Joint Oncology Collaboration for Proactive Symptom Assessments by a Lay Health Worker

NCT03737058

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1. PURPOSE OF THE STUDY

a. Brief Summary

The purpose of the LEAPS program is to understand how a trained lay health worker who engages with newly diagnosed patients after a diagnosis of an advanced stage of cancer can help to improve patient satisfaction with their decision-making, activation, quality of life, and healthcare resource utilization.

b. Objectives

We hope to better understand how to help improve patients' careafter a diagnosis of advanced cancer. We want to better understand the influence of a local lay health coach on improving patient's efficacy, quality of life, and satisfaction. We also want to know the impact of the program on healthcare resource utilization (emergency department, hospitalization, hospice utilization).

c. Rationale for Research in Humans

Because this is a novel program focused on helping patients better understand their goals of care, human subjects must be used for this project.

2. STUDY PROCEDURES

a. Procedures

Unite Here Health will institute a novel program focused on providing patients with a lay health coach who will engage patients with goals of care after a diagnosis of cancer. Unite Here Health will enroll patients into the study after a new diagnosis of cancer or after a diagnosis of cancer that has progressed to a worsening stage. Unite Here Health staff will identify patients for the program through primary care physicians, oncologist referrals, and hospitalization daily notice of admissions and emergency department reports which Unite Here Health routinely receives as part of usual care. Patients without capacity to consent verbally will not be eligible for the study.

The Unite Here Health staff will contact eligible patients by telephone to introduce the study. If the patient is interested, he/she will be randomized into the usual oncology care arm versus the lay health worker intervention arm. Patients randomized into the intervention will be assigned a lay health worker who will contact the patient to begin the intervention. The intervention includes: education on early advance care planning,

documenting goals of care, assessing symptoms, and coordinating community services (such as home health, home visits, and home hospice).

The Unite Here Health staff, as part of their usual assessments, will conduct the following assessments for patients enrolled in the intervention and the usual oncology care arm at time of randomization and at 6 and 12 months after enrollment: a satisfaction with decision-making survey to compare changes in satisfaction, a patient activation measure survey (PAM survey), and the Functional Assessment of Cancer Therapy - General quality of life survey. At these time points, additional data collected as part of usual care will also be assessed for each patient. This includes: healthcare utilization (total number of emergency department visits and hospitalizations, referral to palliative care, and hospice receipt). This data will be abstracted from the patients' claims data that Unite Here Health routinely reviews and collects.

b. Procedure Risks

The risks to subjects will be minimized as this is a study that provides usual oncology care. As part of the study intervention, additional support services will be provided to patients. Usual care procedures at the local site ensure sound procedures to minimize data sharing risk. There are no identifiers that will be collected or shared with the Stanford PI.

c. Use of Deception in the Study

No deception will be used.

d. Use of Audio and Video Recordings

No recordings will occur.

e. Alternative Procedures or Courses of Treatment

The study could improve documentation of patients' overall goals of care and could lead to a reduction in unwanted healthcare utilization. No standard of treatment will be withheld from patients. There are no potential risks to the patients involved in the study other than breach of confidentiality however no identifiers will be collected or shared with Stanford PI in the analysis of the data.

f. Will it be possible to continue the more (most) appropriate therapy for the participant(s) after the conclusion of the study?

Yes

g. Study Endpoint(s)

The primary endpoint is the Edmonton Symptom Assessment System (ESAS) at 12 months.

3. BACKGROUND

a. Past Experimental and/or Clinical Findings

We implemented a trial at the VA Palo Alto Health Care System that assigned a lay health worker to patients with advanced cancer. In this study, we found improvements in patient satisfaction and reduction in healthcare utilization at the end of life. However, it is unclear if such an effort will improve quality of life and improve satisfaction and reduce healthcare utilization outside of the VA system.

b. Findings from Past Animal Experiments

None

4. PARTICIPANT POPULATION

a. Planned Enrollment

At the local site, Unite Here Health will enroll a total of 180 patients into the study. Inclusion criteria are as follows:

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 capacity to verbally consent.

