FINAL PROGRESS REPORT

TITLE OF PROJECT
Developing an Interactive, Patient-Centered mHealth Tool to Enhance Post-Cystectomy Care

GRANT AWARD NUMBER
K08HS024134

INCLUSIVE DATES OF PROJECT
04/01/2016 – 03/31/2019

ORGANIZATION
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ACKNOWLEDGMENT OF AGENCY SUPPORT
$464,524

STRUCTURED ABSTRACT (250 words max)

Dr. Angela Smith's long-term career goal has been to become an independently funded physician-scientist who is actively engaged in health information technology (HIT) interventions that improve the process and outcomes of care of surgical patients following discharge. Her career development plan within the executed K08 project integrated didactic coursework with practical mentored research experience in the design and conduct of intervention studies. Dr. Smith's educational aims on this project were successfully reached: 1) obtain education and skills in intervention development, patient-centered outcomes (PCO) research, qualitative research and clinical trials 2) develop expertise to implement HIT and mHealth technologic advances in the surgical field 3) gain experience in quality improvement methodology, and 4) obtain pilot data to support a multi-institutional trial. Dr. Smith cultivated professional aptitudes including grant writing, efficient balance between clinical and research activities, and an improved understanding of ethics in research. Using radical cystectomy as a model, the research developed and tested an electronic, internet-based mHealth tool that collects PCO data on key symptoms, functional status, and medication adherence while providing timely feedback to patients and clinicians. The work will provide the preliminary data for a multi-site, randomized study to rigorously test the effectiveness of the mHealth tool. The mHealth tool is significant as a practical way to improve the quality of care for cancer patients undergoing major surgery and, reduces the high rate of post-discharge complications and readmissions.

PURPOSE

Readmissions following major surgical oncology procedures are prevalent and costly with cystectomy for bladder cancer having the highest rate of complications and readmissions. Patient-centered outcomes, including symptoms, functional status, and medication adherence, represent potential treatment targets following hospital discharge. The purpose of this study is to explore novel strategies, which incorporate patient-centered outcomes and improve post-discharge care for radical cystectomy as well as other surgical oncology procedures that have the potential to reduce post-surgical readmissions with dramatic public health impact.

SCOPE

As a urologic oncologist and surgeon, Dr. Smith has always had a desire to improve the lives of cancer patients undergoing surgery. Her long-term career goals has been to become an independently funded, productive surgeon-scientist doing meaningful research to improve the quality and outcomes of post-surgical care in cancer. Dr. Smith has accomplished in big part this by developing and evaluating the effectiveness of innovative mHealth strategies that can rapidly identify and appropriately address potentially serious problems experienced post-discharge by cancer patients undergoing surgery.

To date, Dr. Smith's research has used secondary data and prospective cohort studies of cancer patients post-cystectomy to identify risk factors for complications and hospital readmission. The factors her research had identified (e.g., lapses in post-discharge care, geographical barriers, and poor patient education) suggested the need to develop innovative post-discharge strategies that reduce expensive and morbid post-surgical complications and hospital readmissions, and improve patient-centered outcomes (PCOs).Innovative and pragmatic health information technology (HIT) mHealth tools hold the potential to achieve these goals in the post-cystectomy population.

To achieve the career goals and objectives of developing innovative mHealth tools, Dr. Smith followed the next step in her career development: (1) research training in intervention development (with knowledge in PCO research, qualitative research, and quality improvement methods), HIT and mHealth, and clinical trials and (2) preliminary studies that will provide pilot data to support the subsequent R01 submission to rigorously evaluate the mHealth tool. Thus, the mentored research and career development activities outlined in this K08 project have allowed her to build on her strong research foundation to achieve these training and research goals. During

the K08 award period, Dr. Smith was integrally involved in every step of the scientific process supporting and executing the proposed research.

To achieve her long-term goal of becoming an established and productive surgeon-scientist, Dr. Smith capitalized on her unique interdisciplinary mentoring team and the remarkable resources available at the University of North Carolina by accomplishing the following short-term objectives during the K08 program:

Objective 1: Obtain education and skills in intervention development, PCO research, qualitative research, and clinical trials through formal training and mentored research.

Objective 2: Develop expertise to implement HIT and mHealth technologic advances in the surgical field.

Objective 3: Gain experience with quality improvement methodology.

Objective 4: Obtain pilot data to support a multi-institutional trial funded by an R01 grant.

METHODS

Objective 1: Obtain education and skills in intervention development, PCO research, qualitative research, and clinical trials through formal training and mentored research.

