

AWARD NUMBER: W81XWH-19-1-0512

TITLE: Long-term Outcomes of Localized Prostate Cancer Survivors

PRINCIPAL INVESTIGATOR: Ronald C. Chen, MD, MPH

CONTRACTING ORGANIZATION: University of Kansas Medical Center, Kansas City, KS

REPORT DATE: August 2021

TYPE OF REPORT: Annual Report

PREPARED FOR: U.S. Army Medical Research and Development Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGEForm Approved
OMB No. 0704-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. **PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.**

1. REPORT DATE August 2021		2. REPORT TYPE: Annual		3. DATES COVERED 01Aug2020-31Jul2021	
4. TITLE AND SUBTITLE Long-Term Outcomes of Localized Prostate Cancer Survivors				5a. CONTRACT NUMBER W81XWH-19-1-0512	
				5b. GRANT NUMBER	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Ronald C. Chen, MD, MPH E-Mail: rchen2@kumc.edu				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) University of Kansas Medical Center Research Institute, Inc., MSN 1039, 3901 Rainbow Boulevard Kansas City, KS 66103-2937				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Development Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT Background: Patients with localized prostate cancer face a confusing decision among many options. The standard options in current guidelines range from active surveillance, surgery, and radiation therapy (RT, various forms). Surgery and RT have evolved/improved significantly. Patients need long-term outcomes (quality of life, cancer control/recurrence, and survival) of modern treatments in order to help them make a treatment decision; however, these data do not exist. The current literature includes outcomes of older surgery and RT modalities no longer commonly used today, or short-term outcomes of modern treatments. This means that patients today do not have the information they need to make an informed decision, and must use outdated data of older prostate cancer treatments. In 2010, the study team worked with a national group of stakeholders including patients to design this study to provide data that are directly relevant to patients and stakeholders. With funding from AHRQ, PCORI and NCI, we enrolled a population-based cohort of newly-diagnosed patients, and have followed them prospectively/annually. Here, we propose to study 8-10 year outcomes.					
15. SUBJECT TERMS					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			19b. TELEPHONE NUMBER (include area code)
Unclassified	Unclassified	Unclassified	Unclassified		USAMRMC

Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

TABLE OF CONTENTS

	<u>Page</u>
1. Introduction	4
2. Keywords	4
3. Accomplishments	5
4. Impact	7
5. Changes/Problems	8
6. Products	9
7. Participants & Other Collaborating Organizations	9

INTRODUCTION

Patients with localized prostate cancer face a confusing decision among many options. The standard options in current guidelines range from active surveillance, surgery, and radiation therapy (RT, various forms). Surgery and RT have evolved/improved significantly. Patients need long-term outcomes (quality of life, cancer control/recurrence, and survival) of modern treatments in order to help them make a treatment decision; however, these data do not exist. The current literature includes outcomes of older surgery and RT modalities no longer commonly used today, or short-term outcomes of modern treatments. This means that patients today do not have the information they need to make an informed decision, and must use outdated data of older prostate cancer treatments. In 2010, the study team worked with a national group of stakeholders including patients to design this study to provide data that are directly relevant to patients and stakeholders. With funding from AHRQ, PCORI and NCI, we enrolled a population-based cohort of newly-diagnosed patients, and have followed them prospectively/annually. Here, we propose to study 8-10 year outcomes.

KEYWORDS

*Prostate Cancer
Cancer Registry
Active Surveillance
Quality of Life*

ACCOMPLISHMENTS

The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction.

- **What were the major goals of the project?**
 - List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project identify these dates and show actual completion dates or the percentage of completion.

Investigators and staff are at the University of Kansas Medical Center and University of North Carolina at Chapel Hill. The major goals of the project, as outlined in the approved SOW, are as follows:

