AWARD NUMBER: W81XWH-21-1-0087

TITLE: Improving Outcomes in Lethal Prostate Cancer Through Guideline-Concordant Use of Bone-Modifying Agents

PRINCIPAL INVESTIGATOR: Aaron Mitchell

CONTRACTING ORGANIZATION: Sloan Kettering Institute for Cancer Research

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Fort Detrick, Maryland 21702-5012

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Improving Outcomes in Lethal Prostate Cancer Through Guideline-Concordant Use of Bone-Modifying Agents

5a. CONTRACT NUMBER
W81XWH-21-1-0087

5b. GRANT NUMBER

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
Aaron Mitchell

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Sloan Kettering Institute for Cancer Research
1275 York Avenue New York, NY
10065-6007

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

We used SEER-Medicare data to identify BMA underuse and overuse among prostate cancer patients, and then evaluated key patient, provider, and practice characteristics for association with underuse (~68% receive BMAs appropriately) and overuse (~1/3 non-candidate patients received BMA despite guidelines) [Aim 1]. We conducted in-depth interviews with prostate cancer clinicians to further understand barriers and facilitators to appropriate BMA use (analysis ongoing) [Aim 2A]. We will apply findings from Aim 1 and Aim 2A to refine a multi-pronged interventional strategy intended to reduce BMA underuse and overuse. Starting with a set of evidence-based healthcare interventions, we will use our findings to incorporate additional components tailored to correcting the identified barriers [Aim 2B]. We will pilot this intervention strategy within the MSK Alliance, a hybrid academic-community network of oncology providers in the Eastern US, to assess feasibility and efficacy [Aim 3].

15. SUBJECT TERMS
Prostate cancer; bone modifying agent; guideline-concordant care; care quality; supportive care; metastatic cancer; medical overuse;

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRDC
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TABLE OF CONTENTS

1. INTRODUCTION:

We will use SEER-Medicare data to identify BMA underuse and overuse among prostate cancer patients. We will then evaluate key patient (income, race, rural residence), provider (specialty, patient volume), and practice (location, academic affiliation) characteristics which we hypothesize may be associated with underuse and overuse **(Aim 1)**. We will conduct in-depth interviews with prostate cancer clinicians to further understand barriers and facilitators to appropriate BMA use **(Aim 2A)**. We will apply findings from Aim 1 and Aim 2A to refine a multi-pronged interventional strategy intended to reduce BMA underuse and overuse. Starting with a set of evidence-based healthcare interventions, we will use our findings to incorporate additional components tailored to correcting the identified barriers **(Aim 2B)**. We will pilot this intervention strategy within the MSK Alliance, a hybrid academic-community network of oncology providers in the Eastern US, to assess feasibility and efficacy **(Aim 3)**.

2. KEYWORDS:

Prostate cancer; bone modifying agent; guideline-concordant care; care quality; supportive care; metastatic cancer; medical overuse;

3. ACCOMPLISHMENTS:

What were the major goals of the project?

Aim 1, Major Task 1: Identify and describe BMA underuse
Target completion date: June 2022
Actual completion date: July 2022

Aim 1, Major Task 2: Identify and describe BMA overuse
Target completion date: September 2022
Actual completion date: October 2021

Aim 2, Major Task 1: Conduct physician interviews to better understand determinants of BMA use
Target completion date: March 2023
Actual completion date: Ongoing, 75% completed

Aim 2, Major Task 2: Apply SEER-Medicare and interview findings to refine intervention strategy
Target completion date: July 2023
Actual completion date: Ongoing, 25% completed

Aim 3, Major Task 1: Pilot of Intervention Strategy
Target completion date: September 2024

Aim 3, Major Task 2: Assessment of Pilot Results
Target completion date: September 2025

What was accomplished under these goals?

Aim 1, Major Task 1: Identify and describe BMA underuse

This Aim was completed, with results published in *Prostate Cancer and Prostatic Diseases*, https://pubmed.ncbi.nlm.nih.gov/35798857/ . The primary finding was that among patients with metastatic CRPC to bone, about 68% receive BMAs appropriately. This has been relatively stable in recent years.

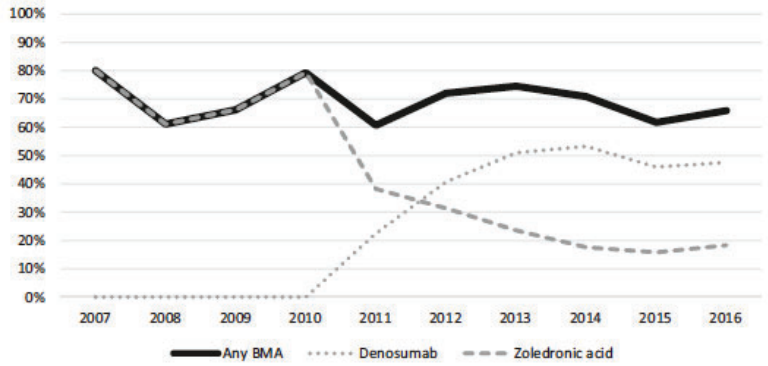
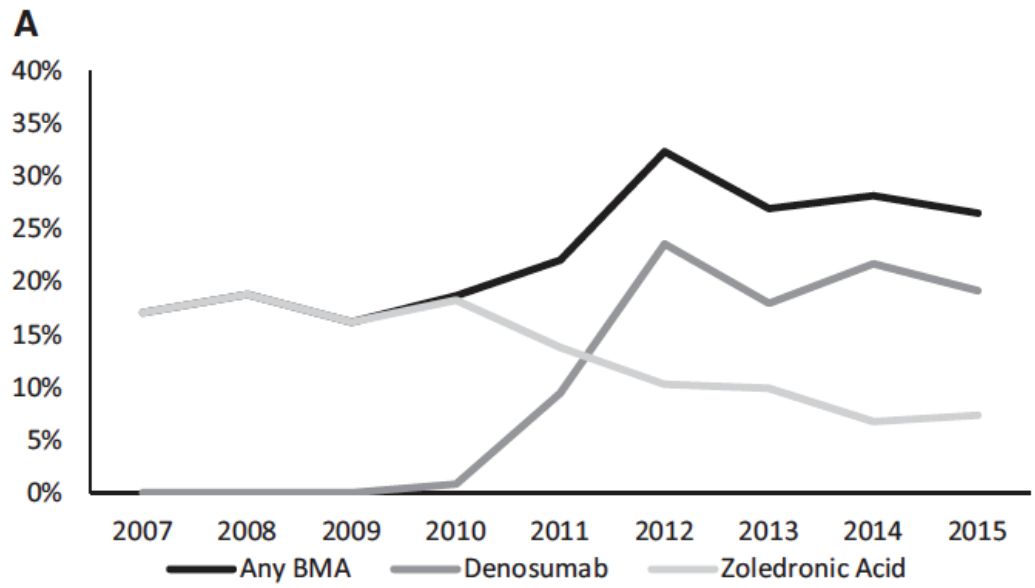