Training for intervention development, PCO research, qualitative research, and clinical trials will be provided through didactics, coursework and experiential learning. As a KL2 Scholar, I completed HPM 794 (Patient-Reported Outcome Measurement & Research) to obtain an overview of PCO measurement and the importance of collecting PCOs in healthcare delivery settings to enhance patient-doctor communication and decision-making. During year 1 of the K08, I plan to attend a Qualitative Research Summer Intensive Program that includes several brief courses in qualitative research methodology (http://researchtalk.com/qrsi-2014/). I will also enroll in HBEH 753 (Qualitative Research Methods) to provide a foundation for qualitative research methods. Hands-on experience with formative research will be obtained during years 1 and 2 of the K08 under the guidance of Dr. Bennett. I will conduct semi-structured interviews and analyze qualitative findings to identify PCOs important to patients, caregivers, and providers. During my final year as a KL2 Scholar, I began these interviews; interviews will be completed during the first year of my K08. This will allow me ample time to complete both Aims 2 and 3. In addition, I will gain experience in HIT intervention development through research conducted in Aim 2, with the mentorship of Dr. Weinberger. Dr. Weinberger has extensive experience with the design and evaluation of pragmatic interventions. With his support, I will develop the necessary skills to conduct pragmatic intervention research in the surgical field. With regard to training in clinical trials research, I have completed a basic course in clinical trial design, which provided me with a foundation in understanding RCTs. However, during Year 2 of the K08, I will obtain additional training by attending the NIH Summer Institute on Behavioral RCTs (http://obssr.od.nih.gov/training_and_education/annual_Randomized_Clinical Trials_course/RCT_info.aspx), which will provide a thorough grounding in the conduct of RCTs while addressing strategies for appropriate statistical analysis, evaluation of the quality of RCTs, and selection for appropriate strategies for enrollment, randomization, and retention of participants. I will also enroll in advanced methodology courses, including HPM 781 (Seminar in Comparative Effectiveness Research) during Year 2 and HBEH 753 (Advanced Research Methods) and HPM 771 (Intro to Regression Models for Health Services Research) during Year 3.

Objective 2: Develop expertise to implement HIT/mHealth technologic advances in the surgical field.

Understanding how to develop and implement HIT tools will be critical to my ability to develop meaningful mHealth interventions in the surgical field. During years 1-2, didactic instruction will include EPID 795 (Introduction to Public Health Informatics) and HPM 620 (Implementing Health Informatics Initiatives) to provide an overview of implementation of informatics programs and projects in health organizations and facilitating information use for the purpose of improving quality of health services and efficiency of processes. These courses will provide a foundation for HIT methodology, which will be essential to my career development and enhance my potential for making meaningful contributions to HIT intervention research. I have applied to the NIH

mHealth Training Institute (http://obssr.od.nih.gov/training_and_education/mhealth), which is designed to provide tools to successfully add mobile health technologies to research in a collaborative team environment. The workshop, led by a panel of experts, provides an overview of the multidisciplinary aspects of mobile and wireless research and also follows a project from conception through dissemination. I will also use the IDEO Human-Centered Design Toolkit, an open-source guide for implementing user-centered design (http://www.ideo.com/work/human-centered-design-toolkit/). These experiences will provide the foundation of knowledge necessary to develop an mHealth tool. To understand methods to implement HIT, I will also attend the Training Institute for Dissemination and Implementation Research in Health during year 2, a 5-day training program to provide participants with a thorough grounding for dissemination and implementation research in health (http://conferences.thehillgroup.com/OBSSRinstitutes/TIDIRH2014/). As part of the program, I will apply these processes to successfully integrating my mHealth tool within the healthcare setting. I will also attend the mHealth Summit and Wireless Health conferences, mobile health conferences which present the latest innovations and research in healthcare delivery. I will apply what I learn while working with Bernard Fuemmeler (member of my Research Advisory Committee) as I design and refine my mHealth tool.

Objective 3: Gain experience with quality improvement methodology.

Integrating PCOs into a post-surgical mHealth intervention has the overall goal of improving the patient experience through quality improvement (QI), with the ultimate aim of reduction of complications and readmissions. It will be necessary to understand QI methodology and then apply this knowledge by participating in a QI initiative of a meaningful intervention. As such, I will enroll in the Institute for Healthcare Improvement Open School QI Practicum during year 2, which consists of courses designed to explain the process of conducting QI projects in real-world settings (http://www.ihi.org/education/ihiopenschool). I will also enroll in HPM 760 (Healthcare quality and information management) during year 2 to address quality improvement methodologies as it relates to information management infrastructure and design of quality data dashboards. Experiential learning will occur under the guidance of Dr. Michael Pignone (Director of the UNC Healthcare Institute for Quality & Innovation and Associate Chair for Quality Improvement), a member of my Research Advisory Committee. In addition to overseeing my experiential learning, Dr. Pignone will ensure that my research design is rigorous, feasible, and assesses relevant QI outcomes.

