced training for clinicians (stemming from current phase 1 program with EES); 4) form a community of practice to support trained clinicians in the longitudinal application of the PPC approach.
Time Commitment (Level of Effort): 0.6 calendar months
Supporting Agency: VHA Geriatrics and Extended Care Line
Name and address of funding agency's Grant's Officer:
Marianne Shaughnessy, PhD, CRNP
Director, Facility-Based Programs Policy
Department of Veterans Affairs
810 Vermont Ave (10NC4)
Washington, DC 20420
E-mail: marianne.shaughnessy@va.gov
Phone:
Performance Period: 10/1/2018-9/30/2019
Level of funding:
Brief description of project's goals:
Goal of this project is to identify and implement a reliable and efficient process for eliciting goals and preferences for complex, multi-morbid Geriatric patients. The process is designed to facilitate the achievement of patients' health outcome goals and to reduce the burden of medical and mental health morbidities.
% Overlap: None.

Title: Patient Priorities Care Intervention for Older Adults with Dementia
Role on project: Co-Investigator
AIMS: 1) Adapt the Patient Priorities Care (PPC) program for a population of cognitively-impaired Veterans and their caregivers with expert input from a clinical team at the Michael E. DeBakey VA Medical Center; 2) Pilot the Patient Priorities Care (PPC) program developed in aim 1 with 20 Veterans with cognitive impairment and their caregivers; 3) Evaluate how the mobility, activities of daily living (IADLs), and social engagement of Veterans change due to implementation of Patient Priorities Care (PPC).
Time Commitment (Level of Effort): 0.6 calendar months
Supporting Agency: South Central MIRECC

Name and address of funding agency's Grant's Officer:
Wendell S. Perkins
Budget Analyst
South Central MIRECC, Little Rock, Arkansas
Central Arkansas Veterans Healthcare System
4300 West 7th Street
Little Rock, AR 72205
E-mail: Wendell.perkins@va.gov
Phone:
Performance Period: 12/2018-09/2020
Level of funding:
Brief description of project's goals:
Adapt PPC for dementia care to explicitly define priorities of Veterans with dementia and their caregivers in the EHR, guide clinicians to change treatments to better align with priorities, and objectively measure if treatments help to achieve priorities.
% Overlap: None.

Title: Project # IK2RX001241-01A2: Improving Veteran Transitions from VA Community living Centers to the Community
Role on project: Co-mentor, (PI: Mills)
AIMS: 1) Understand current environment, discharge planning, and outcomes in community living centers (CLCs); 2) Development of the Everyday Competence Assessment and Planning for Community Transitions (ECAP-CT) toolkit for CLC interdisciplinary team members using information gathered in aim 1; 3) Effectiveness trial of ECAP-CT toolkit in the Houston and Tuscaloosa CLCs.
Time Commitment (Level of Effort): 0.1 calendar months
Supporting Agency: VA Rehab R&D
Name and address of funding agency's Grant's Officer:
Jay Freedman
Special Program Manager & Career Development Program
Veterans Affairs Rehabilitation Research and Development Service
810 Vermont Ave., NW
Washington, DC 20420
E-Mail: jay.freeman@va.gov
Phone:
Phone:
Performance Period: 07/2014-06/2022
Level of funding: sub-award
Brief description of project's goals:
Mentored, Career Development Award developing and testing intervention to improve transitions from VA long-term care facilities to home and to reduce failures to transitions and avoidable readmissions.
% Overlap: None.

CURRENT

Title: HSR&D Project # IIR 16-075 (Application # 1 I01 HX002204-01A2) Patient Centered Care for Individuals with Advanced Liver Disease
Role on project: Co-PI (MPI: Naik & Kanwal)
AIMS: 1) To develop risk stratification models of advanced liver disease (AdvLD) prognosis; 2) To describe patients' experiences and goals of AdvLD care; 3) To identify clinicians' perceptions of opportunities and barriers to patient-centered AdvLD care.
Time Commitment (Level of Effort): 3.0 calendar months
Supporting Agency: VA HSR&D Research Line
Name and address of funding agency's Grant's Officer:
Cathie Plouzek, PhD, PMP
Health Services Research and Development (10P9H)
Office of Research and Development, VA Central Office

Department of Veterans Affairs
810 Vermont Avenue NW
Washington, DC 20420
Phone:
Cell:
E-mail: cathie.plouzek@va.gov
Performance Period: 05/2018-04/2021
Level of funding: (total)
Brief description of project's goals: Study will develop prognostic models for advanced liver disease predicting mortality, complications, and hospitalizations as well as a mixed methods qualitative exploration of patients, caregivers, and health professionals' values, goals, and expectations of care and outcomes in the setting of advanced liver disease.
% Overlap: None.

Title: Southeast Texas Geriatric Workforce Enhancement Program (SETx-GWEP)
Role on project: PI
AIMS: Establish an interprofessional geriatrics education and training consortium to engage primary care providers and the full spectrum of healthcare and community health professionals in a highly targeted integrated geriatrics and primary care training model to improve health outcomes for older adults.
Time Commitment (Level of Effort): 1.20 calendar months
Supporting Agency: Health Resources and Services Administration
Name and address of funding agency's Grant's Officer:
Nina Tumosa
Program Contact
553 Bragg Hill Rd
Fairlee, VT, 05045-4405
Email: ntumosa@hrsa.gov
Phone:
Performance Period: 07/01/2019-06/30/2024
Level of funding:
Brief description of project's goals:
Collaborators will develop and deliver programming for the SETx-GWEP to advance a healthcare workforce that provides optimal, value-conscious care to older adults and their families that maximizes patient and family engagement and improves healthcare processes and outcome for older adults.
% Overlap: None.

Title: Patient Priorities Care: Dissemination and Scaling Phase for Patients with Heart Failure
Role on project: Co-Investigator (PI: Tinetti)
AIMS: Building on the pilot work of the original Patient Priorities Care pilot project, the aims of the Houston site will support project dissemination and scaling. Dr. Naik and the BCM team will work to prepare technical assistance, products, and training that enables adoption of Patient Priorities Care. They will participate in training of expert faculty as well as provide consultation to practices and clinicians implementing Patient Priorities Care.
Time Commitment (Level of Effort): 1.2 calendar months
Supporting Agency: John A. Hartford Foundation
Name and address of funding agency's Grant's Officer:
Mark Barreiro, MS
Senior Grants Officer
The John A. Hartford Foundation
55 E. 59th Street
16th Floor
New York, NY 10022-1713
E-mail: mark.barreiro@johnhortford.org
Phone:
Performance Period: 11/2018-10/2022
Level of funding: sub-award
Brief description of project's goals:

Develop and pilot test a model of patient goals directed care to guide integration of primary and specialty care services in a certified patient centered medical home.
% Overlap: None.