The total number of patients with cancer who are members of Unite Here Health are 200 per year. Therefore we anticipate that we will feasibly be able to enroll 180 patients into the study during the first 18 months.

b. Age, Gender, and Ethnic Background

The age range is > 18, gender is both male and female, and ethnic population is Hispanic, Asian/Pacific Islander, Non-Hispanic White, Non-Hispanic Black, American Indian, and Alaskan Native.

c. Vulnerable Populations

We will not enroll children or pregnant women. The study will be offered to all patients regardless of economic status. Patients who are unable to consent to participation will not be included.

d. Rationale for Exclusion of Certain Populations

Children are not included because the study is focused on adult patients with cancer. Additionally, Unite Here Health does not have any members less than the age of 18.

e. Recruitment Details

All eligible patients at Unite Here Health will be identified and referred into the study by the primary oncologist, primary care physician, or through daily inpatient and emergency

department reports which are routinely sent to the Unite Here Health staff as part of usual care.

f. Eligibility Criteria

i. 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 capacity to verbally consent.

ii. Exclusion Criteria

Inability to consent to the study due to lack of capacity as documented by the referring physician.

Patients without a newly diagnosed malignancy or patients without relapse of disease.

g. Screening Procedures

There are no screening procedures for enrollment in the study.

h. Participation in Multiple Protocols

There are no other studies ongoing at Unite Here Health that may lead to dual enrollment in studies.

i. Payments to Participants

No payment will be provided.

j. Costs to Participants

No costs will be charged to the participant.

k. Planned Duration of the Study

Patients will be enrolled in the study for a total of 12 months from the date of enrollment.Analysis of participant data in aggregate is estimated to take 8 months.

5. RISKS

a. Potential Risks

As part of the study, patients will receive either usual care or will be assigned into the intervention. Patients assigned to the intervention will receive a lay health coach assigned to educate patients in goals of care, assist with symptom assessments, and coordinate community care (such as home hospice, home health services). All patients in the study will receive 3 surveys at baseline, 6 and 12 months after study enrollment: satisfaction with decision, patient activation, and quality of life assessment. receive satisfaction

surveys with their care (CAPHS-G). These will be anonymous surveys and will not be linked to the patient.

b. Procedures to Minimize Risk

We will not obtain identifiable records. For analysis purposes, all patients enrolled into the study will be assigned a unique identifier number. Data will be provided to the Stanford PI in aggregate. Patients will be coded and no direct identifiers will be linked to the patient. All data will be kept in a secure REDCAP database without any patient identifiers other than a unique identifier code.

6. BENEFITS

The benefit from this study will help to inform whether a lay health coach can improve patient satisfaction, quality of life, and reduce healthcare utilization for patients diagnosed with advanced cancer.

7. PRIVACY AND CONFIDENTIALITY

All participant information and specimens are handled in compliance with the Health Insurance Portability and Accountability Act (HIPAA) and privacy policies of Stanford University, Stanford Health Care, and Stanford Children's Health.

Stanford –CareMore-Oncology Institute of Hope and Innovation- Lay Health Worker Symptom Assessment Quality Improvement Pilot

Identifying Patients

- All patients with newly diagnosed cancer Stage 3 or 4 or hematologic malignancies requiring Medical Oncology will be included in the program.

1) Patients will be categorized as either "High Risk" or "Low-Risk" based on the following criteria:
1) High Risk: All metastatic cancer patients as well as all patients on active chemotherapy, all patients with symptom scores 4 or above, or any change in symptom of greater than 2 points from prior assessment
2) Low Risk: Patients who are not on chemotherapy and are undergoing routine follow-up/surveillance, who have no symptom scores of 4 or above, and no change in symptom scores
3) Three months after a non-metastatic patient has completed adjuvant chemotherapy or treatment, he/she will be transitioned to low-risk status unless trigger event occurs as above.

Patient Engagement

- LHW will contact all patients via telephone who meet the criteria prior to their first oncology appointment
- LHW will schedule an initial oncology consultation appointment with the patient within 5 days of initial contact
- LHW will discuss program
- LHW will prepare the patient for their upcoming initial consultation with an oncologist
- LHW will invite and encourage the patient to include anyone in the conversation such as family/caregiver and encourage the patient to include anyone who may potentially be attending future oncology appointments with the patient.
    - If necessary, the LHW will offer to reschedule the call to accommodate patient's request for others to be present during conversation.
- LHW will provide contact information for patients to use in the event of any future triggers and provide a list of all the appropriate triggers to the patient and the care circle.
    - Triggers Include:
    - Disease progression
    - Unexpected side effects
    - Potential change of treatment
    - ED visit or hospital use
    - If for any reason patient does not feel comfortable
    - Life situation changes in a manner that potentially impacts symptoms
    - Oncologist refers patient back to the LHW
    - Patient family members need education/clarification/support

Introduction of HVCCP

- Explain the purpose is to help patients maintain symptom relief.
    - The LHW is here to support the patient throughout this process
- Identify symptom control resources, which the oncologist may later prescribe as appropriate (including palliative care resources).

