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I. LifeCourse Overview

Study Title: LifeCourse-Robina Late Life Supportive Care
Short Title: LifeCourse
Study Start Date: 10/22/2012
Study End Date: 12/31/2018

Intervention Participant End Date: Intervention patients and KFFs will be inactivated following their last survey follow-up in Q4 2016. The following measures will be completed to notify study participants and complete inactivation:

- The last Survey Due date will be 12/31/2016. The Dillman method will be followed and the participant will not be inactivated until the survey is received or the window is closed.
- Patients are called prior to each survey due date to determine the survey mode. During this call, research staff will verbally notify the patient that data collection is coming to an end and confirm they understand this will be the last survey. A voicemail message will be left including contact information as appropriate.
    - KFFs will not receive a notification phone call message.
- Once the final survey is returned to research or the window is closed, the PPT Intervention Final Inactivation Notification Letter or KFF Intervention Final Inactivation Notification Letter will be mailed.

- The inactivation date for all PPTs and KFFs inactivating due to study close will be 12/31/2016. Research will enter the inactivation date and track the letter mail date in the database.

Comparison Participant End Date: Comparison patients and KFFs will be inactivated following their last survey follow up in Q1 2017. The inactivation procedures will be the same as the intervention participant procedures outlined above with minor modifications:

- The last Survey Due date will be 3/31/2017. The Dillman method will be followed and the participant will not be inactivated until the survey is received or the window is closed.
- The inactivation date for all PPTs and KFFs inactivating due to study close will be 3/31/2017. Research will enter the inactivation date and track the letter mail date in the database.

Study Phases: The LifeCourse study was divided into 3 phases:

- Pre-pilot patient enrollment (10/22/2012-3/22/2013). Enrollment is closed for this study phase. All intervention and data collection activities are the same as full pilot protocol previously approved by Quorum.
- Full-pilot encompasses intervention participants enrolled from 7/9/2013-12/31/2018.
- Comparison group enrollment began on 4/15/2014 and will end 12/31/2018.
- Beginning 10/15/2014 or upon receiving IRB approval, whichever comes first, all intervention and comparison participants will be enrolled in the full research project.
    - All intervention and comparison patient participants will be mailed a letter and consent form and asked to re-consent in to the study going through December 2018.
    - If LifeCourse does not receive a signed form within a week, a care team member will call the patient (3 call attempts).
    - [Intervention only] If after 3 call attempts there still isn't a response, the care guide will ask the patient about re-enrollment at their next meeting.
    - [Comparison only] Comparison patient participants signed consent forms that expire 12/31/2016. As of 2/18/2015, 27 participants have not re-enrolled.
    - Once a patient re-consent form is received, a letter and consent form will be mailed to all associated KFFs.
        - If LifeCourse does not receive a signed form within a week, a care team member will call the patient (3 call attempts).
    - Care team members will be re-consented in-person.
    - All participants will have the opportunity to withdraw at any time. For those that decline to re-consent, their participation will end as previously scheduled (intervention in December 2014 and comparison in December 2016).
    - The KFF 2.0 role will be discontinued at this time. KFF 2.0 participants will be asked to re-consent in to KFF 1.0 level. For those that decline to re-consent, their participation will continue as previously planned and end as previously scheduled (intervention in December 2014 and comparison in December 2016)

Study Type: Social-Behavioral, intervention-based research using Protected Health Information (PHI) via an Electronic Health Record (EHR) as well as various data collection methods (surveys and/or interviews). No other alternative models are available to patients and caregivers. Usual care is the only viable current alternative. There is no deception or withholding of information in this study.

Study Sites:

Intervention Group Sites: Allina Health System hospitals and hospital-based clinics, Augustana Health Care Center (Augustana), Walker Methodist Health Center (Walker Methodist) in Minneapolis, New American Academy in Minneapolis and Eden Prairie. Augustana and Walker Methodist are Skilled Nursing Facilities (SNF) with Transitional Care Units (TCU). Augustana, Walker Methodist and New American Academy and are non-Allina facilities.

Comparison Group Sites: Allina Health System hospitals and hospital-based clinics and participants from intervention group sites that decline enrollment.

Study Groups:

- Intervention Group: Participants enrolled in this LifeCourse group will receive the care team intervention approach and will fill out surveys regarding their quality of life, and their (or their loved one's) care experience.
- Comparison Group: Participants enrolled in this LifeCourse group will not receive the care team intervention approach and will receive usual care. They will only fill out surveys regarding their quality of life and their (or their loved one's) care experience.
- Somali Listening Circles Sub-Study: Participants enrolled in the listening circles will provide information and feedback in an effort to improve LifeCourse intervention model implementation within the Somali community.

www.ClinicalTrials.gov: 01746446

II. Specific Aims

Our primary aim is to test the LifeCourse model.

A. Hypotheses

1. Patients participating in LifeCourse will see an increase in support for their goals and wishes over time.
2. Patients and primary caregivers participating in the LifeCourse intervention group will have stable quality of life experiences or slower decreases in a negative quality of life trajectory as compared to the patients and caregivers in the comparison group.
3. Patients and primary caregivers participating in the LifeCourse intervention group will have more positive patient experiences as compared to patients and primary caregivers in the comparison group.
4. Patients and primary caregivers participating in the LifeCourse intervention group will have more positive access and coordination as compared to patients and primary caregivers in the comparison group.
5. Care team members participating in the LifeCourse intervention group will have higher wellbeing or slower increases in burnout as compared to care team members in usual care teams.
6. LifeCourse intervention group patients will choose to enroll in hospice at an increased rate compared to usual care, including comparison group patients.
7. Hospice length of stay will increase for patients participating in the LifeCourse intervention group compared to usual care and the comparison group patients.
8. LifeCourse intervention group patients will have lower total cost of care compared to patients in usual care including comparison group patients.

B. Research Questions(s)

1. Do patients enrolled in the LifeCourse intervention group see an increase in support for their goals and wishes over time?

2a. Do patients participating in the LifeCourse intervention group have stable quality of life experiences or slower decreases in negative quality of life trajectory as compared to patients in the comparison group?

2b. Same question focused on primary caregiver identified by the patient.

2c. Same question focused on secondary caregiver(s) identified by the patient. To be discontinued when all KFF 2.0 participants have completed the study (intervention December 2014 or comparison December 2016)

3a. Do patients participating in the LifeCourse intervention group have higher patient experience scores compared to patients in the comparison group?