Title: VA Quality Scholars Program: Coordinating Center for the VA Quality Scholars Program
Role on project: Program Director
AIMS: 1) To iteratively enhance the existing VAQS curriculum in partnership with VAQS senior scholars. 2) To facilitate recruitment, performance, and placement of interprofessional clinicians who will be the next generation of quality scholars. 3) To link fellows with senior scholars across VAQS sites and the spectrum of VA quality and patient safety programs.
Time Commitment (Level of Effort): 3.0 calendar months
Supporting Agency: VA Office of Academic Affiliations
Name and address of funding agency's Grant's Officer:
Bonnie S. Graham, MBA
Director, San Francisco VA Health Care System
4150 Clement St.,
San Francisco, CA 94121
E-mail: bonnie.graham@va.gov
Phone:
Performance Period: 07/2014-09/2021
Level of funding: (annually)
Brief description of project's goals:
The VA's premier training program for post-doctoral physicians and doctoral-trained nurses in quality improvement and patient safety across eight national VA centers. The Coordinating Center delivers a national curriculum, conducts program evaluation, manages a week-long Summer Institute, and assists with program recruitment, marketing, and internet communications
% Overlap: None.

Title: VA Advanced Fellowships in HSR: Advanced Fellowships Program in Health Services Research (MD/PhD Post-doctoral Fellowships Program)
Role on project: Program Director
AIMS: Program Goal 1: To produce interprofessional team scientists who embrace an HSR identity and contribute to improvements in healthcare outcomes and services in VA. Program Goal 2: To develop a pipeline of interprofessional team scientists by recruiting, mentoring and developing social, organizational and behavioral scientists through formative post-doctoral training in HSR. Program Goal 3: To integrate clinical and operations partners into fellows' mentoring teams and cultivate implementation and partnership research training as a cardinal element of our Education and Training mission.
Time Commitment (Level of Effort): 1.8 calendar months
Supporting Agency: VA Office of Academic Affiliations/HSR&D Service
Name and address of funding agency's Grant's Officer:
Science Officer: Karen Sanders, MD
Deputy Chief Academic Affiliations Officer
Veterans Health Administration
Department of Veterans Affairs
810 Vermont Ave NW
Washington, DC 20420
E-Mail: karen.sanders@va.gov
Phone:
Performance Period: 02/2015-09/2022
Level of funding:
Brief description of project's goals:
Direct the overall health services research fellowships for advance MD and PhD post-doctoral fellows. This program has been continuously funded since 2004 (successful renewal in 2015).
% Overlap: None.

Title: Big-Data Scientist Training Enhancement
Role on project: Program Director

AIMS: Objective 1: All BD-PCOR Fellows participate in a Core Curriculum. Objective 2: BD-PCOR Fellows participate in an interprofessional mentoring program. Objective 3: BD-PCOR fellows conduct mentored research leading to scholarly products. Objective 4: BD-PCOR Fellows work with their mentors to identify relevant didactic learning opportunities.
Time Commitment (Level of Effort): 0.6 calendar months
Supporting Agency: VA OAA/National Cancer Institute
Name and address of funding agency's Grant's Officer:
Deborah Ludke, MHA
Administrative Officer, Advanced Fellowships and Professional Development
Long Beach VA Medical Center (11/111)
5901 East Seventh Street
Long Beach, CA 90822
E-mail: Deborah.ludke@va.gov
Phone:
Performance Period: 10/2015-09/2022
Level of funding: annual
Brief description of project's goals:
Houston BD-STEP program goal is to provide mentored-training for quantitative scientists from engineering, natural sciences, and computing in large dataset analytical models using VA healthcare data infrastructure.
% Overlap: None.

Title: Project # PR181562: Risk of hepatocellular cancer after virological cure with direct acting antiviral agents in individuals with hepatitis C (subject grant)
Role on project: Co-Investigator (PI: Kanwal; Co-PI: Chhatwal)
AIMS: 1) To examine determinants of HCC in virologically cured patients and develop a risk prediction model for HCC in these patients; 2) To evaluate benefits versus harms of HCC surveillance in virologically cured patients; 3) To develop HCC Simulator, an online interactive tool for physicians and patients that provides the short- and long-term value of HCC surveillance in different risk groups.
Time Commitment (Level of Effort): 0.6 calendar months
Supporting Agency: Department of Defense Office of Congressionally Directed medical Research Programs (CDMRP)
Name and address of funding agency's Grant's Officer:
Annmarie Gersch, Ph.D.
Science Officer
Congressionally Directed Medical Research Programs (CDMRP)
US Army Medical Research Materiel Command (USAMRMC)
1054 Patchel Street
Ft. Detrick, MD 21702-5024
PH:
Email: annmarie.gersch.ctr@mail.mil
Performance Period: 07/2019-06/2022
Level of funding:
Brief description of project's goals:
The goal of this study is to examine the risk and determinants of hepatocellular carcinoma (HCC) in patients with chronic hepatitis C (CHC) virologically cured with new direct acting antiviral agent (DAA) regimens and to identify cost-effective strategies for early detection of HCC in those patients.
% Overlap: None.

PENDING

Title: Effect of Patient Priorities Care Implementation in Older Veterans with Multiple Chronic Conditions
Role on project: Principal Investigator
AIMS: 1) Using our primary care-research partnership, we will conduct a formative assessment of PPC

implementation for Veterans with MCC and develop implementation tools; 2) Evaluate the effectiveness of PPC in a randomized controlled study at two VA primary care centers; 3) Conduct a summative assessment of implementation outcomes of PPC in VA primary care.
Time Commitment (Level of Effort): 3.6 calendar months
Supporting Agency: VA HSR&D Research Line
Name and address of funding agency's Grant's Officer:
Cathie Plouzek, PhD, PMP
Health Services Research and Development (10P9H)
Office of Research and Development, VA Central Office
Department of Veterans Affairs
810 Vermont Avenue NW
Washington, DC 20420
Phone:
Cell:
E-mail: cathie.plouzek@va.gov
Performance Period: 07/01/2021-06/30/2025
Level of funding:
Brief description of project's goals:
The goal of this study is to determine if the PPC approach can reduce treatment burden and increase care that is better aligned with patient priorities compared to usual care. The study also identifies barriers and promotors to providing the PPC model in routine VA care.**%**
Overlap: None.

OVERLAP
There is no overlap between current projects and this application.

PREVIOUS, CURRENT, AND PENDING SUPPORT (PCPS)

LIANG LI, Ph.D.

PREVIOUS

Title/Grant Number:	Joint analysis of longitudinal outcomes and clinical events in kidney disease / 5R01DK090046-04
Effort:	1.92 Calendar Months, 16% Effort
Supporting Agency:	NIH/NIDDK
Grants Officer:	Kevin Abbott, kevin.abbott@nih.gov
Performance Period:	6/20/2011-5/31/2016
Funding Amount:	
Project Goals:	To develop novel statistical methodology to jointly analyze longitudinal biomarkers and clinical events. PID1289
Specific Aims:	Aim 1: To develop practical methods to relate exposures to the evolution of cohorts as characterized by changes in multi-state distributions defined by joint longitudinal/ time-to-event outcomes Aim 2: To develop practical methods to estimate subject-specific trajectories under flexible joint models and relate these trajectories to treatments, exposures, and clinical events Aim 3: To apply the causal modeling framework of principal stratification to provide unbiased and conceptually coherent analyses of effects of exposures and treatments on a longitudinal outcome while accounting for attrition due to death and ESRD.
Overlap:	None
Title/Grant Number:	Media-rich mobile dissemination of a dysphagia prevention program for head and neck cancer patients during radiation / PP150077
Effort:	0.24 Calendar Months, 2% Effort