Fig. 1 Proportion of patients with bone metastasis who received a bone modifying agent within 180 days after initiating CRPC-defining treatment, over time. Calendar year indicates initiation of CRPC-defining treatment, rather than year of prostate cancer diagnosis.

Aim 1, Major Task 2: Identify and describe BMA overuse

This Aim was completed, with results published in Journal of the National Cancer Institute, https://pubmed.ncbi.nlm.nih.gov/34597380/ . The primary finding was that about 1/3 of patients with metastatic CSPC, who are NOT candidates for bone modifying agents, received them anyway. This rate of overuse increased substantially following the 2010 approval of a new BMA drug denosumab.



Aim 2, Major Task 1: Conduct physician interviews to better understand determinants of BMA use

We recently concluded interviews with 15 oncologists who treat prostate cancer, in both academic and community settings. The key finding regarding BMA UNDERuse (lack of BMA use among patients with CRPC) was that pre-treatment dental evaluation and limited clinic time were identified as the most common barriers, and EMR-based guidance and dental navigation were identified as the most useful potential interventions. Regarding BMA OVERuse (use for patients with CSPC), we identified a knowledge gap among some clinicians that this practice actually is overuse according to guidelines. EMR-based guidance and peer-to-peer physician education were identified as the most useful potential interventions to address overuse.

These results have been submitted as an abstract to the American Society of Clinical Oncology Genitourinary Symposium, to be held in February 2023. Further analysis of the results, including qualitative conceptual mapping of key concepts from the interviews, is ongoing.

Aim 2, Major Task 2: Apply SEER-Medicare and interview findings to refine intervention strategy

Findings from Aim 1, Tasks 1&2 have informed the development of the intervention strategy and rollout plans. The most significant, unexpected finding in this regard was that BMA overuse is driven almost entirely (among the SEER-Medicare population) by medical oncologists; we had anticipated finding that urologists contributed substantially to overuse. This will inform the targeting of the intervention to provider groups. We also saw no evidence of greater overuse or underuse with respect to patient race/ethnicity or income, indicating that we can target the intervention broadly to patients across these demographic groups.

Findings from Aim 2, Task 1 will also directly impact the intervention strategy. Patient dental evaluations and limited clinic time were identified as key barriers to appropriate use. We also identified a knowledge gap that likely contributes to overuse. We are currently applying principles of Implementation Science to design a multi-level implementation strategy informed by a CFIR-to-ERIC mapping process to address all barriers that can be feasibly accomplished.

Aim 3, Major Tasks 1 & 2: Pilot of Intervention Strategy, Assessment of Pilot Results

Piloting of the intervention strategy has not yet begun. We anticipate that this step will be underway in the first half of 2023.

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

Training Goal 1: Foundation in prostate cancer clinical research

Continuous:
Seminar: MSK prostate cancer research meeting
Seminar: MSK genitourinary grand rounds
Conference: ASCO Genitourinary Oncology Symposium

Completed:
Online course: American Society of Clinical Oncology (ASCO), *Fundamentals of Clinical Trials*

In process:
In-person course: *Clinical Research Methodology Curriculum* (Weill Cornell Medical Center)
Online course: *Introduction to the Principles and Practice of Clinical Research* (NIH)

Training Goal 2: Training in implementation science

Continuous:
Seminar: MSK Implementation Science Affinity Group
Conference: Academy Health Annual Conference on the Science of Dissemination and Implementation

In process:
Online seminar: *NCI Webinars in Advanced Implementation Science*
Online course: NCI *Training Institute for Dissemination and Implementation Research in Cancer* (TIDIRC)

Not yet begun:
In-person course: NYU GPH-GU 2135 *Dissemination and Implementation Science in Health Care and Public Health*

Training Goal 3: Training in health disparities research

Completed:
Online conference: Massachusetts General Cancer Center Cancer Equity Colloquium
Online course: *Foundations of Health Equity Research* (Johns Hopkins Health Equity Hub)
Online course: *Application of Health Equity Research Methods for Practice and Policy* (Johns Hopkins Health Equity Hub)

Continuous:
Health Disparities Research Training seminar convened by the Immigrant Health & Cancer Disparities Service (MSK, biweekly)

Not yet begun:
Online course: From Health Disparities to Health Equity, University of Pennsylvania

Online course: Foundations of Social Epidemiology, Johns Hopkins Bloomberg School of Public Health

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?

- Further analyze data from recent qualitative interviews and publish results
- Continue working with clinical (Dr. Morris) and implementation science (Dr. Ostroff) mentors to translate the findings from the recent interview study into the finalized implementation strategy
- Conduct chart reviews of patients with prostate cancer within the MSK Alliance to determine baseline frequencies of BMA overuse and underuse
- Rollout of implementation strategy to MSK Alliance clinical sites
- Continuation of training program, including the accomplishment of the remaining specific training resources that have not yet begun: NYU GPH-GU 2135 course, *From Health Disparities to Health Equity* at University of Pennsylvania, *Foundations of Social Epidemiology* at Johns Hopkins Bloomberg School of Public Health

4. IMPACT:

What was the impact on the development of the principal discipline(s) of the project?