3b. Same question focused on primary caregiver identified by the patient.

4a. Do patients participating in the LifeCourse intervention group have improved access and coordination of care compared to patients in the comparison group?

4b. Same question focused on primary caregivers identified by the patient.

5. Do LifeCourse care team members have higher work-related wellbeing or slower increases in burnout compared to care team members in usual care teams?
6. Do LifeCourse intervention group patients enroll in Hospice at an increased rate compared to patients in usual care including the comparison group?
7. On average, do LifeCourse intervention patients have longer hospice length of stays compared to patients in usual care including the comparison group?
8. Do LifeCourse intervention patients have lower total cost of care compared to patients in usual care including the comparison group?

9a. What is the care team structure needed in order to support intervention group patients and caregivers?

i. How is the team deployed?
ii. In what ways are they successful?
iii. What are their challenges?
iv. How do they adjust the level of intensity of services over time to meet the needs of patients and families while wisely using its resources?
v. How do they partner with other entities internal to Allina and external to the organization?
vi. On what palliative care domains and areas does the team spend the majority of its time and effort?

III. Background and Significance

Patients with late life limiting illness and their families are often at a loss when seeking support within the current U.S. healthcare system. Poor understanding of late life supportive care services, which include advance care planning, palliative care, and hospice services, combined with a lack of systems to promote referral upon diagnosis, result in poor access to services and leave families with the burden of managing end-of-life care for their loved ones.

Those who receive services enter a profoundly fragmented system in which care coordination is overwhelming – patients with late life limiting illness may interact with as many as 130 physicians across 60 practice settings. The result is duplicative and unnecessary medical procedures and conflicting treatment plans across clinical providers and settings that are part of a healthcare system that was built to deliver services to acutely ill patients requiring episodic care, not to patients who are chronically and persistently in need of coordinated care.

While clinicians excel at achieving technical outcomes, oftentimes, they lack the necessary skills and tools to engage patients and their families comfortably and effectively in end-of-life discussions. Without standardized, reliable systems to integrate late life supportive care services into primary care and inpatient settings, patients, families and care providers are at risk for managing within an environment where care is suboptimal and misaligned with the values and wishes of patients and their families.

There is increasing recognition of how knowing the whole person leads to optimal medical care delivery and higher satisfaction with services, to the benefit for patients, families, and care providers. Everyone involved benefit from conversations that lead to a more complete understanding of patients' preferences around living with a life limiting illness that drives care decisions.

With support from the Robina Foundation, the LifeCourse program aims to shift the present late life supportive care paradigm at Allina Health by demonstrating and testing a comprehensive, systemic approach, that is proactive in meeting the unique needs of patients with life limiting illness, their caregivers, and family members. The project will link existing supportive care services to create a unified program; introduces a range of system components designed to address the gaps described above; and integrates these services, systems, processes, and tools into the primary and inpatient care settings.

Increased longevity and healthcare efficacy, resulting in a growing demographic of elders with chronic conditions, compels healthcare organizations to attend to managing chronic conditions well as they move from fee for service to per capita coverage. Driven by an Accountable Care Organization (ACO) approach and partnering with a holistic set of service providers to approach patient care as an ACO community, LifeCourse will try to ensure compassionate, comprehensive, and reliable late life supportive care services that realize the Triple Aim and other critical outcomes for patients, caregivers, and care providers, including to:

- Honor patients' and families' end-of-life wishes and goals
- Reduce the speed of decline or improve the overall quality of life for patients and families
- Improve the patient and family care experience
- Control costs of care for patients with life limiting illness
- Increase access to best practice in end-of-life care
- Improve job satisfaction of interdisciplinary team members

LifeCourse will serve a patient population selected with ever increasing, complex, health needs who, in their final years of life, are in need of a well-designed, coordinated system of care. Patients nearing the end of life are often associated with excessive inpatient stays during the last six months of life; complex medical decisions; significant symptom burden; and complex social, emotional, and spiritual needs for patients and caregivers. The long-term aim of LifeCourse model is to expand to include a wider array of disease categories and more patients with life limiting illnesses throughout the Allina Health system.

Please see the LifeCourse Grant (attached) for additional information.

IV. Conceptual Model of a Late Life Supportive Care Intervention

LifeCourse exists to help patients live well, even while their illness progresses, by empowering them, their family members and caregivers to make medical and non-medical decisions. The cornerstone of the LifeCourse approach is to build trusting relationships with patients and their caregivers by learning the patient's story, beyond their medical condition. The approach also requires relationship building with a wide array of existing service providers, both within and outside of Allina, to facilitate effective, smooth and timely transitions and coordination of care. By knowing patients, ensuring they have access to information and services, and assisting their navigation through the maze of rules, payment and service programs, LifeCourse aims to provide patients and families with the tools they need to drive their health care decisions. LifeCourse staff will remain with patients to assist them in identifying and accessing needed services, share information with service providers so patients and families do not have to start over with every professional they meet, and advocate for patients and identified decision makers as the drivers of care decisions. LifeCourse staff remains with the family after the loss of their loved one to ensure family and friends connect to bereavement services as they choose.

The LifeCourse inter-disciplinary care team consists of non-clinically trained care guides, a nurse, social worker, marriage and family therapist, chaplain and pharmacist, who are available as needed or requested by patients and families to attend to the wide range of needs experienced when facing serious illness. Traditional deployment of major health care models in this country tend to be designed and ordered from the top, without including input from those who deliver services and receive care. The LifeCourse program was created in response to the expressed needs of patients, family members and professionals working in this field. The details of daily work are formed with input from patients, caregivers, professionals and front line staff as they work with patients and families. LifeCourse also builds upon and integrates several foundational concepts, such as Advance Care Planning and Shared Decision Making, into daily work.

V. Research and Evaluation Methods to Assess Effect of a Late Life Intervention

The LifeCourse research design includes measures to assess impact upon the health care system, care team members, and patients and families. Quantitative and qualitative data are collected within a longitudinal design to

both measure effect and inform design and implementation of the LifeCourse model. Daily and weekly care team data are utilized within a process improvement approach that identifies opportunities for change and enhancement. Data collected from care team members informs training, competency development and staff wellbeing. For patients, historical and concurrent control groups are utilized to evaluate program impact within the health care system through measures related to hospice use and length of service, inpatient utilization during the last 6 months of life and total cost of care. The LifeCourse research design also includes a comparison group utilized to assess intervention group impact. Additional measures examine change over time for patients and caregiver, as measured by quality of life, health care experience, access and coordination of care, and the degree to which the patient's goals and wishes are honored.