Supporting Agency: Cancer Prevention & Research Institute of Texas (CPRIT)
Grants Officer: Patricia Moore, cprit@cprit.state.tx.us
Performance Period: 6/1/2015-5/30/2020
Funding Amount:
Project Goals: To provide evidence based speech pathology functional swallow evaluation. PID600053 (Completed 12/31/2019)
Specific Aims:
Aim 1: Pre- and post-treatment and targeted swallowing exercises to head and neck cancer patients during radiation.
Aim 2: To administer an effective adherence program via a mobile health technology application (GuideVue) to head and neck cancer patients during radiation.
Aim 3: To lay the groundwork for future dissemination of this prevention program.
Overlap: None

Title/Grant Number: The Texas Hepatocellular Carcinoma Consortium (THCCC) Core 2: (SCC) / RP150587
Effort: 0.60 Calendar Months, 5% Effort
Supporting Agency: Subaward from Baylor College of Medicine pass through from CPRIT
Grants Officer: Patricia Moore, cprit@cprit.state.tx.us
Performance Period: 6/1/2015-5/31/2020
Funding Amount:
Project Goals: Provide critical statistical, data management, and multi-center study coordination and support for all projects in the consortium. PID600060
Specific Aims:
Aim 1: Use Texas VA datasets to assemble the largest NAFLD-to-HCC study to date (including over 45,000 NAFLD patients in Texas) to determine the number of patients to develop HCC and to identify factors that increase patients' risk for HCC.
Aim 2: Develop risk stratification algorithms based on demographic, clinical, molecular and epidemiological risk factors to identify cirrhosis patients who might benefit from prevention or intensive surveillance.
Aim 3: Identify pathways for chemoprevention related to the role of circadian rhythm and bile acids in AFLD, metabolic syndrome, and HCC.
Aim 4: Identify and validate novel blood markers (tests) for early HCC detection.
Aim 5: Comparative effectiveness randomized controlled trial of strategies to increase HCC surveillance.
Overlap: None

Title/Grant Number: Socioeconomic status, stress, and smoking cessation / 1R01CA190329-01A1
Effort: 0.84 Calendar Months, 7% Effort
Supporting Agency: NIH subaward William Marsh Rice University
Grants Officer: Hartman, Anne anne_hartman@nih.gov
Performance Period: 7/1/2015-11/30/2016
Funding Amount:
Project Goals: Examine the influence of SES and social history, contextual and environmental influences, biobehavioral/psychosocial predispositions, and acute momentary precipitants on stress, smoking lapse, and abstinence among 300 smokers attempting to quit. PID3412
Specific Aims:
Aim 1: Adapt and validate puffMarker to identify discrete episodes of ENDS use
Aim 2: Adapt and validate puffMarker to distinguish between cigarette smoking and ENDS use among dual users of ENDS and cigarettes
AIM 3: Utilize the Project On Track protocol to collect real time, real world data investigating potential determinants of ENDS use among both exclusive ENDS users as well as dual users of cigarettes and ENDS.
Overlap: None

Title/Grant Number: Reducing cancer disparities amongst Latinos in Texas / 3U54CA153505-05S2
Effort: 1.20 Calendar Months, 10% Effort
Supporting Agency: NIH/NCI

Grants Officer: Perruccio, Elizabeth M perruccioem@mail.nih.gov
Performance Period: 9/1/2015-8/31/2016
Funding Amount:
Project Goals: To increase the use of evidence-based biomedical and behavioral procedures and interventions to reduce the cancer burden among Latinos in Texas PID2367
Specific Aims: Aim 1: Evaluate the efficacy of a Motivation and Problem Solving (MAPS) approach to promoting and facilitating cancer risk reduction among high-risk Mexican American individuals.
Aim 2: Assess the effects of MAPS on hypothesized treatment mechanisms.
Overlap: None

Title/Grant Number: Dynamic prediction of clinical outcomes using biomarkers and other prognostic information in longitudinal cohort studies of CKD / 5U01DK103225-02
Effort: 1.2 Calendar Months, 10% Effort
Supporting Agency: Subaward from the University of Pennsylvania/Chronic Kidney Disease Biomarker Consortium
Grants Officer: Paul Kimmel, kimmelp@niddk.nih.gov
Performance Period: 9/1/2015-6/30/2017
Funding Amount:
Project Goals: To develop novel statistical methodology and software for predicting time to event outcomes using longitudinal data. PID3560
Specific Aims: Aim 1: To develop novel statistical methodology and software for predicting time to event outcomes using longitudinal data
Aim 2: To apply the proposed statistical methodology to a kidney transplant data set and dynamically predict the risk of graft failure using longitudinal biomarkers and clinical history.
Overlap: None

Title/Grant Number: Consortium for the Study of Chronic Pancreatitis, Diabetes and Pancreatic Cancer: Coordinating and Data Management Center (CSCPDPC-CDMC)/ 5U01DK108328-05
Effort: 2.11 Calendar Months, 17.61% Effort
Supporting Agency: NIH/NIDDK
Grants Officer: Aynur Unalp-Arida, aynur.unalp-arida@nih.gov
Performance Period: 9/28/2015-8/31/2020
Funding Amount:
Project Goals: Coordinate the research efforts and will manage and analyze the data for the Consortium under the direction of the Consortium Steering Committee (SC). PID3496
Specific Aims: Aim 1: Provide coordination of the Consortium in order to enhance communication and collaboration among Consortium investigators and with the larger scientific communities.
Aim 2: provide scientific and statistical leadership for the Consortium in research strategy, study design approaches, and statistical and computational methods
Aim 3: coordinate Consortium collaborative studies.
Overlap: None

Title/Grant Number: CLL moon shot: other cancers pilot project health maintenance initiatives / 710499-80-111537-19
Effort: 0.36 Calendar Months, 3% Effort
Supporting Agency: MDACC CLL Moon Shot
Grants Officer: Danielle Walsh, 713-563-3642, dmwalsh@mdanderson.org
Performance Period: 12/1/2015-11/30/2016
Funding Amount:
Project Goals: Develop MOST methodology, assist with study design and data analyses. (effort only, no salary support)
Specific Aims: For CLL patients, clinical studies have not shown a benefit to beginning treatment

immediately after diagnosis versus when the disease develops to a set point, known as an indication for treatment. Because of this, doctors often recommend "watchful waiting" for early stage CLL.