Specific Aim 1: Directly compare QOL and decisional regret within 10 years of follow-up in men managed by initial active surveillance, radical prostatectomy and radiation therapy (RT).	Month	Personnel	Site (KUMC/UNC)	Percent Complete
Major Task 1: Complete patient surveys				
Subtask 1: IRB modification to allow extended follow-up of NC ProCESS cohort (University of North Carolina IRB). (Month 1)	1	Dr. Chen	KUMC & UNC	100%
Subtask 2: Modify study databases, including patient tracking database to include new data elements for this proposed study. Obtain USAMRDC ORP HRPO regulatory approval.	1-3	Dr. Chen	UNC	100%
Subtask 3: First round of annual survey	3-14	Dr. Chen	UNC	100%
Subtask 4: Second round of annual survey	15-26	Dr. Chen	UNC	60%
Subtask 5: Data analysis	7-30		KUMC	0%
<i>Milestone(s) Achieved: By the end of month 26, all patients will have patient-reported outcomes data collected at 8-10 years of total follow-up to provide long-term results. By the end of month 30, data analysis will be completed for Specific Aim 1.</i>				In progress
Specific Aim 2: Directly compare sexual, urinary and bowel morbidity requiring medical intervention within 10 years of follow-up in men managed by initial active surveillance, radical prostatectomy and RT.				
Major Task 2: Linkage of NC ProCESS patient cohort data with data from the NC Central Cancer Registry and insurance claims				
Subtask 1: Data linkage by UNC CIPHR core facility staff	25-30	Dr. Kuo	UNC	10%
Subtask 2: Creation of analytic data set from linked data	31	Dr. Katz	KUMC	0%
Subtask 3: Data analysis	31-36	Dr. Katz	KUMC	0%

<i>Milestone(s) Achieved: Completion of Aim 2 will provide data on long-term treatment-related morbidity that require medical intervention.</i>				In progress
Specific Aim 3: Directly compare cancer recurrence and survival within 10 years of follow-up in men managed by initial active surveillance, radical prostatectomy and RT.				
Major Task 3: Assess prostate cancer recurrence				
Subtask 1: Collect patient medical records	16-27	Dr. Chen	UNC	60%
Subtask 2: Abstract medical records to assess prostate cancer recurrence	16-30	Dr. Chen	UNC	50%
Subtask 3: Data analysis	31-36	Dr. Katz	KUMC	0%
<i>Milestone(s) Achieved: Completion of Major Task 3 will provide data on long-term cancer control and recurrence rates for patients in different initial management groups</i>				In progress
Major Task 4: Assess survival and mortality				
Note, this is accomplished by the data linkage step described above (Major Task 2, Subtask 1). Survival/mortality information is contained in the NC Central Cancer Registry data	21-24	Dr. Kuo	UNC	0%
Subtask 4: Data analysis	25-30	Dr. Katz	KUMC	0%
<i>Milestone(s) Achieved: Completion of Major Task 4 will provide data on overall survival/mortality for patients in different initial management groups</i>				Not yet started

- **What was accomplished under these goals?**

- 1) Major Activities:

During Year 2 of the award period, annual telephone surveys with the research participants continued. We completed the first round of annual follow-up surveys (8 years after treatment for prostate cancer). The second round of annual follow-up surveys (9 years post-treatment) are underway with approximately 50% completed. The final follow-up telephone survey (10 years post-treatment) also began during Year 2 of the award period. Processes for initiating this survey included programming updates to the Computer-Assisted Telephone Interview (CATI) software (for software-guided telephone interviews) and the web-based tracking system. Annual telephone surveys include questions about participants' prostate-specific quality of life, anxiety, and assessment of treatment decision regret. We also continue to provide gift cards to participants who complete annual follow-up surveys and return medical records release and HIPAA authorization forms.

We continue to make steady progress collecting medical records: we've requested and collected current medical records for approximately a third of enrolled participants. We have begun abstracting clinical variables (e.g., documented prostate cancer recurrence and associated salvage treatment) and anticipate completing this task by the end of the year.

Further, to reduce attrition of participants enrolled in our study, we developed and mailed a newsletter to all currently enrolled participants with updates on the study progress.

Finally, the process for linking the NC ProCESS patient cohort with claims data (Major Task 2) is underway. Data use agreement applications have been submitted to the applicable data owners for their review and approval. Once data use agreements have been approved, we will begin the process of linking participant survey responses and claims data to form a comprehensive analytic dataset.

2) Specific Objectives:

Specific objectives of the research study are to directly compare patient-reported quality of life outcomes and decisional regret; sexual, urinary and bowel morbidity requiring medical intervention and hospitalizations; and cancer recurrence and survival within 10 years of follow-up in men managed by initial active surveillance, radical prostatectomy and radiation therapy (RT).

The Major Tasks in Year 1 and Year 2 (see table above) outline necessary processes for completing these objectives.

3) Significant Results/Key Outcomes (*including major findings, developments, or conclusions (both positive and negative)*):

During Year 2 of the award period, study staff attempted 617 follow-up phone surveys with 54% of these attempts resulting in a completed phone survey.. There are no major findings to report at this time.

- **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 the upcoming year, we will continue follow-up phone surveys. We will also continue collecting and abstracting medical records. We will prepare an analytic data set to assess the stated objectives of the project. We will link the NC ProCESS patient cohort data with data from the NC Central Cancer Registry and insurance claims data.

