The Effect of A Lay Health Worker Intervention on End of Life Cancer Care: Evaluation of the Engagement of Patients with Advanced Cancer (EPAC) Program

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Version 1 / Version Date (11-16-2016)

PROTOCOL SYNOPSIS

TITLE	**The Effect of A Lay Health Worker Intervention on End of Life Cancer Care: Evaluation of the Engagement of Patients with Advanced Cancer Program**
STUDY PHASE	Evaluation of EPAC Program
INDICATION	Advanced Cancer
PROCEDURE	Lay health worker (LHW) assigned to patients at VAPAHCS with a new diagnosis of Stage 3 or 4 solid tumor cancer or at recurrence or progression of disease for those patients already under oncology care
PRIMARY OBJECTIVE(S)	% of patients in the intervention with goals of care documentation in the electronic health record
SECONDARY OBJECTIVE(S)	Patient Satisfaction with care and decision Utilization and Costs of care End-of-Life utilization and costs of care
TREATMENT SUMMARY	Usual care versus EPAC
SAMPLE SIZE	105 in program arm 108 in usual cancer care arm
STATISTICAL CONSIDERATIONS	Intention to treat

1.0 SPECIFIC AIMS

Aims

The primary aim is to evaluate the effect of integrating a Lay Health Worker (LHW) into oncology care after a diagnosis of advanced cancer or recurrent and progressive disease on percent of patients with documentation of goals of care conversations by oncologists in the electronic health record.

Secondary aims are to assess the effect of the intervention on:

1. Patient satisfaction with decision-making and healthcare
2. Utilization of healthcare resources
3. Total Healthcare costs
4. End-of-life care (30 days prior to death) utilization and costs for subset of patients who died within 6-months and 15-months post-randomization

Hypotheses

Primary Hypothesis: The lay health worker (LHW) program will result in documentation of goals of care conversations by oncologists of at least 75% for patients in the intervention within 6 months of enrollment in the study.

Secondary Hypotheses (to obtain effect sizes): Compared to patients who receive usual oncology care, patients in the program will experience improved satisfaction with decision and healthcare, lower rates of acute care utilization and total healthcare costs at 15-months post-randomization, and lower rates of acute healthcare utilization and lower total healthcare costs at the end-of-life (last 30 days of life).

2.0 PROGRAM ENROLLMENT AND PARTICIPANT ELIGIBILITY

2.1 Enrollment

Location

Veterans were recruited from the Oncology clinics at the VA Palo Alto Health Care System (VAPAHCS) from August 2013-February 2015.

Enrollment Procedures

Each week, the site PI and program coordinator reviewed the list of patients scheduled for clinic appointments for the upcoming month. Please see previous protocol (version 6.0 Date: 8-11-2013) for details of the program enrollment, screening, and consent procedures.

2.2 Participant Criteria

Inclusion criteria

1. Newly diagnosed patients with stage 3 and 4 solid tumors.

2. Patients with recurrent or progressive disease as identified by imaging or biopsy and confirmed by physician.

3. The patients had to be 18 years or older.

Exclusion Criteria

1. Patients who did not have the ability to understand and/or willingness to sign a written informed consent document.

2. Patients who did not plan to receive all of their oncology care at the VAPAHCS (i.e. second opinion referrals).

Criteria for Removal from Study

Any patients or families of patients in the program arm who withdrew consent were removed from the project. Upon removal, usual care was restored for these patients.

2.3 Enrollment Sample

The target number of subjects at the site was approximately 210 (105 per arm) stratified by anatomic site of cancer diagnosis. A total of 213 patients were enrolled in the program with 105 in the lay health worker program arm and 108 in the usual cancer care arm. Data collection occurred at months 6 and 15 after patient enrollment. The data follow-up period occurred for up to 15 months following enrollment for each patient or death (whichever was first).

3.0 MATERIALS AND METHODS

We will use the electronic health record to abstract all relevant variables. As part of the project, a project chart was created for each patient. Patients were assigned a program identification number for all survey data and assessments as outlined in the protocol version 6.0 date: 8-11-2013. This identification number will be used on all subject-specific documents and research-related forms.

All patients were assigned to two arms as listed below.

