Lay Health Workers Educate, Engage, and Activate Patients to Share (LEAPS)

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1.0 SPECIFIC STUDY AIMS

Aims

The overall objective of the study is to improve health-related quality of life and the cancer care experience for health care beneficiaries of Unite Here Health (UHH) in Atlantic City, NJ and Chicago, IL after they receive a new diagnosis of cancer or a relapsed or progressive advanced stage of cancer.

The study aims primarily to determine if the intervention improves a patient's health-related quality of life. Secondarily, the study aims to include the effect on the change in patient satisfaction with decision-making and patient activation, change in health care use and advance directive and goals of care documentation as well as end of life outcomes including health care use and total costs of care.

The intervention consists of trained, culturally sensitive community health workers (CHWs) who assist patients and families in identifying and intervening on complications from social determinants of health, understanding and discussing their care goals, engage in proactive symptom assessment, and participate in care delivery closer to and in patients' homes and communities.

Hypothesis

Compared to patients who receive usual oncology care, patients who partner with CHWs are hypothesized to experience improved health-related quality of life. Secondary outcomes are meant to be exploratory however we expect effects on these outcomes in favor of the intervention.

2.0 BACKGROUND AND RATIONALE

Many patients and families served by Unite Here Health express significant challenges with their cancer care. Many describe significant complications from social determinants of health, poor quality of life with difficult decisions, little understanding of the disease context, uncontrolled symptoms, and treatment and clinic visits that are provided at distances far from their residences. Oncology care delivery for vulnerable patients is often fragmented with poor care coordination, patient-provider communication challenges, and centralization of healthcare services that make care delivery and access even more difficult for vulnerable patients. These barriers in the delivery of care can result in disparate cancer outcomes.

The LEAPS intervention extends the spectrum of care up to 12 months post-enrollment (for patients with newly diagnosed, relapsed or progressive disease). The key elements of the intervention address three major challenges faced by vulnerable patient populations: 1) patients and their families who face social and economic challenges experience challenges in communication with their providers regarding their goals of care and understanding their prognosis; 2) patients experience difficulty in expressing their symptoms to their providers; and 3) patients experience challenges attending their clinic and treatment appointments due to financial burden, travel difficulties and/or lack of social support to drive and accompany them to their visits. (See Appendix for Rationale)

The proposed intervention addresses these three critical care elements by training and deploying culturally-sensitive, community-based health care workers who assist patients and families in identifying complications from social determinants of health such as transportation, financial or housing, discussing goals of care and advance care planning, proactively assess cancer-related symptoms with oversight from a UHH nurse, and assist in coordinating care delivery at home through leveraging telephonic discussions and home visits.

3.0 STUDY ENROLLMENT AND PARTICIPANT ELIGIBILITY

3.1 Study Enrollment

Location

Health beneficiaries of UHH newly diagnosed cancer or relapsed or recurrent cancer may be referred by oncology provider clinics who partner with UHH.

Enrollment Procedures

UHH Staff assigned to the program will target potential patients on an ongoing basis using their claims data system. This includes data from a variety of sources including but not limited to Daily Inpatient Reports; referrals from hospital staff, PCPs and Specialists; referrals from other UHH staff such as those working in customer service; and referrals from Union staff and participants. The study staff will review all potential patients with newly diagnosed or recurrent disease no matter the stage or type to determine eligibility for the program. After the site PI and

study staff conduct proper screening (see below section titled “Screening Procedures” for specific details), the program will be explained to patients and patients will then be enrolled in the study.

Screening Procedures

The Site PI and staff will utilize the following claims data system documents and procedures to also screen for patients who fit the inclusion criteria listed in 3.2. Screen failures will not be included in the study data. The PI will keep a record of history and reasons for screen failures; however, any patient information gathered during this process will be destroyed.

Consent Procedures

The study staff will discuss the intervention with the patient, at the first point of contact, after eligibility has been confirmed. The study staff will introduce the program and describe the program aims and objectives. Patients will be provided adequate time to make an informed decision regarding their participation. Patients who refuse participation or have no capacity for decision-making or consent will not be included in the study.

If a patient is interested and consents verbally, he/she will be provided a welcome letter with basic information and contact phone numbers for the project. The patients will be randomized by Stanford biostatistician using a computer-generated ordered list of randomized numbers in each city. For all patients assigned to the LEAPS intervention arm, the community health worker will contact the patient to begin the intervention procedures that include assisting patients with understanding their goals of care, documenting goals of care, proactively assessing symptoms, and coordinating home-based or community-based care delivery. The intervention will be provided in addition to the usual care processes (Intervention details are provided in Appendix B).

