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TITLE: Effect of Diabetes and Obesity on Disparities in Prostate Cancer Outcomes

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CONTRACTING ORGANIZATION: Washington University
                                              Saint Louis, MO 63130

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Effect of Diabetes and Obesity on Disparities in Prostate Cancer Outcomes

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5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)

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13. SUPPLEMENTARY NOTES

14. ABSTRACT
The Veterans Affairs (VA) prostate cancer cohort is an ideal study sample to study disparities in predictors of adverse prostate cancer outcomes. We have successfully merged and cleaned the data on prostate cancer clinical characteristics and BMI calculations over multiple time points. Results from this study will help prostate cancer patients at high risk for recurrence or prostate cancer related death by identifying potential modifiable factors.

15. SUBJECT TERMS
Prostate cancer, disparities, VHA and VACCR data, obesity, mortality, survival, recurrence

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1. **INTRODUCTION:**
The purpose of this study is to utilize a prostate cancer cohort from the VA hospitals to explore the association between obesity (at prostate cancer diagnosis and during follow-up) and prostate cancer recurrence and mortality; type II diabetes (at prostate cancer diagnosis and during follow-up) and prostate cancer recurrence and mortality; as well as the combined effect of obesity and type II diabetes on the risk of prostate cancer recurrence and mortality.

2. **KEYWORDS:**
Prostate cancer, race, type II diabetes, obesity, disparities, mortality, survival analysis

3. **ACCOMPLISHMENTS:**
   What were the major goals of the project?

   1. Team Meeting
      a. Review grant and progress of recruitment in parent study – Year 1, Month 1 – 100% complete
      b. Team Meetings will occur monthly throughout the award – Year 1-3, Monthly – 100% complete
      c. Interview and hire staff – Year 1, Month 2 – 100% complete
   2. Regulatory review and IRB
      a. Complete and submit forms for regulatory review – Year 1, Month 1-2 – 100% complete
      b. Complete and submit IRB forms for review – Year 1, Month 2-3 – 100% complete
      c. Obtain approval for regulatory and IRB forms – Year 1, Month 4 – 100% complete
   3. Study team will obtain and assess data
      a. Finalize variables and codes needed for analysis – Year 1, Month 5-6 – 100% complete
      b. Clean and organize data by participants ID – Year 1, Month 6-8 – 100% complete
      c. Run frequencies, report, and correct any errors found – Year 1, Month 9-11 – 100% complete
   4. Perform analyses
      a. Finalize data analysis plans – Year 1, Month 11-12 – 100% complete
   5. Manuscript Development – Year 2 – 25% complete
      a. AIM 1 – To examine the effects of type 2 diabetes mellitus on prostate cancer outcomes and how race modifies the relationship.
      b. AIM 2 – To examine the effects of obesity on prostate cancer outcomes and how race modifies the relationship.
      c. AIM 3 – To examine the effect of racial difference in the interaction between type 2 diabetes and obesity on prostate cancer outcomes.
      d. Additional analyses
   6. Presentations – Year 2

   What was accomplished under these goals?

1. Major activities: Finalized variables needed to run analyses, cleaned and organized data, ran frequencies and corrected any errors (e.g., removed duplicate cases, corrected reporting errors in height and weight measurements and TNM staging).
2. Specific objectives: Finalize data analysis plan in order to run analyses.
3. Significant results or key outcomes:
   - Identified in previous research using VA data methods to reduce inconsistencies with height and weight measurements of patients.
   - Finalized key variables to merge important datasets.
4. Other achievements:
   - Removed variables that were "biologically impossible", >84' and <48" and >700lbs and <75 lbs based on methods previously published by Das, et al.
   - Issue: Large number of patients over 500 pounds. Solution: expanded the obese category into Obese I, Obese II, Obese III according to WHO guidelines.
   - Issue: Missing height data and heights under 48 inches. Solution: Use highest frequency of height measurement among patient visits for single individual.
5. For AIM's 1 and 3, pharmacy and co-morbidity data have been requested.
   AIM 1 – Data requested
   AIM 2 – Data analysis tables developed
   AIM 3 – Data requested
6. Presentations – DOD PCRP IMPaCT Conference 2016

What opportunities for training and professional development has the project provided?
Nothing to Report

How were the results disseminated to communities of interest?
Results presented and disseminated at the 2016 DOD PCRP IMPaCT Conference, community partners within our Program for the Elimination of Cancer Disparities meetings, and 2 presentations at Washington University School of Medicine Urologic seminars.