Our study on the overuse of BMA agents (Aim 1, Major task 2), published in October 2021, has already begun to focus attention on this problem within the field. Our study was published with an invited editorial by a world-leading expert in prostate cancer bone health (Dr. Silke Gillessen: Journal of the National Cancer Institute 114(4), pp. 635-636), highlighting the importance and scope of this problem both in the US and abroad. Informally, we have heard of a peer institution planning a similar effort as ours to reduce overuse. We anticipate that our findings will continue to draw attention to this form of overuse and generate additional attempts to reduce it.

What was the impact on other disciplines?

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Nothing to report

What was the impact on technology transfer?

Nothing to report

What was the impact on society beyond science and technology?

Nothing to report

5. CHANGES/PROBLEMS:

Nothing to report

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

No problems or delays have been encountered during the reporting period

Changes that had a significant impact on expenditures

No significant changes in expenditures during the reporting period

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

Nothing to report

Significant changes in use or care of human subjects

Nothing to report

Significant changes in use or care of vertebrate animals

Nothing to report

Significant changes in use of biohazards and/or select agents

Nothing to report

6. PRODUCTS:

- **Publications, conference papers, and presentations**

Journal publications.

Aaron Mitchell, Akriti Mishra, Katherine Panageas, Allison Lipitz-Snyderman, Peter Bach, Michael Morris. Real-World Use of Bone Modifying Agents in Metastatic Castration Sensitive Prostate Cancer. *J Natl Cancer Inst*. 2021 Oct 1:djab196.
Published
Federal support acknowledged

Aaron Mitchell, Akriti Mishra Meza, Katherine Panageas, Allison Lipitz-Snyderman, Azeez Farooki, Michael Morris. Real-World Use of Bone Modifying Agents in Metastatic, Castration-Resistant Prostate Cancer. Prostate Cancer and Prostatic Diseases.
Published online ahead of print
Federal support acknowledged

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

Nothing to report

Other publications, conference papers and presentations.

Barriers to Guideline-Concordant Use of Bone Modifying Agents for Prostate Cancer.
Aaron Mitchell, Sonia Persaud, Susan Chimonas, Azeez Farooki, Jamie Ostroff, Paul Palyca, Andrew Salner, and Michael Morris.
Conference abstract, submitted to 2023 American Society of Clinical Oncology Genitourinary Symposium

- **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:	Aaron Mitchell
Project Role:	PI
Researcher Identifier (e.g. ORCID ID):	0000-0003-3639-3515
Nearest person month worked:	6
Contribution to Project:	Overseeing design, organization, and execution of all study goals
Funding Support:	Current award, NCI, National Institute of Health Care Management

Name:	Akriti Mishra
Project Role:	Biostatistician
Researcher Identifier (e.g. ORCID ID):	0000-0002-3477-5037
Nearest person month worked:	2
Contribution to Project:	SEER-Medicare data analysis
Funding Support:	Current award, NCI, Departmental funds

Name:	Susan Chimonas
Project Role:	Qualitative Researcher
Researcher Identifier (e.g. ORCID ID):	0000-0002-7742-5950
Nearest person month worked:	1
Contribution to Project:	Conducting physician interviews
Funding Support:	Current award, Departmental funds

Name:	Sonia Persaud
Project Role:	Research Data Assistant
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	1
Contribution to Project:	Organizing physician interviews and analyzing data
Funding Support:	Current award, Departmental funds

Name:	Allison Lipitz Snyderman
Project Role:	Collaborator
Research Identifier:	0000-0003-2423-2220
Nearest person month worked:	1
Contribution to Project:	Provides methodological advice.
Funding Support:	Departmental

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

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Yes, please see appendix.

Partnering Organizations

Lehigh Valley Cancer Institute, Allentown, PA
Contribution: Collaboration

Hartford Hospital, Hartford, CT
Contribution: Collaboration

8. SPECIAL REPORTING REQUIREMENTS

None.

9. APPENDICES:

Updated Other Support information for the PI and mentors is attached.

OTHER SUPPORT

MITCHELL, AARON

NEWLY ACTIVE

*Title: Understanding the Importance of Industry Relationships for Cancer Care Quality, Outcomes, and Costs
*Major Goals:
*Status of Support: Active
Project Number: 1R37CA264563-01A1
Name of PD/PI: Mitchell, A
Source of Support: National Cancer Institute
Primary Place of Performance: Sloan Kettering Institute For Cancer Research
Project/Proposal Start and End Date (MM/YYYY): 8/1/2022 - 7/31/2027
*Total Award Amount (including Indirect Costs):
Person Months: 3.6

*Title: Improving Outcomes in Lethal Prostate Cancer through Guideline-concordant use of Bone Modifying Agents
*Major Goals:
*Status of Support: Active
Project Number: W81XWH-21-1-0087
Name of PD/PI: Mitchell, A
Source of Support: Congressionally Directed Medical Research Programs
Primary Place of Performance: Sloan Kettering Institute For Cancer Research
Project/Proposal Start and End Date (MM/YYYY): 9/30/2021 - 9/29/2025
*Total Award Amount (including Indirect Costs):
Person Months: 6.32

*Title: Understanding the Guideline-Discordant Use of Bone Modifying Agents in Prostate Cancer
*Major Goals:
*Status of Support: Active
Project Number: 1R03CA259863-01
Name of PD/PI: Mitchell, A
Source of Support: National Cancer Institute
Primary Place of Performance: Sloan Kettering Institute For Cancer Research
Project/Proposal Start and End Date (MM/YYYY): 4/1/2021 - 3/31/2023
*Total Award Amount (including Indirect Costs):
Person Months: 1.2

ACTIVE

*Title: Can Conflict of Interest with the Drug Industry Harm Patients?
*Major Goals:
*Status of Support: Active
Project Number: AWD-GC-260700
Name of PD/PI: Mitchell, A
Source of Support: National Institute for Health Care Management Research and Educational Foundation
Primary Place of Performance: Sloan Kettering Institute For Cancer Research
Project/Proposal Start and End Date (MM/YYYY): 1/1/2021 - 12/31/2022 NCE
*Total Award Amount (including Indirect Costs):
Person Months: 0.12

OVERLAP:

None.