Overlap: None

Title/Grant Number: Using game mechanics to improve among stem cell transplant/ 2R42CA168107-03
Effort: 0.6 Calendar Months, 5% Effort
Supporting Agency: Subaward via Radiant Creative Group, LLC
Grants Officer: Patricia A Weber; weberpa@mail.nih.gov
Performance Period: 12/1/2015-11/30/2018
Funding Amount:
Project Goals: To develop an innovative interactive online intervention that utilizes novel social game mechanics to promote improved self-management behaviors among patients who have undergone hematopoietic stem cell transplantation for treatment of leukemia and lymphoma. PID4024
Specific Aims: To determine the impact of the intervention during the post-HSCT phase, and to evaluate changes and trends in the psychosocial and behavioral outcomes during the immediate post-HSCT recovery phase. The proposed study will advance scientific knowledge on the impact of game mechanics and social networking on patient behavior, and will provide insights, evidence, and guidance on how to build practical online social intervention systems to support behavioral change in AYAs.
Overlap: None

Title/Grant Number: Visualizing T-cell Trafficking/ RP160013
Effort: 0.12 Calendar Months, 1% Effort
Supporting Agency: Cancer Prevention & Research Institute of Texas (CPRIT)
Grants Officer: Patricia Moore, cprit@cprit.state.tx.us
Performance Period: 3/1/2016-2/28/2020
Funding Amount:
Project Goals: To develop SSTR2-based methods for marking T-cells in vitro and following T-cells in vivo. PID600080
Specific Aims: 1) Test the hypothesis that human somatostatin receptor type 2 (SSTR2)-based reporters can be created that are deficient in signaling and do not interfere with T-cell function in vitro.
2) Test the hypothesis that non-invasive signaling deficient SSTR2-based reporter imaging can be used to localize T-cells in tumors and assess their expansion at the tumor site.
3) Test the hypothesis that imaging T-cells expressing signaling deficient SSTR2-based reporters can be used to predict tumor response.
4) Test the hypothesis that T-cells expressing signaling deficient SSTR2-based reporters persist against a subsequent tumor challenge. Thus, this proposal uses innovative methods to address significant unmet needs required to advance T-cell therapy.
Overlap: None

Title/Grant Number: Eliminating tobacco-related disparities among African Americans / R01MD010362-01
Effort: 1.2 Calendar Months, 10% Effort
Supporting Agency: NIH via Subaward agreement Rice University
Grants Officer: Zhang, Xinzhi zhangx12@mail.nih.gov
Performance Period: 03/03/2016-11/30/2016
Funding Amount:
Project Goals: To examine the influence of social determinants, biobehavioral/psychosocial predispositions, contextual/environmental influences, and acute momentary precipitants on smoking lapse and abstinence amount 200 African American

smokers attempting to quit. PID4126

Specific Aims: Aim 1: Influence of demographics and social history, bio-behavioral/psychosocial predispositions, contextual and environmental influences, and acute precipitants on smoking lapses among AA smokers.
Aim 2: Influence of demographics and social history, bio-behavioral/psychosocial predispositions, contextual and environmental influences, and acute precipitants on early and long-term abstinence from smoking among AA smoke.

Overlap: None

Title/Grant Number: Using hunger training to enhance weight loss and modulate cancer-related biomarkers in women at high risk for breast cancer; a pilot study / 1R21CA215415-01A1

Effort: 0.24 Calendar Months, 2% Effort

Supporting Agency: NIH/NCI

Grants Officer: Tanya Agurs-Collins, collinsta@mail.nih.gov

Performance Period: 8/11/2017-7/31/2019

Funding Amount:

Project Goals: To pilot test the synergistic effect of adding Hunger Training to a highly-disseminated, evidence-based lifestyle intervention (Diabetes Prevention Program; DPP) on weight loss outcomes and on metabolic and breast cancer risk biomarkers in a sample of obese postmenopausal women. PID6143. Effort completed as of 6/1/2018; PI left institution.

Specific Aims: Aim 1: Determine the feasibility of adding Hunger Training to the DPP using the following criteria: accrual rates >50%, attrition rates <20% and, in the DPP-plus-HT group, training protocol adherence rates >75%.
Aim 2: Estimate the magnitude of effect sizes and variation in outcome variables for the DPP-only and DPPplus- HT interventions on changes in weight; in metabolic and breast cancer risk biomarkers (e.g., fasting insulin and BG levels, levels of glycosylated hemoglobin, insulin resistance, adiponectin, interleukin-6, and Creactive protein); and in proposed behavioral mediators (e.g., reduction in total energy intake, overall eating frequency, percent of eating events occurring at or below the average fasting blood BG level).

Overlap: None

Title/Grant Number: Using hunger training to enhance weight loss and modulate cancer-related biomarkers in women at high risk for breast cancer; a pilot study / 1R21CA215415-01A1

Effort: 0.12 Calendar Months, 1% Effort

Supporting Agency: NIH/NCI

Grants Officer: Agurs-Collins, Tanya, collinsta@mail.nih.gov

Performance Period: 8/11/2017-7/31/2019

Funding Amount:

Project Goals: To pilot test the synergistic effect of adding Hunger Training to a highly-disseminated, evidence-based lifestyle intervention. PID6143

Specific Aims: Aim 1: Determine the feasibility of adding Hunger Training to the DPP using the following criteria: accrual rates
>50%, attrition rates <20% and, in the DPP-plus-HT group, training protocol adherence rates >75%.
Aim 2: Estimate the magnitude of effect sizes and variation in outcome variables for the DPP-only and DPPplus-
HT interventions on changes in weight; in metabolic and breast cancer risk biomarkers (e.g., fasting insulin and BG levels, levels of glycosylated hemoglobin, insulin resistance, adiponectin, interleukin-6, and Creactive protein); and in proposed behavioral mediators (e.g., reduction in total energy intake, overall eating frequency, percent of eating events occurring at or below the average fasting blood

BG level).
Overlap: Completed 5/31/2019

Title/Grant Number: Eliminating tobacco-related disparities among African Americans/5R01MD010362-04
Effort: 1.3 Calendar Months, 10.83% Effort
Supporting Agency: NIH/NHMD Subaward via Utah University
Grants Officer: Xinzhi Zhang, zhangx12@mail.nih.gov
Performance Period: 08/28/2017-01/31/2021
Funding Amount:
Project Goals: To examine the influence of demographics and social history, bio-behavioral and psychosocial predispositions, contextual and environmental factors, and acute individual and contextual precipitants on smoking lapse and abstinence. PID 5129 Effort complete as of 1/31/2019.
Specific Aims: Aim 1: Influence of demographics and social history, bio-behavioral/psychosocial predispositions, contextual and environmental influences, and acute precipitants on smoking lapses among AA smokers.
Aim 2: Influence of demographics and social history, bio-behavioral/psychosocial predispositions, contextual and environmental influences, and acute precipitants on early and long-term abstinence from smoking among AA smoker.
Overlap: None

Title/Grant Number: Affective science and smoking cessation: Real time real world assessment/ 1R01CA224537-01
Effort: 0.5 Calendar Months, 4.17% Effort
Supporting Agency: NIH via subaward from University of Utah
Grants Officer: Rebecca Ferrrer, ferrerra@mail.nih.gov
Performance Period: 01/1/2018-12/31/2022
Funding Amount:
Project Goals: To create a more detailed and comprehensive conceptual model of the role of distinct emotions in self-regulation. PID6397 Effort complete as of 12/31/2018.
Specific Aims: Aim 1: Models the impact of distinct emotions on SRC and smoking lapse, both in the moment and as trajectories over time. Aim 1 will also examine how the impact of specific emotions may differ based on the levels of other emotions (e.g., “blended” emotional states).
Aim 2: Investigates whether the associations of affective experience with SRC and lapse are modified by contextual factors.
Overlap: None

