

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

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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					
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TABLE OF CONTENTS

	<u>Page</u>
1. Introduction	6
2. Keywords	6
3. Accomplishments	6
4. Impact	8
5. Changes/Problems	10
6. Products	13
7. Participants & Other Collaborating Organizations	16
8. Special Reporting Requirements	18
9. Appendices	18

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 – 18*
- *Major Task 2:*
 - *Completed: Subtask 1-9*

Specific Aim 2: We proposed to conduct a pilot research project providing research training experience to CRNs and collecting data on clinical trial patient participants that conducted telemedicine visits. This included collection of safety and protocol compliance data from our target population as well as patient and provider perceptions of telemedicine.

- *Major Task 1:*
 - *Partially Completed: Subtask 1-3*
 - We identified and trained a CRA for our research project and trained and oriented two CRNs.
- *Major Task 2:*
 - *Partially Completed: Subtask 1, 2, 3, 4 and 5*
 - We designed and generated a RedCap database for project data collection of patients, nurses, and providers enrolled in our telemedicine project. We have prospectively identified patients and providers for these cohorts and performed a retrospective chart review on demographic and clinical characteristics. This demographic and clinical information has been annotated on RedCap with 40 patients total. **Subtask #3** is ongoing as we plan to analyze data of patients designated for the Pre-Telemedicine Cohort as a matched-control sample.
- *Major Task 3:*
 - *Nothing to report*
- *Major Task 4:* We proposed to determine safety protocol compliance as defined by rates of serious adverse events (SAEs), rates of grade 3 and 4 toxicity, and rates of protocol deviations before and after telemedicine adoption

- *Partially Completed: Subtask 1 & 3*
- determine rates of SAEs from patients in the Telemedicine Cohort. Specifically of the 40 patients enrolled in the pilot program, 9 patients experienced an SAE during the time they were monitored through telemedicine visits. We will plan to compare this with rates of SAE in matched patients in the Pre-Telemedicine Cohort. We will additionally analyze information on grade 3/4 toxicities and protocol deviations.
- *Major Task 5: we proposed to compare patient and provider (physician and nursing) perceptions of telemedicine, and specifically as it relates to clinical trials participants.*

- *Completed: Subtask 1 and 2*

- Generated distinct questionnaires for patients, physicians, and nurses and obtained IRB-approval (8/30/2022) to distribute these questionnaires (**Table 1**). These surveys were distributed quarterly to patients enrolled in clinical trials during the pilot program and providers engaged in clinical trials research and telemedicine visits.

- **Table 1: Completed Questionnaires**

Participant Type	Participant Number	Questionnaire Number
Patient	40	72
Nurse	7	20
Physician/APP	15	39

- *Completed: Subtask 3 & 4*

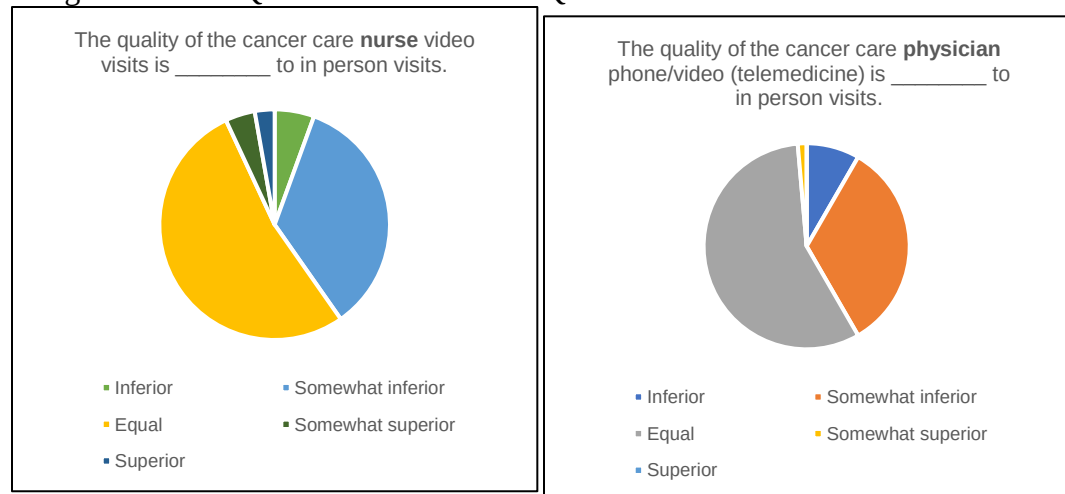
- Collected provider and patient perception data in 2023. Patients were offered identical questionnaires at three quarters during their telemedicine experience in 2023. These questionnaires consisted of three sections, which asked about baseline perceptions on telemedicine, specific perceptions on nursing encounters via telemedicine for clinical trials, and specific perceptions on physician encounters via telemedicine for clinical trials. A total of 40 patients completed 72 questionnaires; 32 patients completed 2 questionnaires and 8 patients completed 1. The median age of the 40 patients was 61 and 83% were White and only 5% were Black. Of these 40 patients, 100% had English as their preferred language. Patients were distributed across several lines of systemic therapy, including adjuvant (10%), first-line metastatic disease (43%), second-line (35%), and third-line and beyond (12%). Please see **Table 2** below for more details.