We will continue efforts to reduce attrition and keep participants engaged by providing gift cards to participants who complete surveys and return medical records release forms. We will create and mail a newsletter with project updates to enrolled participants; and trace participants who may be lost to follow-up.

IMPACT

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

Nothing to Report

- **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

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**

Nothing to Report

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

Nothing to Report

- **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

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

PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

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

Ronald Chen	PI		1	Leads the study, overseeing its execution. Holds weekly meetings with research staff and monthly meetings with co-investigators.	
Matt Nielsen	Co-I (subcontract PI)		1	Oversees the UNC subcontract; meet monthly with PI; provides clinical and research expertise.	
Aaron Katz	Co-I		1	Guides data linkage for this study; assists in overseeing and troubleshooting data collection progress; provides research	

				expertise to the study.	
Deborah Usinger	UNC Project Manager		4	Manage all day-to-day aspects of the project; e.g., tracking of data collection, regulatory processes, liaison with Carolina Survey Research Laboratory and Sheps Center for Health Services Research – Web Development Services	
Sarah Walden	UNC Research Assistant		12	Prepare mailings (e.g., gift card incentives to participants for each survey completion), contacting facilities for medical records collection, medical record abstraction; primary point person for NC ProCESS participants.	

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

The following outlines changes in the active other support for the PI and key personnel:

- Dr. Chen is no longer supported by the following:
 - Enhancing Survivorship Care Planning for Patients with Localized Prostate Cancer Using A Couple-focused Web-based Tailored Symptom Self-Management Program; # R21-CA21516-01
 - Testing the Efficacy of a Couple-focused, Tailored mHealth Intervention for Symptom Self-Management among Men with Prostate Cancer and Their Partners; # R01-NR016990-01A1
 - Disparities in care of prostate cancer survivors, a population-based cohort study; #R21-MD012464-01
 - North Carolina Prostate cancer Comparative Effectiveness & Survivorship Study (NC ProCESS): A Stakeholder-Driven, Population-Based Prospective Cohort Study; #CER-1310-06453
 - Optimizing the effectiveness of routine post-treatment surveillance in prostate cancer survivors; # CER-1503-29220

- Investigation of Circulating Tumor Cells from Cancer Patients Undergoing Radiation Therapy
- Cancer Center Core Support Grant; # P30-CA016086-40
- Survivorship Care Plan and Patient Navigation In Prostate Cancer Survivors
- Dr. Chen currently receives support from the following:
 - Cancer Center Support Grant; # P30 CA168524; 2.4 calendar months
 - Prospective Comparative Study of Outcomes with Proton and Photon Radiation in Black and White Men with Prostate Cancer; # PCS-2017C1-0422; 2.4 calendar months
 - Long-Term Outcomes of Localized Prostate Cancer Survivors; # W81XWH-19-1-0512; 1.296 calendar months
 - Prostate cancer comparative outcomes of new conceptual paradigms for treatment (PC CONCEPT); 1.8 calendar months
 - Patient and Investigator Voices Organizing Together (PIVOT) Across the Translational Research Continuum; P30 CA168524-09S4 SUPPL; .72 calendar months
- Dr. Nielsen is no longer supported by the following:
 - Optimizing the effectiveness of routine post-treatment surveillance in prostate cancer survivors; # CER-1503-29220
 - Enhancing Survivorship Care Planning for Patients with Localized Prostate Cancer Using A Couple-focused Web-based Tailored Symptom Self-Management Program; # R21-CA21516-01
- Dr. Nielsen currently receives support from the following:
 - Ostomy Telehealth Self-Management Training for Cancer Survivors; # R01-CA204193-01A1; 1.2 calendar months
 - SCH: INT: AURA-Connecting Audio and Radio Sensing Systems to Improve Care at Home; #R01-LM013329-01-02; 0.12 calendar months
 - Long-Term Outcomes of Localized Prostate Cancer Survivors; # W81XWH-19-1-0512; 0.36 calendar months
 - North Carolina Prospective Prostate Cancer Cohort Study; no number; 0.12 calendar months
- Dr. Katz currently receives support from the following:
 - Prospective Comparative Study of Outcomes with Proton and Photon Radiation in Black and White Men with Prostate Cancer; # PCS-2017C1-0422; 6 calendar months.
 - Prostate cancer comparative outcomes of new conceptual paradigms for treatment (PC CONCEPT); 1.8 calendar months
- **What other organizations were involved as partners?**

Nothing to Report