AWARD NUMBER: W81XWH-21-1-0732

TITLE: Implementation of Kidney Cancer-Specific Training for Clinical Research Nurses

PRINCIPAL INVESTIGATOR: Lauren Evans

CONTRACTING ORGANIZATION: Sloan Kettering Institute for Cancer Research
New York, NY

REPORT DATE: October 2022

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

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1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
October 2022	Annual	30Sep2021-29Sep2022

4. TITLE AND SUBTITLE

Implementation of Kidney Cancer-Specific Training for Clinical Research Nurses

5a. CONTRACT NUMBER
W81XWH-21-1-0732

5b. GRANT NUMBER

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)

Lauren Evans, Patricia Fischer, Susanne Gornell, Chung-Han Lee
Robert Motzer, Robert Goodman, Alisa Ritea, Cindy Puzio

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

Sloan Kettering Institute of Cancer Research
1275 York Ave
New York, NY 10065

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

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

During the review period, investigators and mentors are credited in initiating a renal cell cancer clinical research nurse-specific training and orientation program for three clinical research nurse trainees. We have also mentored the clinical research nurse trainees in the beginning stages of the research project.

15. SUBJECT TERMS Clinical trial nursing, Training, Telemedicine					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON USAMRDC
a. REPORT Unclassified	b. ABSTRACT Unclassified	c. THIS PAGE Unclassified	Unclassified	20	19b. TELEPHONE NUMBER *(include area code)*

Standard Form 298 (Rev. 8-98)
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1. INTRODUCTION:

Clinical trial development has been critical for improving the outcomes of patients with kidney cancer, with the approval of 13 new treatments in the last 15 years. With proper oversight, clinical trials provide patients safe, early access to new medications that are promising. However, access to these novel treatments can be limited by the availability of expertise. Clinical research nurses (CRNs) are critical members of the patient's medical team that ensure that new medications can be delivered ethically, safely, and effectively. We hypothesize that having CRNs that are specialized in kidney cancer will improve the safety and tolerability of patients treated on clinical trials by improving the management of side effects and making sure patients adhere to the schedule and rules of the clinical trial.

To improve the access of disease-specific CRNs, we propose a project with two specific aims:

Specific Aim 1: Establish a kidney cancer–specific CRN training program

Specific Aim 2: Perform a pilot project to study the safety and quality of care when integrating telemedicine into clinical trial nursing

2. KEYWORDS:

Clinical trial nursing, Training, Telemedicine

3. ACCOMPLISHMENTS:

What were the major goals of the project?

Specific Aim 1: To establish a kidney cancer-specific fellowship program for CRNs

- Major Task 1: Train and orient CRN trainees who have limited experience in management of kidney cancer patients in research setting
- Major Task 2: Educate CRN trainees on kidney cancer pathophysiology, disease and symptom management, clinical research nursing practice, nursing research, and clinical trial operations

Specific Aim 2: To conduct a pilot research project providing research training experience to CRNs

- Major Task 1: Train and orient CRN trainees and CRA
- Major Task 2: Collection of safety and protocol compliance data from target populations

- Major Task 3: To compare healthcare utilization via outpatient and inpatient points of care before and after telemedicine adoption
- Major Task 4: To determine safety and protocol compliance as defined by rates of SAEs, rates of grade 3 and 4 toxicity, and rates of protocol deviations before and after telemedicine adoption
- Major Task 5: To compare patient and provider perceptions of telemedicine as a contributor to encountered SAEs

What was accomplished under these goals?

Specific Aim 1:

- *Major Task 1:*
    - *Completed: Subtasks 1 – 11*
    - *Ongoing: Subtask 12 – 18 will be delayed by 6 months to be completed in months 12-18*
- *Major Task 2:*
    - *Completed: Subtask 2, 3, 5, 6, 8, 9*
    - *Ongoing: Subtask 1, 4, 7 are ongoing as per schedule*

Specific Aim 2:

- *Major Task 1:*
    - *Completed: Subtask 1-3*
- *Major Task 2:*
    - *Completed: Subtask 1, 2, 3*
    - *Ongoing: Subtask 4 (ongoing patient accrual as per timeline), Subtask 5 (ongoing data collection as per timeline)*
- *Major Task 3:*
    - *Nothing to report*
- *Major Task 4:*
    - *Completed: Subtask 1*
- *Major Task 5:*
    - *Completed: Subtask 1 and 2*
    - *Ongoing: Subtask 3 as per schedule*

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

Include participation in conferences, workshops, and seminars not listed under major activities.

CTN trainee 1, 2, 3 attending didactic lectures
CTN trainee 2, completed one on one mentoring
CTN trainee 1 completed participation in research project, trainee 2 has ongoing participation in research project,
CTN trainee 1, 2, 3 participated in journal club and weekly clinical trial research meetings.

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?
.

Research for specific aim 2 will be published in a manuscript describing the perceptions of telemedicine in clinical trial management

4. 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

5. CHANGES/PROBLEMS:

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

Significant changes in use or care of human subjects

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?