- *Note:* Here is a good place to address palliative care and begin the intake/ESAS. In addition, connect the patient with individual and group-based opportunities (support groups at the Cancer Institute) for emotional support involving interaction with trained professionals and other people undergoing similar health challenges

❖ Invite and encourage the patient to include anyone in the conversation such as family/caregiver and encourage the patient to include anyone who may potentially be attending future oncology appointments with the patient. Ask patient "are there any members of your family that you think will be part of your care?'

- *Note*: If necessary, offer to reschedule the call to accommodate patient's request.

❖ Provide ESAS for baseline assessment

Prior to each patient's first oncologist appointment:

Educational Materials

❖ LHW will discuss educational materials such as videos/handouts with patients
❖ All cancer patients will be educated on the general topics of chemotherapy, radiation, and surgical approaches to treating cancer and potential side effects.
- LHW will discuss available handouts and reading materials with patients during the initial phone conversation
  - Front office staff will provide patients with handouts for their specific diagnosis, chemotherapy and symptom management (constipation, diarrhea, nausea, etc.) upon check out

Edmonton Symptom Assessment System (ESAS)

1) During the initial phone conversation the LHW will screen patients for symptom management using Edmonton Symptom Assessment System (ESAS) tool (attached)
2) After the initial consultation, LHW will review patient list with Physician Assistant to determine patient risk stratification and will contact and screen all high-risk patients via telephone on a weekly basis and all low risk patients on a monthly basis
3) LHW will input data into Rabbit EHR via ESAS/PHQ-9 template
4) Physician Assistant will review findings of ESAS results through EHR and if patient scores 4 or higher PA will notify the treating oncology practitioner and initiate usual care process for identified symptom management
5) Treating oncology practitioner must review/treat and agree with appropriate orders for any positive findings noted on the ESAS
6) PA will place necessary orders for referrals and notify the treating oncology practitioner via Rabbit e-mail

❖ Referrals will be requested via the CareMore Utilization Management Provider Portal

Patient Symptom Complaints/Triages

- When LHW pilot patients contact staff with a symptom related complaint, staff will create and assign a triage message to the appropriate provider per the most up to date Mid-Level Triage schedule

- The oncology PA will then assess and treat the patient's symptoms per the symptom management algorithms provided to them
- PA will follow each triage message to ensure that the treating oncology practitioner is following all LHW protocols

After Hour Calls

- When a patient contacts exchange after hours (between 5pm-8:30am Monday-Friday and all day Saturday/Sunday), the on-call treating oncology provider will be paged per the standing protocol.
- All patients will be instructed to identify themselves as pilot program patients to both the exchange service as well as to the treating oncology provider who takes the call.
- The treating oncology provider will assess and treat the patient's symptoms per the symptom management algorithms
- If the treating oncology provider feels that patient requires urgent evaluation which cannot wait until business hours, patient will be referred to the nearest emergency department.
- The treating oncology provider is required to notify the PA about the call on the next business day. The message to the PA will include the reason for call, recommended treatment and outcome.
- PA will ensure that the treating oncology provider has followed symptom management algorithms
- PA will recommend more aggressive symptom management to the treating oncology practitioner if applicable.

Patient Satisfaction, Mental and Emotional Health

- All Surveys are to be done by research team and will be conducted when patients enroll and again 5-months post enrollment

No Shows

- If a patient is a no show to his/her office visit appointment LHW will contact the patient 3 times (1 time per week) in an effort to reschedule patient's appointment
- In the event the LHW is unable to reach patient/reschedule patient's appointment, LHW will send an Outlook e-mail to PA/Hilda Agajanian/Dr. Richy Agajanian/Caremore

Exit Criteria

- Patient Preference
  - If patient notifies staff of the Oncology Institute he/she does not wish to continue care, staff must place a triage the reason patient does not want to continue care at the practice and must notify LHW/PA/Hilda Agajanian/Dr. Agajanian and the treating oncology practitioner via Rabbit e-mail
  - Death
  - Staff must follow standard office policy for documenting and marking the chart whenever a patient expires
  - Staff must notify the LHW and site leader as well as the treating oncology practitioner
  - LHW will ensure that chart has been appropriately documented in EHR
- Disqualification
  - If at any point during the staging/screening process a patient is noted to not have invasive cancer, he/she will be removed from the study list
- Date and reason of exit will be documented in EHR