CURRENT/PENDING/PREVIOUS SUPPORT
MORRIS, MICHAEL

NEWLY ACTIVE:

Title: The Prostate Cancer Clinical Trials Consortium: Application for Coordinating Center with Affiliate Clinical Research Sites
Major Goals:
Status of Support: Active
Project Number: DoD W81XWH2220020
Name of PD/PI: Scher, H
Source of Support: Congressionally Directed Medical Research Programs
Primary Place of Performance: Sloan Kettering Institute For Cancer Research
Project/Proposal Start and End Date (MM/YYYY): 9/30/2022 - 9/29/2026
Total Award Amount (including Indirect Costs):
Person Months: 1.2
Contact: N/A

Title: MATCHES: Making Telehealth Delivery of Cancer Care at Home Effective and Safe (Administrative Core)
Major Goals: 1) to conduct impactful pragmatic trials of telehealth in oncology, 2) to analyze a large existing cache of multidimensional observational data characterizing telehealth utilization and outcomes, 3) to train investigators and equip them with the skills necessary to innovate within an evidence-based framework, and 4) to integrate telehealth with other data streams and create and apply analytic methods to transform the field of precision care delivery.
Status of Support: Active
Project Number: 1P50CA271357-01
Name of PD/PI: Morris, M / Morris, M
Source of Support: National Institutes of Health
Primary Place of Performance: Sloan Kettering Institute For Cancer Research
Project/Proposal Start and End Date (MM/YYYY): 8/1/2022 - 7/31/2027
Total Award Amount (including Indirect Costs):
Person Months: 1.2
Contact: Cline Vanderpool, vanderpool@mail.nih.gov

Title: Minimizing salivary gland and renal toxicity arising from PSMA-targeted alpha therapy
Major Goals: By providing robust and durable responses, a novel radiotherapeutic agent called [225Ac]-PSMA- 617 has the potential to change the treatment landscape for end-stage prostate cancer patients, and has delivered impressive results in clinical trials, including some complete responses. Treatment with [225Ac]-PSMA-617, however, is severely limited by salivary gland toxicity. In response, we are proposing a clinically translatable method to refine treatment with [225Ac]-PSMA- 617 and other PSMA-TRT agents by reducing toxicity to salivary glands and kidneys without compromising treatment efficacy, helping to extend the lives of mCRPC patients while maintaining their quality of life.
Status of Support: Active
Project Number: 1R01CA262675-01A1
Name of PD/PI: Pillarsetty, N
Source of Support: National Institutes of Health
Primary Place of Performance: Sloan Kettering Institute For Cancer Research
Project/Proposal Start and End Date (MM/YYYY): 5/1/2022 - 4/30/2027
Total Award Amount (including Indirect Costs):
Person Months: 1.2
Contact: Jacek Capala, capalaj@mail.nih.gov

Title: Understanding the Guideline-Discordant Use of Bone Modifying Agents in Prostate Cancer
Goals: Treatment with bone-modifying agents is beneficial for some groups of prostate cancer patients but harmful for others. Though this class of drugs is in widespread use, little is known about the extent of underuse among patients who would benefit from them or overuse among patients who would be harmed. We propose to quantify the prevalence of underuse and overuse of bone-modifying agents in prostate cancer, to inform the need for future interventional work to improve utilization. We will measure the prevalence of the underuse and overuse of bisphosphonates for patients with metastatic cancer. We will describe trends in

the relative use of denosumab and estimate excess costs from its overuse.
Name of PI: Mitchell, Aaron
Source of Support: National Institutes of Health
Status of Support: Active
Project Number: R03 CA259863
Primary Place of Performance: Sloan Kettering Institute For Cancer Research
Project/Proposal Start and End Date (MM/YYYY): 4/1/2021 - 3/31/2023
Total Award Amount (including Indirect Costs):
Person Months: 0.48
Contact: Michael Halpern, michael.halpern@nih.gov

Title: A Pilot Study of 177Lu-PSMA-617 and Stereotactic Body Radiotherapy (SBRT) for the Treatment of Castrate Sensitive, Oligometastatic Prostate Cancer
Major Goals:
Status of Support: Active
Project Number: AWD-GC-259449
Name of PD/PI: Zelefsky, M
Source of Support: Imaging and Radiation Sciences Program Seed Grant
Primary Place of Performance: Sloan Kettering Institute For Cancer Research
Project/Proposal Start and End Date (MM/YYYY): 3/1/2020 - 2/28/2023
Total Award Amount (including Indirect Costs):
Person Months: 1.2

ACTIVE

PC200085 (PI: Mitchell) 9/30/2021 -9/29/2025 0.60 calendar
Congressionally Directed Medical Research Programs
Title: Improving Outcomes in Lethal Prostate Cancer through Guideline-concordant use of Bone Modifying Agents
Goals: The overall goal of this project is to improve the quality of life and outcomes of men with lethal prostate cancer by reducing overuse and underuse of BMAs. Aim 1: Identify and describe patient, provider, and practice factors associated with BMA overuse and underuse among men with lethal prostate cancer. Aim 2: Refine an intervention strategy to reduce BMA overuse and underuse. Aim 3: Pilot an intervention strategy to reduce BMA overuse and underuse.
Role: Co-Mentor
Contact: Jason Wong
Overlap: No Overlap

5 UG1 CA233290-02 (PI: Morris / Aghajanian / Lee / Tallman / Zivanovic) 3/6/2019 - 2/28/2025 0.60 calendar
NCI
Title: Network Lead Academic Participating Site: Memorial Sloan Kettering Cancer Center
Goals: This goal will be achieved through the continued successful development and execution of definitive, randomized, clinical treatment and advanced imaging trials across a broad range of diseases and diverse patient populations.
Role: Principal Investigator
Contact: Margaret Mooney
Overlap: No Overlap