Name: Lauren Evans
Role: PI
Nearest person month worked: 1.80 cal months

Name: Patricia Fischer
Role: Facilitator/Mentor
Nearest person month worked: 1.20 cal months

Name: Susanne Gornell
Role: Facilitator/Mentor
Nearest person month worked: 0.00 cal months / per the application

Name: Robert Goodman
Role: CRN Trainee
Nearest person month worked: 1.20 cal months / per the application
No additional funding support is available for the trainee

Name: Alisa Ritea
Role: CRN Trainee
Nearest person month worked: 1.20 cal months / per the application
No additional funding support is available for the trainee

Name: Cindy Puzio
Role: CRN Trainee
Nearest person month worked: 1.20 cal months / per the application
No additional funding support is available for the trainee

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

Please see updated support documentation

What other organizations were involved as partners?

Nothing to report

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS:

QUAD CHARTS:

9. APPENDICES:

Previous/Current/Pending Support: Lauren Evans

Current

**Title: Implementation of Kidney Cancer Specific Training for Clinical Research Nurses*
*Major Goals/Aims: To establish a kidney cancer-specific fellowship program for CRNs
2. To conduct a pilot research project providing research training experience to CRNs.
*Status of Support: Active
Project Number: W81XWH2110732
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 - 9/29/2023
*Total Award Amount (including Indirect Costs):

Role: Principal Investigator

Name of Contracting/Grants Officer:: Medha Darshan, M.S., MAT, Science Officer | Grants Officer Representative |US Army Medical Research and Development Command (USAMRDC), medha.s.darshan.civ@health.mil,

Person Months (Calendar/Academic/Summer) per budget period.

	Year (YYYY)	Person Months (##.##)
1.	2022	1.80 calendar
2.	2023	1.80 calendar

OVERLAP: None

Completed
None

Previous/Current/Pending Support
Fischer, Patricia

Previous Support

None.

Current Support

KC200301P1 (PI: Evans) 09/30/2021 – 09/29/2023 1.20 calendar
Congressionally Directed Medical Research
Implementation of Kidney Cancer-Specific Training for Clinical Research Nurses
We propose the development of a formal RCC CRN fellowship program to provide clinical training alongside RCC-specific mentorship, didactic lectures, and clinical and translational research training. CRN Trainees will be paired one-to-one with CRN and Physician Mentors during the fellowship, which will contain a clinical orientation phase, an education phase, and a research phase.

Aim 1: To establish a kidney cancer-specific fellowship program for CRNs
Aim 2: To conduct a pilot research project providing research training experience to CRNs
Aim 2a: To compare healthcare utilization via outpatient and inpatient points of care before and after telemedicine adoption
Aim 2b: To determine safety and protocol compliance, defined as rates of SAEs, rates of grade 3 and 4 toxicity, and rates of protocol deviations before and after telemedicine adoption.
Aim 2c: To compare patient and provider perceptions of telemedicine as a contributor to encountered SAEs.

Role: Facilitator/Mentor

Overlap: None.

Name of Contracting/Grants Officer: Joshua D. McKean, Grants Officer
Email: joshua.d.mckean3.civ@mail.mil |
Address: Department of the Army, US Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick, MD 21702-5014

Pending Support:

None

Previous/Current/Pending Support
Gornell, Suzanne

Previous Support

Title: Adaptive Immune Response to Nivolumab in Patients with Advanced Renal Cell Carcinoma
Role: Research Nurse
Sponsoring Agency: American Cancer Society
Effort: 3.0 CM
Funding Amount:
Performance Period: 1/1/2017–12/31/2020 (NCE)
Name of Grants Officer at Sponsoring Agency: American Cancer Society Extramural Research Department
Contact Information for Grants Officer: grants@cancer.org
Goals/Specific Aims: The goal of this study is to assess the safety and feasibility of neoadjuvant nivolumab administration in patients with resectable, high-risk, nonmetastatic renal cell carcinoma.
Overlap: None.

Current Support
KC200301P1 (PI: Evans) 09/30/2021 – 09/29/2023 0.00 calendar*
Congressionally Directed Medical Research
Implementation of Kidney Cancer-Specific Training for Clinical Research Nurses
We propose the development of a formal RCC CRN fellowship program to provide clinical training alongside RCC-specific mentorship, didactic lectures, and clinical and translational research training. CRN Trainees will be paired one-to-one with CRN and Physician Mentors during the fellowship, which will contain a clinical orientation phase, an education phase, and a research phase.
*No measurable effort/no salary support requested

Aim 1: To establish a kidney cancer-specific fellowship program for CRNs
Aim 2: To conduct a pilot research project providing research training experience to CRNs
Aim 2a: To compare healthcare utilization via outpatient and inpatient points of care before and after telemedicine adoption
Aim 2b: To determine safety and protocol compliance, defined as rates of SAEs, rates of grade 3 and 4 toxicity, and rates of protocol deviations before and after telemedicine adoption.
Aim 2c: To compare patient and provider perceptions of telemedicine as a contributor to encountered SAEs.

Role: Mentor

Overlap: None.

Name of Contracting/Grants Officer: Joshua D. McKean, Grants Officer
Email: joshua.d.mckean3.civ@mail.mil |

Address: Department of the Army, US Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick, MD 21702-5014

Pending Support:
None