3.2 Participant Criteria

Inclusion criteria

1. Newly diagnosed patients with a cancer diagnosis.
2. Patients with any relapse or progressive disease (any cancer diagnosis) as identified by imaging or biopsy and confirmed by physician.
3. The patients must be 18 years or older.
4. Patients must have the ability to verbally consent and understand study procedures.

Exclusion Criteria

1. Inability to consent to the study.
2. Patients without a newly diagnosed malignancy or patients without relapse of disease.
3. Patients not eligible for fund benefits.

Criteria for Removal from Study

Any patients or families of patients in the intervention arm who withdraw consent will be removed from the study. Upon removal, usual care will be restored for these patients.

3.3 Enrollment

The target number of subjects at the site is 160 (80 per arm). Patient enrollment will continue until sample size is reached (anticipated 24 months). Data collection will occur at baseline and months 4 and months 12 for each patient in the study. The data follow-up period (to assess utilization will occur for up to 12 months following each patient enrollment or death (whichever is first)).

4.0 MATERIALS AND METHODS

After a patient is enrolled in the study, the patient will be registered and entered into the project database (CarMa) and assigned an identification number. The identification number will be used on all subject-specific documents and research-related forms.

During registration, patients will be randomized to two arms (Arm A: Usual Care or Arm B: LEAPS Intervention). Specifically, the patients will be randomized 1:1 using a simple randomization strategy in each site into two arms at each site.

All patients, throughout the study, will be asked to complete three surveys: 1) patient health-related quality of life (using Functional Assessment of Cancer Therapy – General (FACT-G) and 2) satisfaction with decision-making (Satisfaction with Decision Scale) and 3) the patient activation measure (Patient Activation Measure-13). A trained study staff member will administer the surveys at baseline (month 0) and again at 4 months and 12 months for patients in the intervention and usual care arm. Participant information will be entered into the CarMa database within 7 calendar days. Study team members will conduct electronic health record chart review of each participant and abstract date of the following: goals of care documented by oncology clinician, advance directive, and Physician Order for Life Sustaining Treatment. All health care claims data will be provided by UHH to the study team for each participant in the study at the study end which will consist of all charges and paid claims for total costs including outpatient, inpatient and pharmacy services. All study team members will be blinded to the randomization assignment. Only the community health workers will know the study assignment and the local site coordinator at each site.

As part of usual care, study PI and team members redesigned benefits such that any member of UHH with cancer will also receive waived copays if they choose to seek care at the preferred

provider in Atlantic City. We will also provide each member with access to transportation and other services to receive care at the preferred provider.

- Arm A: Usual Care (Control) / No Intervention
  Patients in this arm receive "usual" care coordination from their care coordination team which includes case management by a registered nurse practitioner to address financial concerns, care navigation and coordination.

- Arm B: LEAPS/ Intervention Group
  The intervention will be comprised of a CHW assignment with a baseline introduction (either telephonic or in-person) of the program followed by a visit (telephonic or in-person) with the community health worker to screen for health-related social needs, identify and refer to community resources for any identified complication from social determinants of health and to begin intervention regarding goals of care and symptom management. All CHWs have undergone standardized training with additional supervised visits to gain skills in engaging patients and families in goals discussion and in symptom assessment algorithms (see Appendix for Details).

  The CHW will contact patients based on patients' ongoing needs but will provide at a minimum weekly support from time to enrollment up to 4 months post-enrollment and then monthly from 4-months post-enrollment until 12-months post-enrollment. The CHW will also conduct meetings with patient's family and caregivers at the same time intervals where possible. The intervention details are provided in the Appendix.

Lay Health Worker Training

The PI and UHH staff provide ongoing training for the CHWs through formal classroom training (See Appendix for a list of topics covered), biweekly case rounds, shadowing and role plays. All CHWs will also be provided with previously tested and developed standardized training manuals that are refined based on feedback from stakeholders at UHH. The manuals include a highly detailed workflow of the project, from enrollment to completion. CHWs also will receive training on what to say during patient contact, advanced care planning conversations, documentation of advance care planning, the study calendar, data management, and key contact information. CHWs will also receive training on symptom management.

Supervision of the Lay Health Worker

The community health worker will be supervised by the RN at the Unite Here Health Fund offices in Chicago and Atlantic City. The RN will ensure that the protocol is carried out correctly and address any issues that may arise in the LHWs' workflow. The CHWs at each site (2 0.4 FTE in Chicago, 3 0.3 FTE in Atlantic City) will participate in monthly meetings with the rest of the project members (at both Stanford and UHH) to review study accrual and program goals. At

these meetings, the RN will be responsible for providing a report on project progress and project issues incorporating feedback from the LHWs.