VI. Subject Population

Age Range: 18 years or older
Sex Breakdown: All
Race/Ethnicity: All
Language/Literacy: English, Spanish, Russian and Somali Speakers (patients and KFFs): An interpreter will be available for all aspects of the LifeCourse project including enrollment, data collection and intervention activities. In addition, all related materials will be translated as needed.

- [NOTE: Spanish, Russian, and Somali participants were not enrolled as part of the main/core intervention or comparison study. LifeCourse did not move forward with enrollment due to: a limited number of eligible patients. All documents that were translated were never implemented and thus the English survey v5 was never implemented. The only Somali participants enrolled were part of the Somali Listening Circles sub-study.

Groups: LifeCourse care team members, intervention and comparison patients and potential caregivers identified by enrolled patients

VII. Enrollment Goals

- LifeCourse's goal is to enroll approximately 600 patients in the intervention group and 600 patients in the comparison group. Each of the enrolled patients may identify up to 10 caregivers, which will potentially provide a total of 12,000 caregivers. These enrollment goals will provide sufficient data to determine if the LifeCourse model affects outcomes. In addition, LifeCourse will engage with up to 25 care team members.
- LifeCourse will need to approach and invite approximately 20,000 patients for each group (assuming a 25% enrollment rate) in order to reach the 5,000 patient goal for the intervention and comparison groups.
    - PPT Survey Feedback Sub-study (Intervention and Comparison)
        - LifeCourse's goal is to enroll approximately 150 patients over the course of the project.
            - A new cohort of participants may be invited to participate whenever a patient experience survey has been revised and approved by Quorum. Each cohort will have up to 30 participants.
        - LifeCourse will need to approach and invite approximately 300 patients (assuming a 50% enrollment rate) in order to reach the 150 patient goal over the course of the project
    - PPT/KFF Experience Interview Sub-study (Intervention Only)
        - LifeCourse's goal is to enroll approximately 150 patients already enrolled in the intervention group and 450 caregivers for the semi-structured interview study over the course of the project
            - A new cohort of participants will be invited to participate every 6 months. Each cohort will have up to 30 participants.
        - LifeCourse will need to approach and invite approximately 300 patients and 900 caregivers enrolled in the intervention group, to participate in semi-structured interviews (assuming a 50% enrollment rate) in order to reach the 150 patient goal and 450 caregiver goal over the course of the project

- Somali Listening Circles Sub-Study
  - LifeCourse's goal is to recruit approximately 60 Somalis to participate in the listening circles.
  - LifeCourse will need to invite approximately 180 potential participants to reach the 60 enrollment goal.

VIII. Screening

Potential participants will go through a two stage screening process. In screening stage 1, LifeCourse patients enrolled through Allina will be identified through the electronic health record. A Crystal report will be written to prospectively identify a potential patient population. Since the number of patients identified using the criteria below (8a-8b) through Allina's EHR will likely be too numerous, this population will be further risk stratified using a comorbidity index and other potential indicators of interest until LifeCourse has a manageable weekly count of potential enrollees. Potential LifeCourse patients identified by community partners (Augustana and Walker Methodist) will be manually reviewed to determine eligibility. In the same manner, Spanish-speaking, Russian-speaking, Somali-speaking and African American potential participants may be identified by their primary care provider and then screened manually through electronic chart review to determine eligibility. Regardless of enrollment method, all potential patients will be reviewed according to a standard screening procedure. [NOTE: Spanish-speaking and Russian-speaking participants were not enrolled as part of this study (4/7/2016)]

A. Screening Stage 1

1. Inclusion Criteria
   i. Patient has an Allina Primary Care provider, Senior Care Transitions (SCT) provider, or Geriatric Services of Minnesota (GSM) provider. (SCT and GSM are Allina providers that visit patients in non-Allina facilities.)
   AND
   ii. Age ≥ 18
   AND
   iii. Patient's medical chart indicates an on-going or significant medical condition.
2. Conditional Criteria

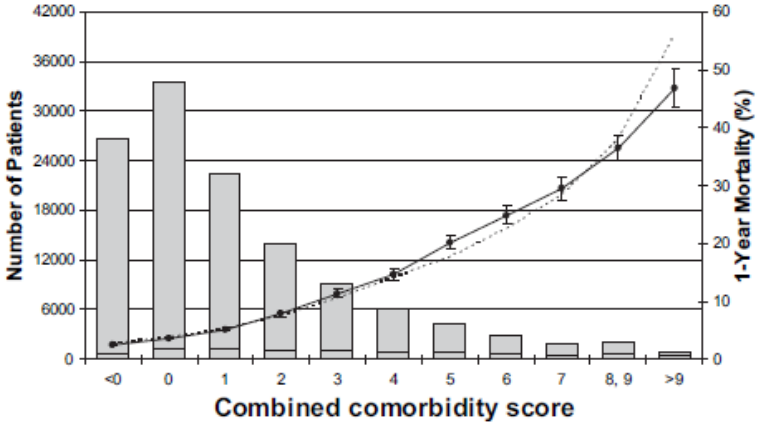
   Conditional criteria will be used to narrow the patient population identified by the Crystal report to a more manageable amount for the care team.

   i. Hospital admissions:
      a. 2 or more hospitalizations in the past 12 months
      OR
      b. 1 or more ICU stays in the past 12 months
      OR
      c. 2 or more ER visits in the past 12 months
      OR
   ii. Frailty or proxy measures for frailty:
      a. FAST score ≥ 3
      OR
      b. Proxy measures include procedure and/or diagnostic codes for unintentional weight loss (5-10% of body weight in the last 3-6 months), BMI < 25, dysphagia, feeding tube, late stage pressure ulcers, upper urinary tract infection(s) from catheterization, recurrent falling/fractures, sepsis, cellulitis, and aspiration pneumonia.
      OR
      c. Any changes in late-loss Activities for Daily Living (ADL)

      OR
   iii. Comorbidity Index:

A cut point will be determined based on the distribution of the comorbidity risk index score in Allina's patient population and prospective feedback from the clinical panel. The comorbidity score looks at all diagnoses and assigns a weight for predicting mortality based on an aged population (e.g., ≥ 65) of Medicare recipients. It is derived from a combination of the Charlson and Elixhauser comorbidity indices, which have been used in the hospital setting and administrative claims databases for patient prognosis since the early eighties (1, 2). The score ranges from a minimum value of -2 to a maximum value of 24. Multiple diagnoses in the same major disease category are counted once. Further detail on the development and validation of the comorbidity score can be found here (3). See table and figure below for further interpretation:

CONDITION	WEIGHT
Metastatic solid tumor	5
Congestive heart failure	2
Dementia	2
Renal failure	2
Weight loss	2
Hemiplegia	1
Alcohol abuse	1
Any tumor	1
Cardiac arrhythmias	1
Chronic pulmonary disease	1
Coagulopathy	1
Diabetes with end organ damage	1
Deficiency anemia	1
Fluid and electrolyte disorders	1
Liver disease	1
Peripheral vascular disorder	1
Psychosis	1
Pulmonary circulation disorders	1
HIV/AIDS	-1
Hypertension	-1



1 Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. Journal of chronic diseases. 1987;40(5):373-83.
2 Elixhauser A, Steiner C, Harris DR, Coffey RM. Comorbidity measures for use with administrative data. Medical care. 1998 Jan;36(1):8-27.
3 Gagne JJ, Glynn RJ, Avorn J, Levin R, Schneeweiss S. A combined comorbidity score predicted mortality in elderly patients better than existing scores. Journal of clinical epidemiology. 2011 Jul;64(7):749-59.

3. Exclusion Criteria
    i. Patient resides in a zip code which does not lie partially within a 45 mile radius from the Allina Health Commons in Minneapolis, Minnesota.
    ii. Patient has not visited an Allina facility, affiliate, or community partner within the last year.
    iii. Patient is eligible for hospice.
    iv. Patient is actively dying.
    v. Patient is abusive or is discharged against medical advice (AMA).
4. Vulnerable Subjects
    i. LifeCourse will invite vulnerable patients to enroll, including:
    ii. Critically Ill Patients
    iii. Cognitively Impaired Patients
    iv. Mental Health Patients
    v. Chemical Dependency Patients
    vi. Elderly Patients, some of whom may have cognitive impairment and/or be institutionalized.
        a. Dementia affects almost two million Americans each year. It is estimated that at least half of patients living with end-stage dementia (including Alzheimer's disease or Vascular Dementia) will die within 6 months of fracturing a hip or developing pneumonia, a rate far higher than that faced by patients who are cognitively intact. Recent studies suggest that patients facing end-stage dementia are in greater need of pain medication and palliative care than they are currently receiving. Therefore, this population is one of the primary focuses of this study.
        b. At the time of initial consent, not all subjects will have the capacity to give informed consent. If it is determined that the patient is unable to consent to participate due to cognitive impairment, the Legally Authorized Representative (LAR) will sign consent forms for the patient.

B. Screening Stage 2

1. Concurrently to screening stage 1 in screening stage 2, the study team will use retrospective EHR data to develop, analyze, and validate an all-cause mortality model for prognostic patient identification for the planned Phase 2 of the LifeCourse study.
2. All health record data will be retrieved on all patients who are 18 years or older at the time of their index encounter between 2005 and 2014 and have signed Allina's research data release form.
    i. The following EHR data will be included as part of this analysis:
        - Patient demographics
        - Current and historical clinical data
        - Diagnoses and problem list
        - Orders
        - System administrative data (billing, usage)
        - Proxy measures for functional status which may reside in notes
3. The Allina EHR data set will be merged with a historical death index data set obtained from the Minnesota Department of Health to assess mortality follow-up more completely than what currently resides in the EHR.
4. The data will then be randomly split into a development and validation cohort.

5. Using a combination of traditional statistical techniques (multivariate logistic regression and Cox proportional hazards regression) and data mining techniques, the team will use the development cohort to create a parsimonious algorithm that flags potential death.
6. Once the prognostic model has been developed it will be tested on the validation cohort. If the model has achieved performance goals in terms of validity, reliability, and projected patient enrollment goals it will be used to help prospectively select patients in Phase 2 of the LifeCourse study.

C. PPT Survey Feedback Interview Sub-Study
   1. The cognitive debrief sub-study will use the same criteria as Section VIII A above
   2. A LAR /proxy will not be invited to participate in this study as the proxy survey does not include a Patient Experience Survey.

D. PPT/KFF Experience Interview Sub-Study
   1. Patients- At each round researchers will identify 40 patients for which we have survey data.
      i. A LAR/proxy will not be invited to participate as they do not complete the patient experience survey.
   2. KFFs
      i. KFFs enrolled in study and/or identified by a patient (referenced above) will be invited to participate in interview.
      ii. Other friends or family members (not already enrolled in LifeCourse) will be invited to participate if a patient identifies them in the initial recruitment call as someone who might be interested in taking part in the interview.

E. Somali Listening Circles Sub-Study
   1. New American Academy will be responsible for recruiting individuals to join focus groups.
      i. Age ≥ 18
      ii. Groups will be divided by age and gender:
         - Women
         - Male elders/leaders in community
         - Young adults

IX. Patient Referral

Please see eligibility criteria included in Section 8a-8b above for more information. As mentioned above, potential participants will be screened by the LifeCourse team to determine if they meet eligibility criteria. An attempt will be made to recruit participants across the entire late-life disease spectrum.

- If a patient has a current relationship with an Allina Health System hospital and hospital-based clinic provider, a MHI care coordinator, VPCI coordinator, ANW social worker, or a member of the Advanced Care Team (ACT) that staff member would contact the patient regarding LifeCourse referral (See *LifeCourse Referral Script)*.

X. Patient Enrollment

A. Enrollment Scheduling and Encounter
   1. If a patient doesn't have a current relationship with an individual listed above, a LifeCourse team member will contact the patient (See *LifeCourse Recruitment Script).*If patient was identified as a potential intervention group participant:
      i. An MD Invitation letter may be sent to potential intervention group participants. This letter would introduce the LifeCourse project and be sent by LifeCourse staff on behalf of the potential participants Allina provider (See MD Invitation letter).

ii. For patient's referred by providers, a LifeCourse team member will be present at the potential participant's clinic/hospital in order to introduce LifeCourse following an appointment with the provider.
iii. For patient's identified through the Crystal report, a LifeCourse team member will set-up an appointment to meet with the potential patient participant and any caregivers (LifeCourse uses the term Key Family and Friend-KFF).
iv. If patient is not interested in participating in the intervention, the LifeCourse team member will invite the patient to participate in the comparison group. The enrollment documentation can be mailed to the participant following the comparison enrollment procedures.