CURRENT

Title/Grant Number: Comparative Effectiveness Research on Cancer in Texas (CERCIT) 2.0: Data Core / RP160674
Effort: 0.96 Calendar Months, 8% Effort
Supporting Agency: Cancer Prevention & Research Institute of Texas Subaward via UTMB
Grants Officer: Patricia Moore, cprit@cprit.state.tx.us
Performance Period: 6/1/2016-5/31/2021
Funding Amount:
Project Goals: To create a statewide resource for outcomes and comparative effectiveness research in cancer for Texas. PID4721
Specific Aims: Aim 1: Create Data Resource of linked cancer and claims data for Texas residents.
Aim 2: Use data resource to examine the entire trajectory of cancer care in Texas.
Aim 3: Train the next generation of cancer outcomes and comparative effectiveness investigators in Texas.
Aim 4: Disseminate Findings.
Overlap: None

Title/Grant Number:	Multi-Site Development & Evaluation of a Quantitative 3D Hyperpolarized C-13 MRI Clinical Prostate Cancer Exam/ 5R01CA211150-03
Effort:	0.24 Calendar Months, 2% Effort
Supporting Agency:	NIH/NCI
Grants Officer:	Huiming Zhang, zhanghui@mail.nih.gov,
Performance Period:	03/1/2017-02/28/2022
Funding Amount:	
Project Goals:	Demonstrating new and improved imaging methods that enhance image quality, and consequently, improve sensitivity and specificity of minimally invasive metabolic imaging strategies (1% effort eff 9.1.18, 2% in year 3). PID5247
Specific Aims:	Aim 1: Establish a method for external validation of HP MRI measurements. Aim 2: Implement highly optimized preclinical dynamic HP MRS and MRI protocols and a robust constrained reconstruction algorithm for quantifying tumor metabolism using HP [1-13C]-pyruvate. Aim 3: Develop a data-driven HP MRI protocol and establish imaging characteristics in patients with head and neck cancers.
Overlap:	None

Title/Grant Number:	Socioeconomic status, stress, and smoking cessation / 5R01CA190329-06
Effort:	0.12 Calendar Months, 1% Effort
Supporting Agency:	NIH/NCI Subaward via University of Utah
Grants Officer:	Xinzhi Zhang, zhangx12@mail.nih.gov
Performance Period:	7/1/2017-06/30/2021
Funding Amount:	
Project Goals:	To examine the influence of socioeconomic status and social history, contextual and environmental influences, bio-behavioral/psychosocial predispositions, and acute momentary precipitants on stress, smoking lapse, and abstinence PID5135. Effort to resume in Years 5 and 6
Specific Aims:	Aim 1: Delineates the key hypothesized pathway linking SES to stress to smoking lapse/abstinence. Aim 2: Delineates the key hypothesized links of environment/context and bio-behavioral/psychosocial predispositions with SES, smoking lapse/abstinence, and stress. Aim 3: Examines the dynamic relationships of acute precipitants and stress, and their influence on lapse/abstinence.
Overlap:	None

Title/Grant Number:	Estimating the Cost Trajectories and Projecting the Cost of Cancer Care in the United States: Methodology and Application / 5R01CA225646-02
Effort:	2.4 Calendar Months, 20% Effort
Supporting Agency:	NIH/NCI
Grants Officer:	Martinson Owusu, owusumo@mail.nih.gov
Performance Period:	7/5/2018-6/30/2023
Funding Amount:	
Project Goals:	To develop novel methodology and apply the methodology to estimate and project the future cost of cancer care in the US. PID6729
Specific Aims:	Aim 1: To develop new statistical methods to model the longitudinal incident costs of cancer patients. Aim 2: To improve the net costing approach by developing innovative propensity score methods for the selection of non-cancer controls. Aim 3: To project the cancer care costs in the United States for the next 10 years. Aim 4: To facilitate the reproducibility and application of the methods developed from this project by developing and disseminating user-friendly software programs.
Overlap:	None

Title/Grant Number:	Magnetic resonance Imaging as a Non-Invasive Method for Assessment of

	Pancreatic fibrosis (MINIMAP): a pilot study/ 5R01DK116963-02
Effort:	0.12 Calendar Months, 1% Effort
Supporting Agency:	NIH/NIDDK via subaward from Indiana University
Grants Officer:	Chelsie Bousum, cbousum@iu.edu
Performance Period:	09/20/2018-06/30/2021
Funding Amount:	
Project Goals:	To evaluate non-invasive methods to detect and quantify pancreatic fibrosis. PID7394. FP00004518
Specific Aims:	The objective of this protocol is to perform statistical analysis of de-identified data for the MINIMAP study.
Overlap:	None
Title/Grant Number:	Dynamic Prediction of Renal Failure Using Longitudinal Prognostic Information among Patients with Chronic Kidney Disease and Kidney Transplant / 1 R01 DK118079-01A1
Effort:	2.4 Calendar Months, 20% Effort
Supporting Agency:	NIH/NCI
Grants Officer:	Kevin C. Abbott, Kevin.abbott@nih.gov
Performance Period:	04/1/2019-03/31/2024
Funding Amount:	
Project Goals:	To develop novel DP methods for kidney/graft failure with adjustment for the competing risk by death, external validation and re-calibration, and creating software for routine use in clinical practice. PID7824
Specific Aims:	Aim 1: Develop novel statistical methodology for dynamic prediction. Aim 2: Develop and externally validate dynamic kidney failure prediction models for (a) patients with CKD and (b) KTx recipients. Aim 3: Develop and disseminate web-based dynamic prediction model software for clinical practice.
Overlap:	None
Title/Grant Number:	Phase 1/2 Trial of Indomethacin in Chronic Pancreatitis (The PAIR Trial)/ 5R21DK117212-02
Effort:	0.12 Calendar Months, 1% Effort
Supporting Agency:	NIH/NIDDK Subaward via Mayo Clinic-Rochester
Grants Officer:	Jose Serrano, serranoj@extra.niddk.nih.gov
Performance Period:	7/12/2019-3/31/2021
Funding Amount:	
Project Goals:	To investigate the pancreatic effects of IN in humans, and to correlate changes in a pancreatitis biomarker with changes in clinical symptoms of CP. PID11646 / FP00005110
Specific Aims:	Aim 1: the primary analysis will be a linear random intercept model that incorporates PJ PGE2 data from both baseline and day 28 from all randomized patients Aim 2: we will use multivariate analysis of variance model (MANOVA) with repeated measures. The multivariate outcomes include patient-related outcomes (BPI and PROMIS-10 scores) and PJ PGE2 concentrations between baseline and day 28.
Overlap:	None
Title/Grant Number:	Risk Of Hepatocellular Cancer After Virological Cure With Direct Acting Anitviral Agents In Individuals With Hepatitis C/ W81XWH-19-1-0689
Effort:	0.84 Calendar Months, 7% Effort
Supporting Agency:	DOD via subaward Baylor College of Medicine
Grants Officer:	Baylor College of Medicine, subaward@bcm.edu
Performance Period:	7/1/2019-6/30/2022
Funding Amount:	
Project Goals:	To examine the determinants of hepatocellular carcinoma (HCC) in patients