1 R01 CA244866-01A1 (PI: Diaz / Jones) 9/3/2020 - 8/31/2025 0.36 calendar
NCI
Title: Exercise as Interception Therapy in Primary High Risk Cancer
Goals: In this grant, we will investigate, for the first time, the antitumor effects of exercise on minimally residual disease in patients with high-risk with primary breast, colorectal, or prostate cancer. As such, if successful, the findings of this study could benefit hundred of thousands of patients with or at risk of these cancers and therefore have significant public health impact.
Role: Co-Investigator

Contact: Frank Perna
Overlap: No Overlap

1 R01 CA240759-01A1 (PI: Schwartz) 7/1/2020 - 6/30/2025 1.80 calendar
National Cancer Center
Title: Clinical Qualification of Imaging and Fluid-Based Tumor Monitoring Biomarkers
Consortium Agreement with Columbia University
Goals: Current imaging methods for treatment monitoring in prostate cancer involve lesion-counting of new bone metastases or selected index lesions of soft tissue disease; both focus on progression only and cannot assess the full disease burden. This proposal deploys two validated methods, automated bone scan index (aBSI) and lymph node segmentation, to quantify standard imaging results so that a measure of total disease burden on imaging can be integrated with CTC data in a predictive model.
Role: Principal Investigator
Contact: Charles Lin
Overlap: No Overlap

NO LONGER ACTIVE:

W81XWH-18-2-0060 (PI: Scher) 9/30/2018 - 9/29/2021 2.40 calendar
Congressionally Directed Medical Research
Programs
Title: The Prostate Cancer Clinical Trials Consortium: Application for Coordinating Center with Clinical Research Site Option
Goals: The evaluation of industry standard medical coding and CDISC standards to increase efficiency and interoperability.
Role: Co-Investigator
Contact: Joshua McKean

GC238563 (PI: Morris) 12/31/2017 - 12/31/2020 (NCE) 1.20 calendar
Prostate Cancer Foundation (formerly CaP CURE)
Title: Characterizing mechanisms of sensitivity and resistance to anti-androgen therapy with whole-body
Goals: Current candidate prognostic and predictive biomarkers, such as circulating tumor cells (CTCs), cell-free DNA (cfDNA) and genomic tissue profiling have significant limitations as they only assess a limited component of the total disease burden. By contrast, molecular imaging can represent the entire disease burden on a phenotypic basis, including the primary cancer, bone metastases, nodal disease, and visceral spread.
Role: Principal Investigator
Contact: Audrey Gardner

GC221482 (PI: Morris) 9/1/2013 - 12/31/2020 (NCE) 1.20 calendar
Movember
Title: GAP2 Project
Goals: 1) To define the performance characteristics of [18F]FDHT in patients with mCRPC; 2) To define the relationship between [18F]FDHT uptake and tumor diffusivity and perfusion as assessed by whole-body MRI; 3) To define the relationship between [18F]FDHT uptake, AR expression, serum androgen levels, and androgen levels in biopsy specimens.
Role: Principal Investigator
Contact: Patricio Sepulveda

CURRENT/PENDING/PREVIOUS SUPPORT
BACH, PETER

ACTIVE:

GC227515 (PI: Bach) 1/22/2016 – No end date 1.80 calendar
Kaiser Permanente
Evidence Driven Drug Pricing Project at the Center for Health Policy and Outcomes
This project aims to build and disseminate an evidence base for more rational pricing of pharmaceuticals through a combination of research, dissemination, and collaboration with contractors and consultants, as well as to advance viable policy alternatives to the status quo.
Role: PI
Contact: Murray N. Ross
Overlap: None

GC225493 (PI: Bach) 5/1/2015 - 12/31/2022 0.00 calendar Kaiser Permanente
Institute on Pharmaceutical Pricing: Planning and Strategic Development
The goal of this project is to develop a framework and research plan for evaluating alternative models of evidence-based drug pricing for specialty drugs, with a focus on oncology products.
Role: PI
Contact: Murray N. Ross
Overlap: None

Not numbered (PI: Bach) 4/1/2008 - No end date 0.00 calendar
Canary Foundation
Case Series Analysis of Lung Cancer Natural History
This project involves analyses of primary data collected from three separate study sites which aim to clarify the currently unknown 'natural history' of lung cancer prior to its clinical appearance. This is achieved by collecting and analyzing mortality data in order to identify lung cancer decedents in the screened population, developing a taxonomy to describe findings on CT scans and estimating the probability that individuals who die of lung cancer could reasonably have their cancers caught by annual CT screening when still localized and resectable.
Role: PI
Contact: Don Listwin
Overlap: None

5 R25 CA214255-03 (PI: Begg / Tan) 12/1/2017 - 11/30/2023 NCE 0.00 calendar
NCI
Quantitative Sciences Summer Undergraduate Research Experience (QSURE) Fellowship
Data, the building blocks of knowledge, are becoming ubiquitous in all areas of health sciences, particularly oncology. The MSK QSURE Fellowship program will help increase the number of qualified individuals who conduct quantitative data analysis to inform clinical and policy decisions in cancer. This program also provides opportunities for students from underrepresented minority communities and disadvantaged backgrounds to engage in research projects in quantitative sciences.
Role: Other Significant Contributor
Contact: Sergey Radaev
Overlap: None

1 K08 CA252640-01 (PI: Gillespie) 8/15/2020 - 7/31/2025 0.00 calendar
NCI

Leveraging implementation science to accelerate adoption of shorter-course radiation for breast and prostate cancer
The proposed research is relevant to public health because it addresses the appropriate use of shorter radiation treatments (called "hypofractionation") for breast and prostate cancer, a critical step to improving access to high-value patient-centered cancer care.
Role: Mentor
Contact: Sergey Radaev,
Overlap: None