What do you plan to do during the next reporting period to accomplish the goals?
Performing analyses on specific aims of the study and begin manuscript development, requesting pharmaceutical and co-morbidity data from the VA, draft and finalize manuscript for AIM's 1-3, and present findings.

4. **IMPACT:**
What was the impact on the development of the principal discipline(s) of the project?
The initial analyses are targeting obesity and other co-morbidities and how changes in weight and management of co-morbidities are impacting prostate cancer outcomes. The initial steps of this study which included: requesting data, cleaning data, and data analysis, are laying the foundation for even further analyses.

What was the impact on other disciplines?
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:**
Changes in approach and reasons for change
Nothing to Report

Actual or anticipated problems or delays and actions or plans to resolve them
1. The wait time between date of request for new variables from the VA hospital system or the VACCR and receipt of the data can take several weeks to a month. To work around this future delay, our team has proactively requested all potentially relevant variables for all aims of the study to eliminate the wait time for additional requests in future years.
   UPDATE: We currently have received most data requests and anticipate receiving the final datasets in the coming weeks. The missing data are necessary to finalize Aims 1 and 3.

2. There have been periods of time in which the server used to store and analyze the VA data has been out of service for a number of reasons. This has slowed the process of the study. As of September of 2015, the Administrative Officer of Research has confirmed, through an email to our research team, that the server will be updated soon.
   UPDATE: The VA server has been updated and this is no longer an issue.

3. The wrong cohort was sent with PBM data, which data re-requested and this is currently still in process.

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.
  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?

1. Name: Bettina F. Drake, PhD, MPH
   Project Role: Principal Investigator
   Researcher Identifier (e.g. ORCID ID):
   Nearest person month worked: 3.6
   Contribution to Project: Dr. Drake is the lead investigator on this study.
   Funding Support: DoD Grant

2. Name: Veronica Hicks, MPH
   Project Role: Data Analyst
   Researcher Identifier (e.g. ORCID ID):
   Nearest person month worked: 6
   Contribution to Project: Mrs. Hicks has worked on goals related to this study including data cleaning, management, and analysis.
   Funding Support: DoD Grant

3. Name: Danielle Rancilio, MS, MPH
   Project Role: Research Coordinator
   Researcher Identifier (e.g. ORCID ID):
   Nearest person month worked: 3
   Contribution to Project: Mrs. Rancilio has worked on goals related to this study including data management.
   Funding Support: DoD Grant

4. Name: Ken Carson, MD
   Project Role: Co-Investigator
   Researcher Identifier (e.g. ORCID ID):

Nearest person month worked:	1.2	
Contribution to Project:	Dr. Carson has facilitated access to the data and participated in data cleaning and team meetings.	
Funding Support:	DoD Grant	

5. Name: Melody Goodman, PhD
     Project Role: Co-Investigator
     Researcher Identifier (e.g. ORCID ID):
     Nearest person month worked: 1
     Contribution to Project: Dr. Goodman has worked on goals related to this study by participating in data cleaning and team meetings.
     Funding Support: DoD Grant

6. Name: Thomas Baranski, MD, PhD
     Project Role: Co-Investigator
     Researcher Identifier (e.g. ORCID ID):
     Nearest person month worked: 1
     Contribution to Project: Dr Baranski has worked on goals related to this study by participating in data cleaning and team meetings.
     Funding Support: DoD Grant

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?
Melody Goodman, PhD is leaving the institution on December 31, 2016.

What other organizations were involved as partners?
Nothing to Report

8. SPECIAL REPORTING REQUIREMENTS
COLLABORATIVE AWARDS:
N/A

QUAD CHARTS:
N/A

9. APPENDICES:
None