2. Non-English speakers will not be invited to participate in the comparison arm of the study.
3. If patient is identified as a potential comparison group participant:
    i. A LifeCourse team member will set-up an appointment to meet with the potential patient participant. However, if an in-person enrollment is not possible with a comparison group participant, LifeCourse Staff will mail an introductory letter and consent form. Following, a LifeCourse staff member will call to answer any questions.
    i. If they are not interested in participating in the comparison group, the LifeCourse team will discontinue contact.
4. In-person enrollment may occur at one of the following locations: Any Allina hospital or one of its affiliated clinics, Augustana, Walker Methodist, or eligible participant's homes.
    i. LifeCourse staff will attempt to speak with the participant as their time allows in-person or by phone (e.g., avoid times when providers are rounding, patient is sleeping, etc.). LifeCourse staff will use tele-conference and video-conference technology to facilitate KFF participation as needed. However, verbal consents will not be accepted at this time.
    ii. LifeCourse staff will work with the site to identify the most appropriate times and location to discuss study with the potential participant.
    iii. Participants will be asked if it is a convenient time for them to talk, and if necessary, the LifeCourse staff member will set-up an appointment to speak with them later.
    iv. Potential participants will not be forced to make a decision on the spot and will be given adequate time to consider study participation.
    v. In short, participants will be given as much time as necessary to consider and make a decision about participation in LifeCourse.
    vi. A LifeCourse team member will go through the enrollment process.
    vii. If the patient has cognitive impairments, the LAR will be present during the enrollment encounter.
    viii. If the patient is unable to read due to illiteracy or visual impairment, then an impartial witness will be present.
    ix. A LifeCourse team member will meet the patient and/or LAR at the agreed upon time and go through the consent process (See *LifeCourse Enrollment Script*)
5. If KFF is physically present during the enrollment encounter, they will also be asked to consent at the same time using a similar script based on the appropriate KFF consent form.
6. If the patient would like more time to consider participating in the project or would like to invite additional KFFs to meet with the LifeCourse team, LifeCourse staff will follow up with the participant after the enrollment meeting. If the patient does decide to participate, a member of the LifeCourse team will schedule an additional meeting with the participant and/or KFFs to have them sign the consent forms, discuss the participant's KFFs, and administer the baseline data collection survey.
7. FOR PATIENTS INVITED TO PARTICIPATE IN THE INTERVENTION GROUP: If the patient declines intervention group enrollment (either in-person or via phone), a LifeCourse team member will then invite them to participate in the comparison group.
8. PPT Survey Feedback Interview Sub-Study

i. Information in Section X A. 3 i-iv, viii, and 5 apply to this cohort
   - PPT Survey Feedback Interviews will not be completed with a proxy/LAR as they do not complete a Patient Experience survey.

9. PPT/KFF Experience Interview Sub-Study
   i. Information in Section X A. 3 i-iv, viii, 4 and 5 apply to this cohort
      - PPT/KFF Experience Interviews will not be completed with a proxy/LAR as they do not complete a Patient Experience survey and will not be eligible based on screening criteria.
10. Somali Listening Circles Sub-Study
    i. Participants will be asked to review the consent form and provide consent before the session begins.

B. Recruitment Materials
1. Intervention Group: Patient Consent form, KFF 1.0 Consent form, KFF 2.0 Consent form and Recruitment Brochure. The KFF 2.0 consent form will be discontinued as of 10/15/14 or upon IRB approval, whichever comes first.
2. Comparison Group: Comparison Patient Consent form, Comparison KFF 1.0 Consent form, Comparison KFF 2.0 Consent form. The CKFF 2.0 form will be discontinued as of 10/15/14 or upon IRB approval, whichever comes first.
3. As needed, LifeCourse staff will use the FAQ document (attached) to answer questions and give the Allina website to potential participants in order to provide additional information. The website can be found at: http://www.allinahealth.org/ahs/aboutallina.nsf/page/robina_life_course
4. PPT Survey Feedback Interview Sub-Study
   i. Information and Consent: Survey Feedback Interview form
5. PPT/KFF Experience Interview Sub-Study
   i. Information and Consent: PPT and KFF Experience Interview form
6. Somali Listening Circles Sub-Study
   i. Information and Consent: Somali Listening Circle form

C. Evaluating Informed Consent
1. All potential participants will be asked the following to establish informed consent for the Intervention, Comparison, PPT Survey Feedback Interview Sub-Study, and Somali Listening Circles Sub-Study:
   i. In your own words tell me what you expect as a study participant?
   ii. What do you think you'll get out of the LifeCourse research project?
   iii. What other questions do you have for me that we haven't already answered?
2. It is reasonable that some subjects may lose the capacity to continue to provide informed consent during the course of the study. In these cases, the patient's LAR will be invited to sign continued consent as the proxy.
3. Lastly, if a patient is unable to read, then an impartial witness must be present in order to attest to the accuracy of the information being presented.
4. PPT/KFF Experience Interview Sub-Study
   i. All potential PPTKFF Experience Interview participants will be asked the following to establish informed consent:
      a. Why did I come here today?
      b. Who are we inviting for interviews?
      c. Can you name something that could be a risk for you in this interview?
      d. What can you do if you don't want to answer any more questions?

XI. KFF/CKFF 1.0 and KFF/CKFF 2.0 Enrollment

NOTE: KFF 2.0 and CKFF 2.0 enrollment will be discontinued as of 10/15/14 or upon IRB approval, whichever comes first.

A. KFF/CKFF In –Person Consent & Baseline Data Collection Procedure

If KFF or CKFF are present when the patient enrolls in the LifeCourse intervention or comparison group, the KFF or CKFF will be given the opportunity to consent at that time. See *Patient Data Collection Procedure* for more details. The in-person KFF and CKFF baseline data collection options are:

1. Baseline surveys will be administered immediately following the enrollment process.
2. If the KFF or CKFF shows signs of fatigue or is not able to complete the surveys during the enrollment encounter, the LifeCourse staff either will provide them with a self-addressed stamped envelope to take with them and return their completed survey or invite them to complete the survey over the telephone.