NO LONGER ACTIVE:

GC259552 (PI: Bach) 4/1/2019 - 3/31/2022 7.2 calendar
Laura and John Arnold Foundation
Evidence Driven Drug Pricing Project
The core aim of this grant is to advance federal policy that tackles drug pricing issues in a way that balances patient affordability with sustained incentives for innovation. Its projects can be roughly categorized as focused on helping policymakers and the public to understand the drug pricing system in the US, clarifying the underlying problems both in the narrow and general sense with the drug pricing and reimbursement system, and articulating evidence-based policy alternatives with clear delineation of the tradeoffs and questions they may provoke.
Role: PI
Contact: Vanessa Goodwin
Overlap: None

5 R21 CA235154-02 (PI: Lipitz Snyderman/ Mailankody) 6/1/2019 - 5/31/2022 (NCE) 0.6 calendar
NCI
Linking population-based data sources to examine health disparities in clinical trial participation and outcomes
Goals: The purpose of this proposal is to create a national database that will tell us about older adult patients who have participated in clinical trials. This will allow us to answer questions about what kinds of people participate in these trials, where they are treated, what doctors treat them, and the benefits and risks of such participation, which can influence the future of clinical trials research. Aims: 1) To determine the feasibility of establishing a high-quality linkage across data sources, 2) To determine the validity of the NCT identifier for identifying patients on clinical trials. 3) To utilize the linked databases to address exemplar research questions
Role: Co-Investigator
Contact: Kathleen Cronin
Overlap: None

OSTROFF, JAMIE
NEWLY ACTIVE:

PI: Banerjee/ Ostroff
Title: Empathic Communication Skills Training to Reduce Lung Cancer Stigma
Supporting Agency: NCI R01 CA255522
Address: National Cancer Institute
Performance Period: 9/1/2021 - 8/31/2026
Level of funding:
Project Goals: This clinical trial will test the effectiveness of empathic communication skills (ECS) training targeting community oncology care providers to improve quality of care and reduce stigma experienced by patients diagnosed with lung cancer.
Specific Aims: 1) To evaluate the impact of the ECS training on health care provider primary outcomes (communication and empathic skill uptake) and secondary outcomes (training appraisal, self-efficacy, attitude towards communication with patients); 2) To evaluate the impact of the ECS training vs. Wait List Control on patients' reported primary outcomes (lung cancer stigma), and secondary outcomes (perceived clinician empathy, satisfaction with communication, psychological distress, social isolation).
Role: Principal Investigator
Overlap: None
Person Months: 1.8

PI: Carter
Title: Leveraging Social Media to Increase Lung Cancer Screening Awareness, Knowledge and Uptake in High-Risk Populations
Supporting Agency: NCI 1R01CA263662-01A1
Address: National Cancer Institute
Performance Period:): 9/1/2022 - 8/31/2027
Level of funding:
Project Goals: (1) examine the use of a social media platform to reach high-risk individuals eligible for lung screening; (2) compare the effectiveness of a computer- tailored health communication tool to a web-based ACS Lung Screening Informational Video to improve lung cancer screening: a) knowledge; b) health beliefs; and c) screening uptake and completion in a high-risk population; and (3) Explore the sustainability of a social media-based approach among key stakeholders.
Role: Co-Investigator
Person Months: 1.8

PI: Saracino
Title: Behavioral Activation for Depression in Older Adult Cancer Survivors: Pilot Randomized Control Trial and Implementation Outcomes
Supporting Agency: NCI K08 CA252633
Address: National Cancer Institute
Performance Period: 4/1/2021 - 3/31/2026
Level of funding:
Project Goals: 1) To obtain feedback from key stakeholders (i.e., OACS, social workers, survivorship clinic clinicians) to revise the BA manual content and procedures and develop an understanding of barriers to treatment engagement in OACS; 2) To evaluate implementation outcomes (i.e., appropriateness, acceptability, adoption, feasibility, fidelity, penetration, and sustainability) of BA in cancer survivorship; and 3) To determine the preliminary effects of BA on depression (primary outcome), anxiety, coping, and behavioral activation (secondary outcomes) compared to a Supportive Psychotherapy (SP) control arm.
Role: Co-Mentor
Person Months: 0.0

Title: CCNY-MSK Partnership's pilot award
Status of Support: Active

Project Number: CCNY-MSK Partnerships pilot award
Name of PD/PI: Ostroff, J
Source of Support: PRESIDENTS OFFICE
Primary Place of Performance: Sloan Kettering Institute For Cancer Research
Project/Proposal Start and End Date (MM/YYYY): 3/1/2022 - 2/28/2023
Total Award Amount (including Indirect Costs):
Person Months: 0.60 calendar

ACTIVE

PI: Mitchell
Title: Improving Outcomes in Lethal Prostate Cancer through Guideline-concordant use of Bone Modifying Agents
Time Commitments: 0.60 calendar
Supporting Agency: Congressionally Directed Medical Research Programs PC200085
Address: 1077 Patchel Street Fort Detrick, MD 21702-5024
Contracting/Grant Officer: Jason Wong, PhD
Performance Period: 9/30/2021 - 9/29/2025
Level of funding:
Project Goals: The overall goal of this project is to improve the quality of life and outcomes of men with lethal prostate cancer by reducing overuse and underuse of BMAs.
Specific Aims: Aim 1: Identify and describe patient, provider, and practice factors associated with BMA overuse and underuse among men with lethal prostate cancer. Aim 2: Refine an intervention strategy to reduce BMA overuse and underuse. Aim 3: Pilot an intervention strategy to reduce BMA overuse and underuse.
Role: Co-Mentor

PI: Ahles
Title: CCNY-MSKCC Partnership for Cancer Research, Education and Community Outreach
Time Commitments: 0.22 calendar
Supporting Agency: NCI U54 CA137788-12
Address: National Cancer Institute
Contracting/Grants Officer: Nelson Aquila, DVM
Performance Period: 9/20/2019 - 8/31/2024
Level of funding:
Project Goals: To support and extend the City College of New York - Memorial Sloan Kettering Cancer Center Partnership for Cancer Research, Education and Community Outreach.
Specific Aims: Not applicable
Role: Advisory Committee