	diagnosed with chronic hepatitis C (CHC) who have been virologically cured with the new direct acting antiviral (DAA) regimens. FP00008073 PID11158
Specific Aims:	Aim 1: To examine determinants of HCC in virologically cured patients and develop a risk prediction model for HCC in these patients. Aim 2: To evaluate benefits versus harms of HCC surveillance in virologically cured patients. Aim 3: To develop an HCC Simulator, an online interactive tool for physicians and patients that provides the short- and long-term value of HCC surveillance in different risk groups.
Overlap:	None
Title/Grant Number:	A novel natural history study of medullary thyroid carcinoma: Incorporating the patient perspective to inform advanced disease management / 1R01FD006650-01
Effort:	1.2 Calendar Months, 10 % Effort
Supporting Agency:	NIH/NCI
Grants Officer:	Daniel Lukash, daniel.lukash@fda.hhs.gov,
Performance Period:	9/1/2019-7/31/2023
Funding Amount:	
Project Goals:	To understand the pathway to progressive disease, integrating for the first time patients perspectives. PID8226
Specific Aims:	Aim 1: To fully characterize the disease longitudinally from both the clinical and patient perspectives to understand the significance of each in association with outcome. Aim 2: To derive a treatment algorithm (decision aid) for utilization of MTC drug therapy in which the patient's unique set of values are considered Aim 3: To determine if current and novel biomarkers can be used to enhance decision making in the treatment of advanced disease
Overlap:	None
Title/Grant Number:	Consortium for the Study of Chronic Pancreatitis, Diabetes and Pancreatic Cancer: Coordinating and Data Management Center (CSCPDPC-CDMC) / 2U01DK108328-06
Effort:	2.4 Calendar Months, 20% Effort
Supporting Agency:	NIH/NCI
Grants Officer:	Aynur Unalp-Arida, aynur.unalp-arida@nih.gov
Performance Period:	9/1/2020-6/30/2025
Funding Amount:	
Project Goals:	To provide network coordination and collaborative activities, will provide scientific leadership in study design, statistical support, and computational analyses, and will provide data management and protocol development and execution. PID11706
Specific Aims:	Aim 1: Support Operation and Coordination of CPDPC Aim 2: Continue the Accrual and Follow up of Patients in CPDPC-approved Studies Aim 3: Support the Infrastructure for Biomarker Development, Prevention Studies, and Therapeutic Trials Aim 4: Design and Support New Studies as Selected by the Steering Committee.
Overlap:	This is a continuation of the funded projected. No overlap. Project will not commence until 9/1/2020, then new cycle start date will have effective date of July 1, 2020

PENDING

Title/Grant Number:	Mechanism-based Approach to Pain in Chronic Pancreatitis (MAP-CP Study) / #TBA
Effort:	0.12 Calendar Months, 1% Effort
Supporting Agency:	National Pancreas Foundation subaward via University of Pittsburgh
Grants Officer:	Patter Birsic, pbirsic@pancreasfoundation.org
Performance Period:	10/01/2020-09/30/2021
Funding Amount:	

Project Goals:	To use data and serum collected by the Consortium for the Study of Chronic Pancreatitis, Diabetes, and Pancreatic Cancer as part of the PROCEED study to investigate the subtypes of pain in Chronic Pancreatitis and identify potential biomarkers. MD Anderson is the coordinating center for the PROCEED study and Dr. Li is the lead biostatistician for the consortium. MD Anderson will coordinate and execute statistical analyses for the proposed study.
Specific Aims:	This study is designed to test the hypothesis that patient-derived information can be used to identify pain phenotypes that inform management of chronic pancreatitis-related pain. Aim 1 is designed to determine if individual biomarkers can discriminate pain phenotypes. We will measure expression of selected targets in sera available through the CPDPC and compare across chronic pancreatitis patients stratified by pain characteristic (intensity, temporality, and interference) as well as pain mechanism (nociceptive versus neuropathic). Aim 2 is to re-analyze the data to determine if a combination or panels of targets improve predictive power of biomarkers for pain phenotypes.
Overlap:	None
Title/Grant Number:	Type 1 Diabetes in Acute Pancreatitis Consortium Data Coordinating Center/ 1U01DK127396-01
Effort:	2.4 Calendar Months, 20% Effort
Supporting Agency:	NIH/NCI
Grants Officer:	Karin Johnson, karin.johnson@nih.gov
Performance Period:	12/01/2020-11/30/2025
Funding Amount:	
Project Goals:	The ultimate goal of DCC is to provide administrative, managerial, logistic, regulatory, analytic, and financial support for the Consortium. FP00010575
Specific Aims:	Aim 1: Consortium Coordination. Aim 2: Study Design and Statistical Support. Aim 3: Data and Biospecimen Management, Protocol Development, Monitoring and Execution.
Overlap:	None
Title/Grant Number:	Erythrocyte-derived Nanoparticles for Light Activated Combination of Chemo-phototermal Therapy of Tumors / #TBA
Effort:	0.36 Calendar Months, 3% Effort
Supporting Agency:	NIH Subaward via Radoptics LLC
Grants Officer:	Unable to obtain information at the time of Grant Submission
Performance Period:	9/1/2021-8/31/2023
Funding Amount:	
Project Goals:	To pursue product characterization and in vivo studies using orthotopic tumor models in mice, develop current GMP, and perform preclinical studies. FP00010724_Res1
Specific Aims:	1. Engineer and characterize the photophysical properties and stability of F-IDNETs. 2. Determine the optimum time point for laser irradiation of intraperitoneal ovarian tumor implants in mice by NIR fluorescence imaging. 3. Validate the effectiveness of F-IDNETs for pPTC-mediated destruction of orthotopic ovarian tumor implants in mice. 4. Develop cGMP protocols and scale up the production of F-IDNETs. 5. Perform GLP-toxicity studies of F-IDNETs in rodent and non-rodent models.
Overlap:	None
Title/Grant Number:	Patient-specific Data to Aid Hemodialysis Vascular Access Decision-making/ PA-20-185
Effort:	2.4 Calendar Months, 20% Effort
Supporting Agency:	NIH/NIDDK Subaward via University of Wisconsin Madison
Grants Officer:	Unable to obtain information at the time of Grant Submission

Performance Period: 4/1/2021-3/31/2025
Funding Amount:
Project Goals: Our overall objective is to provide patients and clinicians with the tools to improve outcomes associated with vascular access in chronic hemodialysis by developing a decision model that functions at the critical decision point of access creation/choice. FP00011480
Specific Aims: Aim 1. Identify predictors for the following panel of outcomes among patients with chronic kidney disease (pre-dialysis) or end stage kidney disease by type of vascular access (AVF vs. AVG) placed:
a. Patient survival
b. Number of access-related hospitalizations and hospitalized days
c. Number of access-related surgical and percutaneous procedures
d. Number of AV access infections and catheter-related bloodstream infections
Aim 2. Develop and validate patient-specific prediction models for the proposed panel of outcomes.
Aim 3. Develop and disseminate a web-based tool to facilitate the use of the prediction models in clinical practice and aid provider-patient discussions regarding vascular access decision-making. The finalized prediction models will be programmed into a web-based tool designed to maximize patient engagement and made available for use in clinical practice.
Overlap: None