All patients were surveyed during the program by a blinded, trained research assistant regarding patient satisfaction with healthcare (using the Consumer Assessment of Healthcare Providers and Systems – General survey) at baseline (at time of enrollment) and again at month 6 after enrollment. All patients were surveyed regarding patient satisfaction with decision-making (Satisfaction with Decision Scale) between months 4 and 6 after enrollment (see Survey Measures below). The research assistant administered all surveys by phone and recorded all responses in the patient's program chart.

Arm A: Usual Care (Control) / No Intervention
Patients in this arm received "usual" care from their care team.

Arm B: EPAC (LHW Intervention)/ Intervention Group
The program was comprised of a lay health worker assignment with a baseline introduction (either telephonic or in-person) of the program followed by a visit (telephonic or in-person) with the lay health worker after the first oncology appointment to discuss goals of care within 2 weeks of enrollment in the study. The lay health worker underwent standardized training with additional supervised visits to learn how to engage patients and families in goals discussions (see Training Details below).

The lay health worker contacted patients based on ongoing needs. Lay health worker also conducted meetings with patients, their families, and/or caregivers after an emergency department visit, hospitalization, change in treatment, or unexpected symptom. (The intervention details are provided in the attached Protocol Appendix B).

Patients in the lay health worker program received a two-question assessment of their satisfaction with and likelihood to recommend the care provided by the LHW. The two questions were measured on a scale that ranges from 0 indicating no satisfaction and 5 indicating maximum satisfaction.

Protocol Director: Dr. Patel
Dr. Patel, PI of the program, is responsible for the overall study including corresponding with the site PI to help troubleshoot any challenges in data collection or follow-up.

4.0 STATISTICAL CONSIDERATIONS

Biostatistician: Manisha Desai PhD (Stanford University) and Vandana Sundaram MPH (Stanford University). They will be responsible for providing randomization assignment for patients and analyzing the data.

4.1 Outcome Measurements

None of the listed outcomes relate to safety:

Primary Outcome Measure

Measurement of documentation of goals of care conversations by oncologists in the Electronic Health Record. This includes any mention of patients' care preferences. Hypothesis: 75% of patients in the lay health worker program with documentation of their goals of care and preferences for care within 6 months after enrollment.

Secondary Outcome Measure

Utilization will be evaluated by comparing hospitalizations, emergency department, palliative care referral and consultation, hospice referral and consultation at 6-months post-randomization and 15-months post-randomization, and, for those patients who died at 6- and 15-months post-randomization, 30 days prior to death between the two program groups. We will assess utilization of chemotherapy, radiation, and surgery at 6 months post-enrollment. Total healthcare costs for VA care will be obtained from the VA Palo Alto Decision Support System office and the VA Allocation Resource Center. Total healthcare costs for non-VA care (actual cost paid to non-VA providers) will be obtained from the VA Palo Alto's Office of Business Analytics.

All patients enrolled in the project will be used for the analysis for an intention to treat analysis.

Secondary outcomes also include differences in satisfaction with healthcare and differences in decision-making.

4.2 Sample Size

A total of 105 patients in the program arm was needed to attain significant differences from empiric evidence within 6 months after study enrollment for patients in the intervention of our primary outcome, documentation of goals of care. Sample size is not powered to detect differences in our pre-specified secondary outcomes which include: patient satisfaction, healthcare utilization, and total healthcare. For all secondary outcomes, we will obtain effect sizes and report the results descriptively.

4.3 Data Variables and Analysis

Satisfaction with care was measured when patients were randomized into the program versus the control arm (baseline) and again 6 months after randomization using the validated Consumer Assessment of Healthcare Providers and Systems – General survey. Satisfaction with decision-making was assessed for all study participants between 4 and 6 months after randomization using

the validated 6-question Satisfaction with Decision Scale on a scale ranging from 0, indicating no satisfaction, to 5, indicating maximum satisfaction. A trained research assistant, blinded to the randomization, administered all satisfaction measures telephonically. All responses were entered into the patient's program chart and all data will be abstracted and analyzed from the program chart into a de-identified study database.

The use of the following services for each patient in the program arm and control arm will be collected: chemotherapy, surgery, and radiation utilization, Veterans Administration (VA) and non-VA emergency department (ED) use and hospitalizations, inpatient and outpatient palliative care, and hospice consultation.