Quality of Life Measures

The FACT-G is a quick, validated, 27- item compilation to assess QOL domains with discriminate ability and sensitive to changes in QOL over time.

The Satisfaction with Decision scale is a quick, validated 6-question survey to assess patient experiences with decision-making.

The Patient Activation Measure is a validated measure used to assess patient activation.

Dr. Patel has used these measures with success in a similar project completed at the Palo Alto Veterans Hospital (Palo Alto, CA). Unite Here Health uses Patient Activation Measure as part of usual care at their organization.

If patients feel discomfort while conducting their surveys, they may choose to not complete them. If there are any psychological events that occur during the study, these will be reported to the site PI.

Site PI: Karen Cotter/Regina Curry

Karen Cotter/Regina Curry are responsible for overall study supervision as well as the following:

Conducting biweekly meetings with all study staff members, troubleshooting recruitment and follow-up challenges, participating in the training of the CHWs, ensuring proper data collection, and general upkeep. The site PI is also responsible for interacting with the protocol director at Stanford, Dr. Patel. As this is Dr. Patel's conception, and she piloted at another site, she will be able to provide Karen Cotter/Regina Curry with specific advice and recommendations should challenges arise.

Protocol Director: Dr. Patel

Dr. Patel, PI of the study, is responsible for the overall study including corresponding with the site PI to help troubleshoot any challenges in data collection or follow-up. Dr. Patel is also responsible for assisting the sites in implementing the intervention, following study protocols, and responsible for conducting and overseeing data analysis and manuscript publication.

5.0 STATISTICAL CONSIDERATIONS

5.1 Outcome Measurements

None of the listed outcomes relate to safety.

Primary Outcome Measure

The specific key measurement used to measure the effect of the intervention corresponding to the primary outcome is change in health-related quality of life. The protocol aims primarily to detect a significant (5% significance level) between-group difference from baseline to 4 months (delta

change=4) assuming a within-subject correlation of 0.8 and a standard deviation of the change in score equal to 9.5 based on empirical evidence.

Secondary Outcome Measure

Patient satisfaction and activation will be explored using changes in the Patient Satisfaction with Decision Scale and Patient Activation Measure. Utilization will be measured evaluating comparisons of hospitalizations, emergency department, and referrals to hospice and palliative care. Advanced care planning will be measured by comparing rates of advance directive documentation, Physician Orders for Life-Sustaining Treatment, and goals of care documentation in patients' electronic health record charts. Patient survival will also be compared between groups. Total costs of care will be abstracted from UHH database only to conduct a budget impact analysis and obtain point estimates for refinement of the intervention in anticipation of a larger multi-center trial. A cost-effectiveness analysis is not planned and will not occur until effectiveness has been demonstrated in subsequent studies upon completion of this study.

5.2 Analysis Plan

The Statistical Analysis Plan (SAP) will be prepared prior to the commencement of data analysis. All patients enrolled in the study will be used for the analysis for an intention to treat analysis.

Secondary analyses are for exploratory outcomes only and include differences in satisfaction with decision-making, acute care utilizations and to obtain point estimates on costs of care. Statistical significance of secondary outcomes is for trends only and not represented in this sample size calculation.

5.3 Sample Size

The primary goal is to improve quality of life. A total of 160 patients are needed to attain significant between-group differences from baseline to 4 months after study enrollment for patients. (See Primary Outcome Measure section above).

6.0 DATA MANAGEMENT CONSIDERATIONS

6.1 Data Management

The PI and participating site investigators will maintain adequate and accurate participant case histories with observations and other data pertinent to the study. Original source documents will be transcribed to data collection tools and used to communicate study data to the lead site.

Participating site PI (Cotter/Curry) will be responsible for maintaining the clinical protocol and subjects' study charts, reporting adverse events, and reporting the status of the trial in continuing renewals submitted to their IRB and trial monitoring group(s) as per their facility protocol.

6.2 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 database (CarMa), under password protection, encrypted, and with access limited to specific areas of the database. A chart with all the relevant research patient information will be maintained for each patient at each institution by the local team for that specific institution. Study PI, statistician and research team abstracting information as well as data collectors for claims data and primary oncology team members will remain blinded to the randomization assignment. Study Coordinator at each site may review patient charts for yearly audits.