B. KFF/CKFF Mail Consent & Data Collection Procedure

If patient identifies a KFF or CKFF who is not present at the enrollment appointment, LifeCourse Staff will contact the KFF by mail to inform them regarding the patient's participation in LifeCourse and give them the opportunity to enroll.

C. Potential KFF/CKFF Participant Consent Procedure

1. Determine if address was collected when patient was enrolled.
2. If any KFF/CKFF addresses are missing, the LifeCourse Staff will highlight the needed information and gather at a later date.
    i. LifeCourse staff calls KFF/CKFF, explains the study (similar to when contacting the patient to set up enrollment meeting and obtains an address to send the consent forms.
3. Determine if potential participant should receive KFF/CKFF version 1.0 or 2.0. Then prepare the appropriate Consent Mailing packet including all forms. Hand address envelope, add appropriate postage and place in outgoing mail bin in mailroom.
4. Within 2-3 days of the estimated receipt of consent, call to confirm that participant received mailing and to see if they have questions. If LifeCourse Staff receives the signed consent before the first scheduled call, LifeCourse Staff will make one phone call attempt to ensure that the participant understands the study and does not have any questions. If individual states that they are not interested in participating, thank them for their time and document in database.
5. If KFF/CKFF agrees to participate, ask them to sign the form and return it to LifeCourse.
6. 5 follow-up phone call maximum over a period of 5 weeks after sending the initial consent packet.
    i. 2 follow-up phone calls in Week 1
    ii. 2 follow-up phone calls in Week 2
    iii. 1 follow-up phone call in Week 3
7. If after 5 phone call attempts no response is received from the KFF/CKFF or the KFF/CKFF declines to participate, LifeCourse will confirm with patient during subsequent follow-up surveys if the individual is still a KFF/CKFF (but not inform the patient that the KFF/CKFF has not consented). If it is confirmed that the individual is a KFF/CKFF, LifeCourse Staff then will send the KFF/CKFF Consent and repeat the steps outlined above.
8. PPT/KFF Experience Interview Sub-Study
    i. See Patient Experience Interview in Patient Enrollment Section.

XII. Compensation and Costs to Subjects

A. Intervention group participants will not receive compensation for participating in the LifeCourse research project.

B. PPT/KFF Experience Interview participants will not receive compensation for participating in the sub-study

C. PPT Survey Feedback Interview participants will receive $30 for each interview they complete. The first being the interview at the time of enrollment, and the second being an interview during the 3 month follow-up. The compensation was determined based on the average amount of time needed to complete the survey and interview.

D. Somali Listening Circles participants will receive a $25 gift card to Target or Wal-mart.

E. Comparison group participants will receive the following compensation for their participation:

1. CPPT: A $10 bill will be given to the CPPT after completing an in-person survey OR a $10 bill will be mailed with Survey 1 for baseline and follow-up surveys.
2. CKFF 1.0: A $10 bill will be given to the CKFF 1.0 after completing an in-person survey OR a $10 bill will be mailed with Survey 1 for baseline and follow-up surveys.
3. CKFF 2.0: A $2 bill will be given to the CKFF 1.0 after completing an in-person survey OR a $2 bill will be mailed with Survey 1 for baseline and follow-up surveys. Although the CKFF 2.0 role was discontinued for new enrollees, previously enrolled CKFFs may choose to not re-enroll as a CKFF 1.0 and will thus continue to receive $2 compensation until they inactivate or December 2016.
4. The compensation amount was determined based on the average amount of time needed to complete the survey. CPPT and CKFF 1.0 surveys take 30 minutes on average to complete, and CKFF 2.0 surveys take 10 minutes on average to complete.

F. Participants will not incur other expenses as a result of participating in this study as the LifeCourse model includes all usual care, plus additional enhancements and improved coordination of current services.

G. Patient participants will be charged for all tests and procedures required for the treatment of their medical condition as usual. Additional services may be recommended by the LifeCourse care team, and if the participant chooses to follow the recommendations, they are responsible for the costs. If the participant's health insurance or Medicare requires any co-payment, co-insurance, or deductible, the participant will be responsible for making the payment.

H. If there are barriers to services or treatments, such as financial burden or no coverage by health insurance or Medicare, the LifeCourse team may be able to help using the Bridge Fund.

1. What is the LifeCourse bridge fund?
   i. The LifeCourse Bridge Fund is money available to help reduce barriers to quality of care. The purpose of the LifeCourse Bridge Fund is to provide access to tools and resources that will allow patients to improve their quality of life. Patient needs and wishes will be considered based on goals set by the patient in collaboration with the patient's loved ones and the care guide. Using the LifeCourse Bridge Fund to meet patient needs and wishes should serve the purpose of reducing barriers to the patient's quality of care.
   ii. The LifeCourse Bridge Fund primarily serves to improve patient care and cannot be used simply as replacement for needs and wishes that can be met in other ways. Patients are expected to explore other resources so that the LifeCourse Bridge Fund can be extended to as many patients as would be possible.

iii. The LifeCourse Bridge Fund is a component of the LifeCourse approach to care which is designed to provide supports where there are gaps in the health and services infrastructure. Because the LifeCourse Bridge Fund provides a limited source of money, it is not a long-term solution—it serves as a bridge while the patient and their family work with the care guide to secure long-term medical, social and community supports.

2. How much money is available to me?
   i. Because the LifeCourse Bridge Fund is part of ongoing research, a fixed or capped dollar amount is not defined.
3. What is the process /What can patients expect?
   i. The care guide will work with the patient and family to determine how the fund might reduce barriers to care needed and to improve quality of life.
   ii. Each request for funds will receive the team's attention.
   iii. Other available opportunities to meet needs and wishes will be explored first.
   iv. Patients and caregivers will be approached in an unbiased manner, without regard to gender, race, religion, faith, socio-economic status or beliefs.
   v. The care guide will make sure she or he understands accurately the patient/s needs and wishes. The patient may follow up with the care guide at any time to review, provide further understanding, or give additional input if situation changes.
   vi. The patient, their family, and professionals working with the patient may provide input for a decision.
   vii. The LifeCourse team will make a final decision as to whether the Bridge Fund can be used.
   viii. Where appropriate, the funds will be paid directly to the service or support provider.
4. Examples of possible LifeCourse bridge fund purchases:
   i. Learning how to use a computer, to be able to communicate with family
   ii. Care from the Allina Community Palliative Care team
   iii. Hours of personal care at home, so family can get a break
   iv. Day program participation
   v. Help with transportation

I. **Note: Comparison groups participants will not be eligible to receive financial assistance from the Bridge Fund

XIII. Alternatives to Participation

A. There are not reasonable alternatives (available in a non-research context) that would have the potential for providing the same or similar benefits to subjects enrolled in the LifeCourse Intervention group. No standard treatments are withheld. The LifeCourse model includes all usual care, plus additional enhancements and improved coordination of current services. Comparison group participants will receive usual care and not have access to the LifeCourse care team.
B. No study procedures or courses of treatment will be available to prospective subjects if they elect to not participate in the study.