PI: Ostroff
Title: Optimizing Tobacco Treatment for Smokers Seeking Lung Cancer Screening
Time Commitments: 1.80 calendar
Supporting Agency: NCI R01 CA207442
Address: National Cancer Institute
Contracting/Grants Officer: Stephanie Land, PhD
Performance Period: 8/9/2016 - 11/30/2022
Level of funding:
Project Goals: To test tobacco treatment interventions for implementation within the context of lung cancer screening.
Specific Aims: 1: To identify which of four evidence-based tobacco treatment components contribute to superior cessation endpoints among current smokers seeking lung cancer screening; 2) To estimate the cost and incremental cost-effectiveness of evidence-based tobacco treatment components; 3) To examine

implementation processes and sustainability for disseminating effective models for smoking cessation treatment in lung cancer screening settings.
Role: Principal Investigator

PI: Ostroff
Title: Understanding Tobacco Treatment Refusal Among African-Americans in the Context of Lung Cancer Screening
Time Commitments: 0.0 calendar
Supporting Agency: 3 R01 CA207442-03S1
Address: National Cancer Institute
Contracting/Grants Officer: Gordon B Willis, PhD
Performance Period: 8/9/2019 – 11/30/2022
Level of funding:
Project Goals: The goal of this diversity supplement is to provide mentored research training focused on advancing understanding of recruitment and retention of African American smokers in a tobacco treatment trial.
Specific Aims: Aim 1: To gain a better understanding of participant refusal in a tobacco treatment trial among African- American smokers using a rigorous qualitative approach. Aim 2: To develop and evaluate a recruitment strategy designed to recruit African-American smokers in a tobacco treatment trial.
Role: Principal Investigator

PI: Ostroff
Title: Psychosocial Palliative and Community Research in Cancer
Time Commitments: 0.60 calendar
Supporting Agency: NCI T32 CA009461-36A1
Address: National Cancer Institute
Contracting/Grants Officer: Susan Lim PhD
Performance Period: 9/1/2019 - 8/31/2024
Level of funding:
Project Goals: This training grant support training outstanding, new investigators in Psycho-Oncology.
Specific Aims: Not applicable
Role: Principal Investigator

PI: Thompson
Title: Cancer Center Support Grant (Population Science Research Program)
Time Commitments: 1.80 calendar
Supporting Agency: NCI P30 CA008748-54
Address: National Cancer Institute
Contracting/Grants Officer: Henry Ciolino, PhD
Performance Period: 1/20/2018 - 12/31/2023
Level of funding:
Project Goals: Memorial Sloan Kettering Cancer Center (MSK) is a free-standing institution dedicated to the control of cancer through inpatient and outpatient care, clinical and research training programs, and a broad spectrum of research activities.
Specific Aims: Not applicable
Role: Program Co-Leader

PI: Bricker
Title: Quit2Heal: Rigorous Randomized Trial of a Smartphone Application to Help Cancer Patients Stop Smoking
Time Commitments: 1.20 calendar
Supporting Agency: NCI R01CA253975
Address: National Cancer Institute

Contracting/Grant Officer: Gordon B Willis, PhD
Performance Period: 6/1/2020 - 5/31/2025
Level of funding:
Project Goals: The clinical trial will test the effectiveness of smartphone-delivered tobacco treatment intervention (Quit2Heal) for treatment of tobacco use and dependence among cancer patients.
Specific Aims: 1) To determine whether Quit2Heal has significantly higher biochemically verified 30-day point prevalence smoking cessation at 12 months post-randomization than QuitGuide; and 2) To determine whether Quit2Heal's 12-month smoking cessation outcome is significantly mediated by improvements in cancer-related shame, stigma, depression, anxiety, and knowledge about consequences of smoking vs. quitting after cancer diagnosis.
Role: Subsite Principal Investigator

PI: Gillespie
Title: Leveraging implementation science to accelerate adoption of shorter-course radiation for breast and prostate cancer
Time Commitments: 0.00
Supporting Agency: NCI K08 CA252640
Address: National Cancer Institute
Contracting/Grant Officer: Sergey Radaev, PhD
Performance Period: 8/15/2020 - 7/31/2025
Level of funding:
Project Goals: The proposed research is relevant to public health because it addresses the appropriate use of shorter radiation treatments (called "hypofractionation") for breast and prostate cancer, a critical step to improving access to high-value patient-centered cancer care.
Specific Aims: 1) Identify and characterize positive deviant radiation oncologists (high users of hypofractionation) that will 2) Elucidate implementation strategies and associate them with adoption of hypofractionation across various settings, and 3) Pilot test a multi-pronged strategy that promotes use of hypofractionation in preparation for a large pragmatic multi-center controlled trial.
Role: Co-Mentor

PI: Salz
Title: Effectiveness Trial of a Head and Neck Cancer Survivorship Tool
Time Commitments: 0.30 calendar
Supporting Agency: ACS RSG-18-016-01-CPHPS
Address: American Cancer Society
Performance Period: 7/1/2018 - 12/31/2022 NCE
Level of funding:
Project Goals: This clinical trial is testing the implementation and effectiveness of the Head and Neck Survivorship Tool: Assessment and Recommendations (HN-STAR).
Specific Aims: 1) To evaluate the impact of HN-STAR on patient-centered outcomes; 2) To evaluate the impact of HN-STAR on adherence to guideline-concordant care and 3) To conduct a robust, mixed methods evaluation of the implementation process, including assessments of survivor, provider, and organizational barriers and facilitators that may influence integration of HN-STAR in various NCORP settings.
Role: Co-Investigator

PI: Gillespie
Title: Improving Radiation Contour Quality at the Point of Care by Integrating 3D Image-based Contouring Guidelines, Radiographic Anatomy, and Feedback into the Clinical Workflow
Time Commitments: 0.10 calendar
Supporting Agency: Radiologic Society of North America EI1902
Performance Period: 7/1/2019 - 6/30/2023 NCE
Level of funding:
Project Goals: This study provides radiation oncologists with a novel comprehensive point-of-care educational image-based decision support tool that facilitates the delivery of highly conformal radiation treatments that are safe, effective, and evidence-based.