6.3 Protocol Review and Amendments

The protocol will be reviewed and approved by the Stanford IRB. The Protocol Director will disseminate any protocol amendment information to all participating investigators.

Statistical Analysis Plan (SAP)

Title: Lay Health Workers Engage, Educate, and Encourage Patients to Share (LEAPS)

1.1. Study Aims

1.1.1. Aim 1

The primary aim of the LEAPS program is to evaluate whether trained lay health workers who engage newly diagnosed patients with cancer and patients with newly diagnosed relapsed or progressive disease can improve Health-Related Quality of Life (HrQOL) at 4 months post-enrollment compared to baseline more than usual care.

1.1.2. Aim 2

Secondary aims which a priori defined to be exploratory include the effect of the intervention on changes in health-related quality of life from baseline to 12-months post-enrollment as compared to usual care, changes in patient satisfaction with decision-making and patient activation at 4- and 12-months post-enrollment as compared to baseline, change in emergency department and hospital use within 4- and 12-months post-enrollment, advance directive, goals of care documentation, and Physician Orders for Life Sustaining Treatment documentation at 4- and 12-months post-enrollment, and hospice and palliative care use within 4- and 12-months post-enrollment and total costs of care from baseline to death or 12-months follow-up, whichever is first. In addition, we will evaluate emergency department, hospitalization, hospice and palliative care use and total costs of care in the last 30 days of life among those who died.

2.4. Randomization

1:1 Randomization of participants using simple randomization strategy by site; allocation to either the 12-month intervention combined with usual oncology
care or usual oncology care alone in Atlantic City, NJ and Chicago, IL.

2.5 Blinding

PI, statistician, research assistants, care coordinators and oncology professional team members will be blinded to the randomization assignment. The UHH community or lay health workers will be unblinded to randomization assignment.

3. Outcomes, Exposures, and Additional Variables for Interest

3.1. Primary Outcome(s)

Health-related Quality of Life (HRQoL) (change in scores from baseline to 4 months post-enrollment). Health-related quality of life assessed using the 27-item Functional Assessment of Cancer Therapy – General where scores range from 0-108 with higher scores indicating better health-related quality of life.

3.2 Secondary Outcome(s) – Exploratory Outcomes Only

Health Related Quality of Life is measured by the Functional Assessment of Cancer Therapy-General: a 27-item questionnaire designed to measure four domains of HRQOL in patients with cancer. The scale is on a 5-point Likert-type scale with a score range of 0-108 with higher scores indicating greater HRQoL.

Patient Satisfaction with Decision is measured by the Satisfaction with Decision scale, a six-item scale designed to measure patient satisfaction with healthcare decision. Each item is on a 1-5 scale with higher scores indicating greater satisfaction with decision.

Patient activation is measured by the Patient Activation Measure. Each item rated on 4-point scale (1 strongly disagree to 4 strongly agree, with additional “not applicable” option. Total PAM score = [raw score]/[# items answered excepting non-applicable items] *13 ; can be transformed to a scale with a theoretical range 0–100 based on calibration tables. Raw scores can be converted into activation levels which can also be used as cut-offs:

4. Statistical Analysis Plan

We will present descriptive statistics broken out by intervention group for baseline clinical and demographic variables of interest using continuous (mean, standard deviation, median, interquartile range), and discrete (counts, percentages) where appropriate. We will also tabulate and present for each relevant covariate the percentage of subjects missing a value for that covariate, if applicable.

4.2. Primary Analysis

All patients will be included in the analysis based on their randomization assignment at time of enrollment using intent to treat. Patient data will be modeled at the participant-level.

4.2.1. Statistical Modeling

To assess our primary outcome of the effect of the intervention on change in health-related quality of life from baseline to 4-months post-enrollment between groups, we will calculate expected mean differences between groups by Generalized Estimating Equations (GEE) models where the outcome will be modeled as a function of treatment group, categorical time (baseline, 4 months, 12 months) and an interaction term between treatment group and time with an exchangeable correlation clustered within person. Significance will be assessed between groups overtime using a type III F-test on the interaction term. All ratios will be expressed as referent to the control group.

4.2.2.1. Site-specific Modeling

We will consider refitting primary models for each site separately to explore the effect of site heterogeneity on our results.

<u>Sample Size Considerations</u>

The sample size of 160 participants (80 randomized to the intervention group and 80 randomized to the control group) provides greater than 90% power to detect difference in quality of life between groups (delta change =4) assuming a within-subject correlation of 0.8 and a standard deviation of the change in score equal to 9.5 based on our pilot data. The primary outcome was determined by our community partners.