XIV. Risks and Discomforts

A. Risks and discomforts apply to intervention and comparison group participants.
B. Possible invasion of privacy of a subject or family, including the use of personal information or records.
C. Probing for information that an individual might consider to be personal or sensitive.

D. The research uses procedures already being performed on the subjects for diagnostic or treatment purposes.
E. The risks of the research include study burden and emotional distress from answering potentially sensitive survey questions.
F. There is no risk of physical injury in this study.
G. In order to minimize the risks or discomforts identified above:
    1. All participants will have the option to not answer any question if there is a subject that causes emotional discomfort. LifeCourse care team staff members are trained to deal with these situations and concerns.
    2. *For intervention group participants only: Patients will approve the content that is shared within their EHR in the Patient Story note.
H. If an issue should occur, LifeCourse will follow Allina's standard procedures for reporting.
    1. The PI will be informed and in turn, will inform other research staff about events concerning subject safety (including interim results, breach, adverse events, unanticipated problems involving risks to subjects or others, noncompliance, or complaints) using one of the following modes:
        - By email
        - By in-person meeting
        - By telephone
I. Somali Listening Circles Sub-study
    1. Risk of disclosing information in group setting that could potentially be shared with others outside of the group.

XV. Benefits

There are no known direct benefits for participating in this study. While benefits to intervention group patients and caregivers may accrue, we lack any prospecting data to suggest specific benefits at this time.

XVI. General Overview of Study Procedures

A. All intervention and comparison group research components of LifeCourse are voluntary. The intervention and comparison group patient and caregiver specific consent forms outline the minimum/maximum expectations, but no aspects of the study are required. Participants may decline to complete a specific activity or survey at any time throughout the course of the study
B. Intervention group patients, their caregivers and care team will agree on frequency and preferred mode of communication.
C. All research activities will occur at one of the long-term care facilities (Augustana and Walker Methodist), ANW or UH hospital (Allina Health), New American Academy, patient's or caregiver's home or another location of their choosing.
D. All data collected will be used for research purposes or embedded LifeCourse quality improvement efforts during the course of the study.
    1. Patients
        i. Intervention Group
            a. The patient participant may have contact with the LifeCourse care team a minimum of 1 hour a month over the course of the study. Additional phone call communications or visits, including Supportive Care Conferences may be necessary based on the participants' goals and needs. Shared Decision Making tools will be used to help facilitate conversations. The LifeCourse model is wholistic and assists with coordinating efforts between multiple care providers, community partners, and resources. Caregivers, family members and friends are intentionally included in care to ensure they receive the necessary level of support to be able to care for their loved one.

ii. PPT/KFF Experience Interview Sub-study
   a. Once the patient consent forms have been signed, the LifeCourse team member will ask participants and identified KFFs to take part in both individual and family group interviews that will last up to approximately 30 minutes each. In addition to 30 minutes set aside for the consent process, the total time request will be approximately 1.5 hours.
   b. All KFFs taking part in interviews will be asked to complete a 7-item questionnaire about frequency of contact and caregiving. Non-enrolled KFFs will also be asked to complete a 9-item demographic questionnaire *(*see *Caregiver Questionnaire)*.

iii. Surveys (Intervention Group + Comparison Group)
   a. Once the patient consent forms have been signed, the LifeCourse staff will ask if the patient is willing to continue with the survey. If the patient would prefer to complete the survey independently due to time constraints, physical discomfort or other reasons it is acceptable for the LifeCourse staff to leave the patient survey and a pre-paid envelope to mail it back in. The LifeCourse team must receive the patient's completed baseline survey before the care guide has the initial visit with the patient. Please see *the Patient Data Collection Procedures* which includes survey confidentiality/participation, survey administration guidelines (including phone reminders and option to complete survey by phone) as well as patient and proxy surveys for more information.
   b. NOTE: For Intervention Group Participants: The patient participant will also be invited to provide contact information for those individuals they feel are their primary and secondary caregivers.
   c. If it is determined that the patient will be unable to complete any portion of the survey (due to dementia, illness, etc.), LifeCourse Staff will record the answers they provided and leave. Then LifeCourse Staff will contact the appropriate primary caregiver (LAR) and ask them if it would be appropriate for a proxy to complete a reduced version of the patient survey.
   d. The patient participant will be invited to complete the self-administered follow-up surveys with a LifeCourse Staff member present, by mail, or over the telephone every three months until the end of the study or death. LifeCourse Staff will consult with each other to determine if survey follow-up by mail/phone is appropriate. Then, the LifeCourse Staff will call the participant to determine if their preference is to complete the survey with a LifeCourse Staff member present, over the telephone, or to have the survey mailed to them. If the participant chooses to have the survey mailed to them, then LifeCourse Staff will confirm the participant's contact information and KFF information during the phone call.
   e. During follow-up, the patient will be asked if they would like to identify any additional primary or secondary caregivers.
   f. If the patient has a proxy (LAR), the proxy will assist the LifeCourse Staff in determining if the patient is able to complete some or a portion of the patient survey with or without assistance. If the patient is unable, the proxy may complete a Patient Survey by Proxy as well as their own survey.

iv. PPT Survey Feedback Interview Sub-study
   a. Once the PPT Survey Feedback Interview consent forms have been signed, the LifeCourse team member will ask PPTs if they are willing to do the survey and interview at the time of enrollment or if they prefer to set-up another meeting.
   b. If the PPT prefers a later date, the LifeCourse team member will schedule another meeting.

c. When it is time for the 3 month follow-up, a LifeCourse team member will call and schedule a time to meet and go through the survey and survey feedback interview.
d. During the PPT Survey Feedback Interview, the PPT will:
- Be asked to think out loud and share comments while they complete the survey, which will take 30 minutes to complete on average.
- Once the survey has been completed, the LifeCourse team member will use the questions on the PPT Survey Feedback Interview Script to conduct a semi-structured interview (approximately 1 hour)
- The survey administration and interview will be digitally recorded.