Objective 4: Obtain pilot data to support a multi-institutional trial funded by an R01 grant.

The long-term goal of this award is to provide necessary training as I transition to an independent surgeon scientist involved in mHealth intervention research to improve the overall patient experience and clinical outcomes. Experiential learning under the mentorship of Drs. Basch and Weinberger will occur while conducting a feasibility study in which I obtain pilot data necessary to conceptualize and conduct a future RCTs. With mentorship from Dr. Weinberger (an expert in pragmatic trial design), I will obtain pilot data during years 2-3 that will serve as the basis for an R01 that I will submit at the beginning of Year 3 of the K08. I expect the R01 to be a pragmatic RCT examining the effectiveness of an innovative post-surgical mHealth tool to improve the overall patient experience and clinical outcomes through the R01 mechanism. To this end, I plan to take part in the NC TraCS R-writing group (co-led by Dr. Weinberger) which specifically helps junior investigators write their first independent investigator-initiated grant. Drs. Weinberger and Basch will provide mentorship as I write the R01 grant application.

RESULTS

For the most recent reporting period (April 2018 to April 2019), we have continued to make progress on my research and career development goals. I have organized objectives and activities according to specific aims of the original proposal below and included my progress in visual form in the Gantt chart below. My clinical and teaching responsibilities continued to be limited to 25% effort (75% research), with ongoing enthusiastic support from my co-mentors and cost-sharing from my Department chair.

Aim 1: Identify high-priority PCOs in the postoperative cystectomy period through patient, caregiver, and provider in-person interviews.
I will conduct in-depth in-person interviews at UNC with post-cystectomy patients, caregivers, and providers to identify outcomes most important to each group following hospital discharge. Interviews will also identify the preferred method for information delivery to patients and providers.

Major Activities: In the past year, I have successfully published a manuscript in Cancer (in press).

Specific Objectives: I have completed all stated objectives: **1) Obtain education and skills in intervention development, PCO research, qualitative research, and clinical trials through formal training and mentored research.** I have completed HPM 794 (Patient-Reported Outcome Measurement & Research) and attended a one-week Qualitative Research Summer Intensive Program that includes several brief courses in qualitative research methodology (http://researchtalk.com/qrsi-2014/). I enrolled in and completed HBEH 753 (Qualitative Research Methods) as well as HPM 760 (healthcare quality and information management). **2) Develop expertise to implement HIT/mHealth technologic advances in the surgical field.** I completed HPM 795 (Intro to Public Health Informatics). **3) Gain experience with quality improvement methodology.** I have enrolled in the Institute for Healthcare Improvement Open School QI Practicum, which consists of courses designed to explain the process of conducting QI projects in real-world settings (http://www.ihi.org/education/ihiopenschool).

Significant Results: Semi-structured interviews of cystectomy patients, caregivers and providers suggest that preoperative education is overwhelming and lacks the ability to distinguish normal from abnormal symptoms. A personalized intervention which provides the right information for the right patient at the right time could provide timely intervention for worrisome symptoms and dramatically improve the perioperative cystectomy experience.

Key Outcomes/Achievements: Project completed- important PCOs identified and incorporated into the mHealth tool as described below. Results disseminated through podium presentation at the AUA annual meeting as well as manuscript publication in *Cancer.*

Aim 2: Develop and test the usability of an Internet-based mHealth tool which tracks PCOs and provides real-time feedback to patients and providers following cystectomy discharge.
I incorporated the findings of Aim 1 to create an internet-based mHealth tool in which PCOs are tracked following hospital discharge from cystectomy, with real-time feedback provided to patients and providers. PCO questions and responses were developed into an mHealth tool using validated questions, and an algorithm with branching logic to drive feedback based upon responses will be developed. Small patient samples (n=12) tested the usability of the tool, permitting iterative design.

Major Activities: Aim 2 is complete. Twelve patients enrolled in the usability testing, which tested and provided feedback on the app. We iteratively incorporated suggestions until no further suggestions were made.

Specific Objectives: Objectives were similar to those described in Aim 1 (including education and skill in intervention development, PCO research, and clinical trials through mentored research, and development of expertise to implement mHealth advances in the surgical field, and gain experience with QI methodology. Please see above for all courses and workshops completed to date.