- **Table 2: Demographic and Clinical Characteristics of Patient Participants**

Age – median (range)	61 years (43-82)
Male Sex, N (%)	34 (85%)
Race, N (%)	
White	33 (83%)
Black	2 (5%)
Other/Unknown/Refused to Answer	5 (13%)
Preferred Language, N (%)	
English	40 (100%)
Other	0 (0%)
Renal Cell Carcinoma type, N (%)	
Clear Cell	33 (83%)

Other	7 (17%)
Line of Systemic Therapy, N (%)	
Adjuvant	4 (10%)
First	17 (43%)
Second	14 (35%)
Third or more	5 (12%)

- Importantly, at baseline, patients expressed preferring in-person visits with nurses in 30 surveys (42%) and physicians in 32 surveys (44%), having no preference with nurses in 17 surveys (24%) and with physicians in 15 (21%), and preferred telemedicine with nurses in 12 surveys (17%) and with physicians in 13 surveys (18%). Approximately 17-18% expressed that their preference on in-person vs telemedicine depended on the type of care visit. In free text responses, patients expressed the convenience and flexibility of having both options. Patients considered themselves to be tech savvy in 35 surveys (49%). Patients were then asked questions specific to their clinical trial encounters with nurses and physicians. When asked about nursing, patients in 52 surveys (72%) felt that a telemedicine visit was equal or better in adequately managing care and patients in 43 surveys (60%) felt that a telemedicine visit delivered equal or superior quality care (**Figure 1**). When asked about physician visits, patients in 47 surveys (65%) felt that a telemedicine visit was equal or better in adequately managing care and patients in 42 surveys (58%) felt that a telemedicine visit delivered equal or superior quality care (**Figure 1**). Patients noted that in-person interactions allowed for a more thorough evaluation and visit.
- Figure 1 Select Questions from Patient Questionnaire



- Clinical research nurses were concurrently offered questionnaires at three different quarters during their telemedicine experience in 2023. A total of 7 nurses completed 20 questionnaires. These questionnaires consisted of two sections, which asked about baseline perceptions on telemedicine and specific perceptions on clinical trials research via telemedicine. In 18 surveys (90%), the nurses expressed preference for in-person visits for clinical trial participants and in 2 surveys (10%), there was no preference between in-person and telemedicine. They

specifically noted a better ability to assess adverse events and toxicities in person. Furthermore, in 17 surveys (85%), the nurses expressed that a telemedicine visit was worse in adequately managing care and delivered inferior quality care. They did note that their experience with telemedicine clinical trial participant visits was positive (50%) or neither positive nor negative (50%).

- Providers (physicians and advance practice providers) were also offered questionnaires at three different quarters during their telemedicine experience in 2023. A total of 15 providers completed 39 questionnaires. These questionnaires consisted of two sections, which asked about baseline perceptions on telemedicine and specific perceptions on clinical trials research via telemedicine. In 34 surveys (87%), providers expressed preference for in-person visits for clinical trial participants and in 5 surveys (13), they expressed no preference. They also noted a more thorough clinical assessment in-person. Furthermore, in 30 surveys (77%), the providers expressed that a telemedicine visit was worse in adequately managing care and in 34 surveys (87%) delivered inferior quality care. They did note that their experience with telemedicine clinical trial participant visits was positive (33%) or neither positive nor negative (51%) in most instances.

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

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CTN trainee 1, 2, 3 attending didactic lectures

CTN trainee 2, completed one on one mentoring

CTN trainee 1, 2 completed participation in research project, trainee 3 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

Program participants (PI, CRN Mentors and CRN Trainees) were unable to complete funded travel due to staffing. Participants are frontline staff and, since the onset of COVID, we experienced staffing shortages and high patient volumes, limiting the ability for nurses to take time off. Therefore, we did not spend funds allocated for travel to conferences for continued education of Clinical Research Nurse (CRN). We requested and were approved for a No Cost Extension (NCE) to spend down our travel fund in 2024. PI has worked with CRN Mentor and Trainees to identify upcoming conferences and professional education seminars. We will complete this by end of NCE.

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**

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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

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: *N/A*

QUAD CHARTS: *N/A*

9. APPENDICES: *N/A*

Previous/Current/Pending Support: Lauren Evans

Previous

None

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 - 9/29/2024 - NCE

**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)

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 – 09/29/2024 - NCE 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

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:

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 – 09/29/2024 - NCE 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

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

Pending Support:

None