Title/Grant Number: Multifunctional Nanoparticle Imaging of Brain Tumors/ 1R01CA259785
Effort: 0.48 Calendar Months, 4% Effort
Supporting Agency: NIH/NCI
Grants Officer: Christopher Hatch, Ch29v@nih.gov
Performance Period: 4/1/2021-3/31/2026
Funding Amount:
Project Goals: To create a new paradigm for approaching brain tumors that enables presurgical planning, surgical resection/tumor photodestruction, and residual tumor evaluation after a single nanoparticle injection. FP00011037
Specific Aims: Aim 1: Test the hypothesis that DM-Dual-Gd can be used to image brain tumors by MR imaging pre-surgery and at surgery (open calvarium) by MR and NIR imaging.
Aim 2: Test the hypothesis that DM-dual-Gd brain tumor detection can be improved using the NIR II window compared to the NIR I window.
Aim 3: Test the hypothesis that DM-Dual-Gd-based nanoparticles enable photodestruction of brain tumors.
Aim 4: Test the hypothesis that surgery guided by DM-Dual-Gd may be used to improve overall survival in mice with high grade glioma compared to standard “naked eye” surgery.
Overlap: None

Title/Grant Number: Prostate Cancer Imagingome/ 1 R01 CA252361-01A1
Effort: 0.6 Calendar Months, 5% Effort
Supporting Agency: NIH/NCI
Grants Officer: Christopher Hatch, Ch29v@nih.gov
Performance Period: 4/1/2021-3/31/2026
Funding Amount:
Project Goals: To functionalize imaging by creating an “imagingome” of orthotopic and metastatic prostate cancer representing clinical milestones in therapeutic progression utilizing focused imaging of prostate cancer patient derived (therapeutic stage specific) xenografts in relevant prostate, bone, and viscera microenvironments. FP00009552_Res1
Specific Aims: Aim 1 Create an in vivo imagingome of orthotopic and metastatic prostate cancer representing clinical milestones in therapeutic progression of prostate cancer. Aim 2 Assess whether alterations in the imagingome can predict response to treatment stage specific therapy.

Overlap:	None
Title/Grant Number:	Thernaostic Nanoparticles for Prostate Cancer/ 1R01CA259598-01
Effort:	0.48 Calendar Months, 4% Effort
Supporting Agency:	NIH/NCI
Grants Officer:	Christopher Hatch, Ch29v@nih.gov
Performance Period:	4/1/2021-3/31/2026
Funding Amount:	
Project Goals:	To engineer nanoparticles (NPs) for imaging and personalized, image-guided photothermal ablation of prostate tumors. FP00011053
Specific Aims:	Aim 1 Optimize PTT conditions and Gd-NM concentrations in vitro using NIR camera and MRTI. Aim 2 Evaluate the feasibility of Gd-NMs as a T1-weighed MRI agent, determine cellular uptake mechanism of Gd-NMs, and assess biotoxicity, in vitro. Aim 3 Evaluate Gd-NM+PSMA assisted prostate cancer imaging, in vivo. Aim 4 Assess the efficacy of Gd-NM+PSMA induced photothermal ablation of prostate cancer, in vivo.
Overlap:	None
Title/Grant Number:	LC200049: Stroma-based Theranostic Approach for Lung Cancer / W81XWH-20-LCRP-IITRA
Effort:	0.36 Calendar Months, 3% Effort
Supporting Agency:	Department of Defense (DOD)
Grants Officer:	Not available for this submission
Performance Period:	09/01/2021-08/31/2023
Funding Amount:	
Project Goals:	To test the hypothesis that a designer SSTR2-based reporter can be created that is signaling deficient in MSC's, yet binds both an imaging and a therapeutic radiopharmaceutical. MSC's expressing this designer theranostic reporter, which home, incorporate, and amplify in the genetically stable lung tumor stroma (microenvironment) can be imaged using an imaging radioligand for "See" and targeting using a therapeutic radioligand with "cross-fire" effect to kill adjacent cancer cells, inhibiting growth of lung cancer for "Treat". FP00011685
Specific Aims:	Aim 1. Test the hypothesis that a SSTR2-based reporter can be created that is signaling deficient in MSC's yet binds both an imaging and a therapeutic radiopharmaceutical. Aim 2. Capitalizing on the tumor stroma, test the hypothesis that MSC's expressing SSTR2-based reporters incorporating into the lung tumor microenvironment, can be imaged using an imaging radioligand. Aim 3. Capitalizing on the tumor stroma, test the hypothesis that MSC's expressing SSTR2-based reporters incorporate into the lung tumor microenviroment, and targeting using a therapeutic radioligand inhibits growth of lung cancer
Overlap:	None
Title/Grant Number:	CA200499: Multimodal Theranostic Approach for Glioblastoma / #TBA
Effort:	0.24 Calendar Months, 2% Effort
Supporting Agency:	Department of Defense (DOD)
Grants Officer:	Not available for this submission
Performance Period:	9/01/2021-8/31/2024
Funding Amount:	
Project Goals:	To provide statistical support for overall goals and specific aims.
Specific Aims:	Not available for this submission
Overlap:	None

OTHER SUPPORT

JAGPREET CHHATWAL

CURRENT SUPPORT

NSF 16-601 (Chhatwal) 08/15/2017 – 07/31/2021 1.35 calendar months
National Science Foundation total costs
Collaborative Research: Smart intervention strategies for Hepatitis C elimination
Goals: In this project, we will estimate the true disease burden of hepatitis C at the state and national level, identify effective control strategies using infectious disease modeling and optimal control theory, and develop decision support tools for practical use by stakeholders.
Role: Principal Investigator
Overlap with proposed project: None.

Research Scholar Grant (Chhatwal) 07/01/2017 – 06/30/2021 2.4 calendar months
American Cancer Society total costs
A personalized surveillance program for hepatocellular carcinoma
Goals: The goal of this proposal is to reduce the burden of hepatocellular carcinoma by identifying effective surveillance programs that improve early detection.
Role: Principal Investigator
Overlap with proposed project: None.

(Chhatwal) 01/31/2018 – 12/31/2020 0.12 calendar months
Foundation for Innovative New Diagnostics total costs
Cost-effective analysis of Simplified diagnostic algorithms for Hepatitis C
Goals: The objective is to evaluate the long-term effectiveness and cost-effectiveness of different HCV diagnostic algorithms that FIND will implement as part of the demonstration research projects in India, Georgia, Myanmar, Vietnam, Cameroon, and Malaysia.
Role: Principal Investigator
Overlap with proposed project: None.

R01 (Samir) 03/01/2019 – 02/28/2023 0.75 calendar months
National Institutes of Health total costs
Development of a Machine Learning Model to Integrate Clinical, Laboratory, Sonographic, and Elastographic Data for Noninvasive Liver Tissue Characterization in NAFLD
Goals: We have developed a set of general-purpose shear wave elastography (SWE) liver image analysis algorithms, termed SWE-Assist. We propose (1) to customize and refine SWE-Assist to create a new high-risk NASH-specific SWE image diagnosis toolkit, termed hrNASH-Det, and (2) to integrate hrNASH-Det with clinical, and laboratory data to create an accurate, non-invasive hrNASH diagnostic tool.
Role: Co-Investigator
Overlap with proposed project: None.

R01 (Deshmukh) 04/01/2019 – 03/31/2023 0.51 calendar months
National Institutes of Health total costs
Optimizing Age-based Anal Cancer Screening among People Living with HIV using Decision Analytic Modeling
Goals: The goal of the proposed research is to identify optimal (effective and cost-effective) age-specific anal cancer screening algorithms considering HSIL management using a Simulation Model of Anal Cancer.
Role: Co-Investigator
Overlap with proposed project: None.