Significant Results: Satisfaction surveys and semi-structured interviews were completed which demonstrated overwhelming support and satisfaction with the mHealth intervention.

Key Outcomes/Achievements: A successful mHealth intervention was developed and iteratively optimized for patient use. We were able to successfully enroll into Aim 3 as described below.

Aim 3: Conduct a pilot study to assess feasibility and acceptability of an Internet-based mHealth tool following cystectomy discharge.

I will administer the mHealth tool to approximately 30 post-cystectomy patients to test feasibility by assessing the whether the tool is used as described (weekly). I will also monitor patient satisfaction (acceptability), complications, readmissions, and resource utilization.

Major Activities: We have begun enrolling patients for this phase of the study. We have had overwhelming success in enrollment. The first 6 of 7 patients approached for the study have agreed to enroll in the last month. We anticipate reaching our accrual goal in the next 4 months.

Specific Objectives: Our objective was to obtain pilot data to support a multi-institutional trail funded by an R01 grant. Experiential learning under the mentorship of Drs. Basch and Weinberger is in process while conducting a feasibility study in which I obtain pilot data necessary to conceptualize and conduct a future RCTs. With mentorship from Dr. Weinberger (an expert in the design of pragmatic trials), I am obtaining pilot data that will serve as the basis for an R01 that I will submit next year. I am drafting the R01 proposal with the assistance of my mentors and have identified key institutional leaders to collaborate with.

Significant Results: In progress.

Key Outcomes/Achievements: In progress.

LIST OF PUBLICATIONS AND PRODUCTS

Results from this study have been published in Cancer and also presented as a podium presentation at the AUA Annual Conference in 2018.

Smith, Mueller, Garren et al. Using Qualitative Research to Reduce Readmissions and Optimize Perioperative Cystectomy Care, Cancer, in press.

Training and Research Activity Timeline

**Green = completed activities / *Yellow = ongoing activities / *Red = upcoming activities*

			K08											
		Award Year	One				Two				Three			
		Quarter	Q1	Q2	Q3*	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Aim 1	Training	*EPID 795: Intro to Public Health Informatics*												
		HBEH 753 Qualitative Research Methods												
		Qualitative Research Summer Intensive Program												
	Research	*Enrollment and data collection*												
		Analyses												
		Abstract & manuscript												
Aim 2	Training	*NIH mHealth Training Institute*												
		IHI Open School Quality Improvement Practicum												
		HPM 620: Implementing Health Informatics Initiatives												
		HPM 760: Healthcare quality and information management												
	Research	*Create algorithm for mHealth tool*												
Aim 3	Training	*HBEH 753 Advanced Research Methods*												
		HPM 781: Seminar in Comparative Effectiveness Research												
	Research	*Enrollment and data collection*												
		Analyses												
		Abstract & Manuscript												
Career Development	Seminars	*UNC TraCS seminar series and KL2 group meetings*												
		RCR Training												
		Cancer Outcomes Research Group												
		Carolina Health Informatics Research Collaborative Group												
		Qualitative Research Working Group												
		mHealth@duke Colloquium												
		AUA Conference												
		ACS Conference												
	Grants	*R01 development & submission (R Writing Group)*												

Abbreviations: HPM=Health Policy and Management; PRO=Patient Reported Outcomes; UNC=University of North Carolina; IH=Institute for Healthcare Improvement; RCR=Responsible Conduct of Research; NIH=National Institutes of Health; RCT=Randomized Controlled Trial; TraCS=Translational and Clinical Sciences Institute; ASCO= American Society of Clinical Oncology; ACS=American College of Surgeons

View Burden Statement

PHS Inclusion Enrollment Report

This report format should NOT be used for collecting data from study participants.

OMB Number: 0925-0001 and 0925-0002
Expiration Date: 10/31/2018

***Study Title (must be unique):** Testing the Utilization of a Mobile Health App for Patients Undergoing Cystectomy Surgery for Bladder Cancer

* Delayed Onset Study? ☐ Yes ☒ No

If study is not delayed onset, the following selections are required:

Enrollment Type ☒ Planned ☐ Cumulative (Actual)

Using an Existing Dataset or Resource ☐ Yes ☒ No

Enrollment Location ☒ Domestic ☐ Foreign

Clinical Trial ☒ Yes ☐ No

NIH-Defined Phase III Clinical Trial ☐ Yes ☒ No

Comments:

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native	0	0	0	0	0	0	0	0	0	0
Asian	0	0	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	1	2	0	0	0	0	0	0	0	3
White	6	10	0	0	0	0	0	0	0	16
More than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	7	12	0	0	0	0	0	0	0	19

Report 1 of 1

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