Specific Aims: The specific aims are 1: Expand eContour content as a clinical decision support resource and 2: Develop and test eContour as a point-of-care educational and feedback tool for residents.
Role: Co-Investigator

NEWLY INACTIVE:

PI: Ostroff
Title: Tobacco Treatment Training for Cancer Care Providers
Time Commitments: 1.20 calendar
Supporting Agency: NCI R25 CA217693-03
Address: National Cancer Institute
Contracting/Grants Officer: Jeanette Korczak, PhD
Performance Period: 8/1/2017 - 7/31/2022
Level of funding:
Project Goals: The goal of this cancer education project is to train oncology care providers to implement tobacco use assessment and treatment (TUT) in their cancer care settings. This project will develop, implement, evaluate and disseminate a skills development course and collaborative training initiative.
Specific Aims: 1) To develop a Tobacco Treatment Training-Oncology (TTT-O) education program and deliver it through in-person workshops and web-based collaborative learning activities with a total of 240 multidisciplinary cancer care provider participants from diverse cancer practice settings; 2) To evaluate the impact of the TTT-O on participants' TUT knowledge, attitudes, self-efficacy and implementation of TUT in participants' clinical settings.
Role: Principal Investigator

PI: Sheffer
Title: Competency-based training to advance clinical proficiencies and reduce disparities in the treatment of tobacco dependence
Time Commitments: 1.20 calendar
Supporting Agency: NCI R25 CA233416
Address: National Cancer Institute
Contracting/Grants Officer: Jeanette Korczak, PhD
Performance Period: 9/1/2019-8/31/2021
Level of funding:
Project Goals: To develop a curriculum to improve awareness, knowledge and clinical proficiency of health care providers in identifying and addressing tobacco-related disparities.
Specific Aims: 1) To develop a training module that advances clinical proficiencies in the treatment of tobacco dependence among groups that experience tobacco-related disparities; and 3) To disseminate the training module among the growing network of accredited tobacco treatment training programs.
Role: Subsite Principal Investigator

PI: Thompson
Title: Cancer Center Support Grant
Time Commitments: 0.90 calendar
Supporting Agency: NCI P30 CA008748-54 S6
Address: National Cancer Institute
Performance Period: 9/1/2020 - 8/31/2021
Level of funding:
Project Goals: Leveraging telehealth for tobacco treatment is a novel way to increase reach for cancer patients; adding a health communication tool via video or brief video virtual advice statement tailored to their diagnosed cancer has the potential to increase patient engagement by presenting personally relevant information.
Specific Aims: 1) examine the effect of (1) an introductory TTP video compared to (2) brief video virtual advice statements compared to (3) usual care (mailed tobacco treatment program brochure) to increase reach (defined as TTP acceptance) among cancer patients who are individuals who currently smoke; 2) examine

the feasibility, acceptability and usability of a group telehealth platform format to deliver a structured 6-week group tobacco treatment program to cancer patients who currently smoke; and 3) using a 2-phase random assignment, pilot randomized control trial, compare the effectiveness of a structured 6-week group telehealth TTP to a structured 6-week individual telehealth TTP to improve: 1) patient engagement; 2) adherence to TTP; 3) effectiveness on quit rates; and (4) overall cost effectiveness.
Role: Co-Investigator

PI: Rolland
Title: Tobacco Status and COVID in the Cancer Center Cessation Initiative
Time Commitments: 0.00 calendar
Supporting Agency: NCI OISE-20-66590-1
Address: National Cancer Institute
Contracting/Grant Officer:
Performance Period: 6/29/2020 - 6/28/2021
Level of funding:
Project Goals: Using this de-identified, patient-level data, the Cancer Center Cessation Initiative (C3I) Coordinating Center at the University of Wisconsin will examine bivariate associations between smoking status and COVID-19 outcomes, and use multivariate logistic regression models to examine associations between smoking status and COVID-19 outcomes, adjusting for patient clinical and demographic characteristics.
Specific Aims: N/A
Role: Principal Investigator

PI: Park
Title: Implementing Virtual Tobacco Treatment in Community Oncology Practices
Time Commitments: 1.80 calendar
Supporting Agency: NCI R01CA214427-02
Address: National Cancer Institute
Contracting/Grants Officer: Brenda Adjei PhD
Performance Period: 2/1/2018 - 7/31/2022
Level of funding:
Project Goals: This project is testing tobacco treatment interventions in national community oncology practices (NCORP).
Specific Aims: 1) To assess the treatment effectiveness of a virtually-delivered intensive treatment (VIT), compared to standard care (SC), in producing tobacco abstinence; 2) To identify patient and practice characteristics associated with treatment effectiveness and 3) To conduct a robust, mixed methods evaluation of the implementation process and assess patient and organizational factors that may influence implementation of tobacco cessation treatment in various NCORP cancer care settings
Role: Subsite Principal Investigator

PI: Thompson
Title: Cancer Center Support Grant
Time Commitments: 1.20 calendar
Supporting Agency: NCI P30 CA008748-53 S1
Address: National Cancer Institute
Contracting/Grants Officer: Stephanie Land PhD
Performance Period: 1/1/2019 - 12/31/2020 NCE
Level of funding:
Project Goals: To improve the reach and effectiveness of tobacco treatment delivery in cancer care.
Specific Aims: The specific aims are to identify and address patient, provider and systems-level barriers to tobacco cessation treatment delivery in our large, multi-site geographically diverse comprehensive cancer care center, and to develop and share practical, scalable, sustainable solutions for optimizing implementation of tobacco treatment in cancer care settings.
Role: Program Leader

OVERLAP:

None.