W81XWH1910690 (Chhatwal) 09/01/2019 – 08/31/2022 1.83 calendar months

Department of Defense total costs
Risk of hepatocellular cancer after virologic cure with direct acting antiviral agents in individuals with hepatitis C
Goals: The overall goal of this study is to examine the determinants of hepatocellular carcinoma (HCC) in patients with chronic hepatitis C virologically cured with the new direct-acting antiviral regimens and to evaluate benefits versus harms of HCC surveillance in those patients.
Role: Co-Principal Investigator
Overlap with proposed project: None.

UM1DA049394 (Williams) 04/01/2019 – 03/31/2023 2.67 calendar months
National Institutes of Health total costs
HEALing Communities Study: Developing and Testing an Integrated Approach to Address the Opioid Crisis (Data Coordinating Center)
Goals: We aim to evaluate the cost-effectiveness and budget impact of interventions that can reduce opioid-related deaths in HEALing Communities Study and other jurisdictions.
Role: Co-Investigator
Overlap with proposed project: None.

NEW
R37 CA231957 (Lubitz)
National Institutes of Health 07/01/2019 – 06/30/2024 1.38 calendar months
Thyroid Nodule Treatment Optimization: A Personalized Approach
Goals: The objective of this proposed research is to harness a comprehensive computer model to simulate individuals with benign and malignant nodules in the U.S. population to identify optimal personalized treatment approaches.
Role: Co-Investigator
Overlap with proposed project: None.

NEW
NSF 18-541 (Gopalappa) 01/01/2020 – 12/31/2023 0.18 calendar months
National Science Foundation total costs
Simulation and Decision-Analysis Algorithms for Integrated Modeling of Diseases: A healthy lives for all approach
Goals: The goal of the proposed research is to develop an integrated multi-disease modeling framework to inform public health strategy plans such as HealthPeople2020 that address social determinants, reduce disparities and aims for healthy lives for all.
Role: Principal Investigator
Overlap with proposed project: None.

NEW
Contract (Chhatwal) 03/01/2020 – 12/31/2020 0.12 calendar months
Task Force for Global Health total costs
Hepatitis C Elimination Simulator: An Interactive Global Analysis and Planning Tool for Hepatitis C Elimination
Goals: To help countries identify effective and affordable policies to diagnose and treat HCV, we are developing an interactive online tool, the Hep C Elimination Simulator that will provide country-level information on the HCV epidemic, model the impact of various diagnostic and treatment strategies on HCV disease burden, estimate the budget impact of different interventions, and track the treatment cascade and progress towards elimination.
Role: Principal Investigator
Overlap with proposed project: None.

NEW

2035361 (Chhatwal) 07/01/2020 – 06/30/2021 0.45 calendar months
National Science Foundation total costs

Mitigation and Suppression of Coronavirus Pandemic with Data-driven RAPID Decisions Using COVID-19 Simulator

Goals: To evaluate and identify effective mitigation strategies using COVID-19 Simulator at the county level in the US by considering testing rates in the absence and presence of COVID-19 pharmaceutical interventions.
Role: Principal Investigator
Overlap with proposed project: None.

NEW

(Chhatwal) 07/01/2020 – 11/30/2020 0.16 calendar months

Johns Hopkins University total costs

Informing State-level COVID-19 Testing and Contact Tracing using the COVID-19 Simulator

Goals: To address several time-sensitive policy decisions at the state and national level, we recently developed and launched an interactive COVID-19 policy simulation model. We propose to extend the COVID-19 Simulator to: (1) Estimate the underlying antibody prevalence of COVID-19 and active COVID-19 cases in each state, and (2)Evaluate minimum testing and contract tracing needed to mitigate the spread of COVID-19 at different phases of reopening in each state.
Role: Principal Investigator
Overlap with proposed project: None.

NEW

(Loomba) 05/20/2020 – 04/30/2023 0.0 calendar months
University of California, San Diego total costs

Non-invasive screening of diabetics for advanced fibrosis due to NAFLD

Goals: This project will enable us to determine the circumstances under which NAFLD screening is efficient and cost-effective and identify optimal screening strategies for individuals based on age, sex, obesity, and other risk factors.
Role: Co-Investigator
Overlap with proposed project: None.

Completed Support

(Chhatwal) 01/01/2017 – 12/31/2018
Gilead Sciences, Inc.

Simulation of Patients Who Fail Treatment in the Era of DAAs in Europe

Goals: The overall goal is to estimate the burden of HCV in five European countries in the era of direct-acting antivirals (DAAs) who will fail to achieve sustained virologic response and will need some salvage treatment.
Role: Principal Investigator
Overlap with proposed project: None.

(Chhatwal) 5/10/2017 – 12/31/2018
Gilead Sciences, Inc.

Cost-effective strategies for elimination of Hepatitis C in Spain's prisons

Goals: The overall goal is to evaluate cost-effective strategies to scale-up HCV treatment in Spain's prisons that can lead to HCV elimination.
Role: Principal Investigator
Overlap with proposed project: None.

Merck (Chhatwal) 08/15/2017 – 06/30/2019 1.8 calendar months
Merck Research Laboratories

Strategies for management of hepatitis C virus: A global optimization tool

Goals: We propose to develop a mathematical tool to inform optimal strategies for management of HCV in different countries that will lead to elimination of HCV by 2030.
Role: Principal Investigator
Overlap with proposed project: None.

AASLD Innovation Fund 01/01/2018 – 12/31/2019 .12 calendar months
American Association for the Study of Liver Diseases
NAFLD Simulator: An online tool for predicting long-term patient outcomes
Goals: We aim to develop an online, open-access tool, NAFLD Simulator, that will simulate the life course of patients with NAFLD and provide information on the long-term risks. This will serve as an educational tool in the clinical setting and aid in shared patient-physician decision-making.
Role: Principal Investigator
Overlap with proposed project: None.

Contractor Services Agreement 02/05/2018 – 03/31/2019 1.56 calendar months
ChangeLab Solutions/CDC
Hepatitis C investment calculator: An online tool for state-level management of Hepatitis C burden
Goals: The objective of this project is to develop the Hepatitis C Investment Calculator, an interactive online tool that allows users to enter state-specific information (e.g. the price of DAAs, testing cost, treatment rates) and evaluate outcomes.
Role: Principal Investigator
Overlap with proposed project: None.

Pending Support
None.

◦**What other organizations were involved as partners?**

MD Anderson Cancer Center (Houston, TX) provided the following types of support:

- In-kind support (partner makes software, computers, equipment, etc., available to project staff)
- Facilities (project staff use the partner's facilities for project activities)

8.SPECIAL REPORTING REQUIREMENTS

◦**COLLABORATIVE AWARDS:**

The Initiating PI and the Collaborating/Partnering PI are submitting separate reports.

◦**QUAD CHARTS:**

Nothing to report.

9.APPENDICES:

Nothing to report.

ADDITIONAL NOTES:

Nothing to report.

MARKING OF PROPRIETARY INFORMATION:

Nothing to report.