Chemotherapy, surgery, and radiation utilization will be measured for all program patients within the 6-month period after randomization. All other healthcare utilization will be measured within the 6- and 15-month period after randomization. The date of death will also be collected from the electronic health record and where missing will be collected from the cancer registrars. ED use, hospitalizations, and hospice use within 30 days of death will be measured for the subset of patients who died within 6- and 15-months post-randomization. Total healthcare costs for VA and non-VA care will be collected by the VA Palo Alto Decision Support System office, the VA Allocation Resource Center and the VA Palo Alto's Office of Business Analytics, and measured during the 6 months prior to randomization for each participant (to test whether patients had similar costs of care prior to their enrollment in the study) and for the 6- and 15-month period after randomization and total healthcare costs will be collected for the 30 days prior to death for the subset of patients who died within 6- and 15-months follow-up. We will measure survival at the 6- and 15-months period after randomization. All patients will be followed through April 6, 2016. Health care utilization and total healthcare costs will be collected through December 6, 2016 to account for an 8-month lag time in service claims from non-VA facilities. We will also collect the following data: age at diagnosis and enrollment in the program, sex, cancer diagnosis and stage, new diagnosis or recurrent cancer, and travel distance to the VAPAHCS.

Statistical Analyses

We will use logistic regression models to compare difference between the two groups for dichotomous outcomes.

We will compare the total number of ED visits and hospitalizations using exact Poisson regression models with an offset term for length of follow-up.

We will use generalized linear models to account for skewed cost data and to compare changes in satisfaction with care between study arms from baseline using ANOVA.

We will compare
survival using Kaplan Meier methods and the risk of death for the two groups after randomization using Cox proportional hazards regression models. For patients who died, we will compare the number of ED visits and hospitalizations in the last 30-days of life, proportion of patients who were enrolled in hospice at the time of death, and total healthcare costs in the last 30 days of life using the models described above. All significance testing will be conducted at a two-sided p-value of 0.05. Statistical analyses will be performed with SAS.

5.0 DATA MANAGEMENT CONSIDERATIONS

5.1 Data Management

All data will be kept on a secure server. All paper surveys collected during the original program enrollment will be transcribed into a database with only a subject identification number that is coded without any patient identifiers. The code will be kept in a locked file in a locked room and only accessible to the study PI and staff listed. The PI and participating site investigators will maintain adequate and accurate participant case histories with observations and other data. Original source documents will be transcribed to data collection tools and used to communicate and analyze study data.

The site PI will be responsible for maintaining the clinical protocol and subjects' program charts and reporting the status of the program in continuing renewals or amendments submitted to their IRB per facility protocol.

5.2 Confidentiality

Members of the local team will be responsible for database records of patient data. The data will be kept in the secure central online study database under password protection, encrypted, and with access limited to specific areas of the database. A chart with all of the relevant research patient information will be maintained at the VA. The Study Coordinator may review patient charts for yearly audits.

5.3 Protocol Review and Amendments

The protocol, the proposed informed consent and all forms of participant information related to the program (e.g. advertisements used to recruit participants) will be reviewed by the Stanford IRB. Any changes made to this protocol will be submitted as a modification and will be approved by the IRB. The Protocol Director will disseminate the protocol amendment information to all participating investigators.

APPENDIX A: DETAILS OF INTERVENTION

Details of the LHW intervention The LHW intervention is designed to improve knowledge, beliefs, values, attitudes and confidence through social support, multimedia education and skills building provided by LHWs to engage in early advance care planning and discussing their care preferences (goals of care) with their providers.

Patients in the intervention arm will receive a 30 minute phone call from the LHW after patient consents and within 2 weeks of randomization into the study for study participation to establish rapport and discuss the importance of early advance care planning.

After the discussion, the LHW will mail a new patient packet that includes advance care planning multi-media educational materials, including an educational brochure from the website Prepareforyourcare.org and a blank VA advance directive form. Thereafter, the LHW will conduct twice monthly 15-minute telephonic or in-person conversations for 6 months after study enrollment or until patient death, whichever is first. In these twice monthly interactions, the LHW will educate patients on principles of goals of care and advance care planning, assist patients in their advance care planning, establishing their preferences for care, identifying their surrogate decision-maker, filing advance directives, and activating them to discuss their care preferences and advance directive with their oncology providers. The LHW will revisit these activities when treatment plans change or if patients experience unexpected emergency department visits or hospitalizations. The LHW will be supervised on-site and meet weekly with a registered nurse to discuss all patient cases.

Recruitment, Retention and Training LHW We will work with the VAPAHCS facility to post an opening for a LHW to be employed for this study. We expect to hire a LHW with no previous medical experience but who is familiar with the VAPAHCS facility and procedures. We have created a LHW training program that includes multimedia didactic, skills-building training drawing from cancer navigation and palliative care. The LHW will participate in an 80 hour-on-line skills-based training and a 4-week in-person observation training led by the facility's palliative care team. Online training activities include 15-content modules in a multi-media internet-based course focused on delivering successful end-of-life care for older adults relationship-building, challenges at the end-of-life, and tools to improve engagement of patients in advance care planning (Stanford University's Internet based Successful Aging (iSAGE) https://aging.stanford.edu/isage-mini-fellowship-overview/). The 4-week in-person training will include: a didactic series focused on challenges in health communication, importance of social support, self-efficacy, and skills-based knowledge and supervised practice to improve patients' engagement in early advance care planning. The LHW will be employed 20 hours a week and expected to provide services to 75 patients per week.

LHW Intervention and Training Details

LHW Personnel Details

Upon review of literature regarding Lay Health Workers (Cherrington et al. 2010 Ethn Dis Recognizing the Diverse Roles of CHWs in elimination of disparities), previous work training community health workers in Honduras and Australia, and upon recommendations of the VA Patient and Family Council, paid positions can often lead to better retention of lay health workers. As part of our pilot in the VA, we hired one paid lay health worker (part-time with benefits) for 20 hours/week. We created a job description and recruitment materials and provided position announcements through the Veterans Patient and Family Council, the VA Palo Alto volunteer office, the VA Palo Alto staff newsletter, and the Palo Alto Veterans Institute for Research newsletter. The Chief of Medical Services and the PI conducted a series of interviews with candidates and recruited and hired one LHW based on communication skills, service-orientation, and references. The paid LHW had completed her undergraduate degree in Biology, was serving as a volunteer in the VA Million Veterans Program, was enrolled in a graduate health education program, and was planning to apply for medical school. She had a keen interest in public health and medicine, had excellent communication skills, and previous experience working with Veterans.

LHW Training

The LHW Training was framed by the Social Cognitive Theory which explains the LHW-patient relationship and its links to self-efficacy, through social support, knowledge, and skills, to engage in early advance care planning (behavior change). The Social Cognitive Theory outcomes include engagement in behavior change (i.e. early advance care planning).

Lay Health Worker Training

The lay health worker training is a multimedia didactic and a skills-building training curriculum that draws from several lay health worker and palliative care training programs. The training begins with basic education focused on the role of the lay health worker in provision of care delivery, including social support, building self-efficacy, and tools to improve patient engagement in health. The training also focuses on understanding care challenges at the end-of-life. Following the month-long series, the lay health worker spends one month in observation and skills building training with the local palliative care team. The LHW is closely supervised for the first two months during all activities with patients and caregivers by a supervising nurse. Throughout the intervention, the LHW participates in weekly discussions of clinical cases with the supervising nurse. Curricula overview outline is as below:

Roles/Duties of LHW

- Expectations and responsibilities of a LHW

Communication

- Explore ways to engage patients' understanding of health information

Working in the Community

- Define community and perspectives that affect LHW activities.
- Discuss frameworks for reaching individuals and groups in the community.

Health Disparities

- Define social determinants of health and issues in health disparities
- Understand what health disparities are and the ones that affect the community
- Define community-engaged partnerships and organizations

Cancer Basics

- Introduction to general cancers
- Understand what cancer is, basic causes, and basic treatments

Understanding of Cancer Care Challenges at the End-of-life

- Cancer 101 training:
- Web-based self-study of Education in Palliative and End-of-Life Care for Oncology consisting of 3 plenary sessions and 15-content modules

Skills Building in Engaging in Advance Care Planning

- 80-hour web-based training in the Stanford University's Internet-based Successful Aging mini-fellowship
- Intensive 4 week observation and integration into palliative care teams
- 2-month mentored supervision by RN during engagement with patients and caregivers
- Meetings with RN to discuss all patient cases weekly
- Frequent, as needed supervision and mentorship by RN provided in-person, by phone, or text