2. Primary Caregiver
   i. During the baseline data collection or subsequent follow-ups, the patient may identify primary caregivers. These caregivers will be invited to participate in the study and go through the recruitment/enrollment process (intervention or comparison group as appropriate). A primary caregiver may be present during the patient's enrollment and may enroll during the same meeting. (See KFF/CKFF 1.0 and KFF/CKFF 2.0 Enrollment in Section 11 above).
   ii. For the purposes of research, on the survey forms, we refer to the primary caregiver as a Key Family or Friend (KFF) 1.0., or comparison Key Family or Friend (CKFF) 1.0. It is LifeCourse's experience that caregivers more readily identified themselves as a key family member or friend rather than a formal caregiver.
      a. Intervention Group
         1. Primary caregivers may be invited to attend visits/meetings with the intervention patient and care guide. The primary caregiver participant may have contact with the LifeCourse care team a minimum of 1 hour a month. Additional phone call communications or visits may be necessary based on the patients' and the primary caregiver's goals and needs.
         2. PPT/KFF Experience Interview Sub-Study
            - KFF caregivers of identified participants will be invited to attend the semi-structured interview consent meeting. Once the patient and KFF consent forms have been signed, the LifeCourse researcher will ask participants and identified KFF caregivers to take part in both individual and family group interviews that will last up to approximately 30 minutes each. The total time request is approximately 1.5 hours
   iii. Surveys (Intervention Group & Comparison Group)
   The LifeCourse Staff will mail consent forms to any primary caregiver identified by the patient. Upon receiving a signed consent form, the LifeCourse Staff will invite the primary caregiver to complete a survey in person, over the telephone, or through mail (approximately 30 minutes) at baseline and follow-ups every 3 months until the end of the study or the death of the patient participant. The focus of the surveys is on the caregiver's quality of life and experience. If the patient dies, the main primary caregiver will be invited to complete a survey (QODD) about the patient's quality of life and experience during the last 7 days of their life in person, over the telephone or through mail.
3. Secondary Caregiver (Intervention Group & Comparison Group)
   i. NOTE: On 10/15/2014 or upon IRB approval, whichever comes first, all KFF 2.0 and CKFF 2.0 will be asked to re-consent as a 1.0. For those that do not agree, they will continue to complete the activities below until the end date listed on the consent form (intervention December 2014 and comparison December 2016).
   ii. During the baseline data collection or subsequent follow-ups, the patient may identify secondary caregivers. These caregivers will be invited to participate in the study and go through the recruitment/enrollment process. (See section 11 KFF/CKFF 1.0 and KFF/CKFF 2.0 Enrollment above)

iii. The LifeCourse Staff will mail consent forms to any secondary caregiver identified by the patient. Upon receiving a signed consent form, the research team will invite the secondary caregiver to complete a survey over the phone, through mail, or in person (approximately 15 minutes) at baseline and follow-ups every 6 months until the end of the study or the death of the patient participant). The focus of the surveys is on the caregiver's quality of life (PROMIS-29).

iv. NOTES:

a. KFF 2.0s do not participant in intervention activities, however; it is acceptable for a KFF 2.0 identified by an intervention group patient to participate in intervention activities if requested by the patient participant. If an individual transitions into a more involved role with the patient and LifeCourse, they will be invited to re-consent as a primary caregiver.

b. All mailed consents and surveys referenced above will use a modified-Dillman method. (See t section 16 B (ii) (Overview of Survey Mailings) above).

c. For the purposes of research, on the consent forms, we refer to the secondary caregiver as a Key Family or Friend (KFF) 2.0., or Comparison Key Family or Friend (CKFF 2.0). It is LifeCourse's experience that caregivers more readily identified themselves as a key family member or friend rather than a formal caregiver.

4. Overview of Survey Mailings

i. Survey mailings will follow a standardized Modified Dillman Method for both intervention and comparison group participants.

ii. A baseline survey will be sent after signed consent from KFF/CKFF is returned to research team. Subsequent surveys will be sent every three months following the patient consent date.

iii. If a KFF/CKFF is present while a patient is completing a survey, it is acceptable to have the KFF/CKFF complete their survey simultaneously or to give them the survey and an envelope to mail it back in.

iv. It is also acceptable to administer surveys over the telephone if this is the participant's preference.

a. Determine if the participant should receive key family member or friend version 1 or 2, attach label with participant's study id and mail appropriate packet.

b. Send Mailing 1 the day after receiving the signed consent form and log date into participant tracking database.

c. If no survey sent back to research team within 7 days of Mailing 1 send date, send Mailing 2 and log date into participant tracking database.

d. If no survey sent back to research team within 7 days of Mailing 2 send date, send Mailing 3 and log date into participant tracking database.

v. Phone Follow-up

a. If still no survey sent back to LifeCourse within 7 days of Mailing 3 send date, call participant until able to speak to them and encourage participant to mail in the survey or complete survey over the phone.

b. Use instructions from Patient Baseline Data Collection for information on how to administer the survey over the phone.

c. Call preferred contact number or cell if none is listed.

d. A maximum of 5 call attempts.

1. 2 follow-up phone calls in Week 1
2. 2 follow-up phone calls in Week 2
3. 1 follow-up phone call in Week 3

e. Leave a message on calls 1 (LM1), 3 (LM2) and 5 (LM2). Do not leave messages on calls 2 and 4.

f. Log each phone call into the participant tracking database, and indicate if and which message was left.

5. Care Team Members

i. During the hiring process for all LifeCourse care team members, the potential hire will be informed of the research component of the position. During the interview or subsequent job offer, it will be explained that the completion of all intervention and data collection activities is strongly encouraged, but is not a job requirement, for all care team members.

ii. During the first week of employment with the LifeCourse care team, a research team member will set up a meeting to attempt to enroll the care team member.

a. Intervention

- One of the key components of the LifeCourse model is a weekly Patient Story Review (PSR). During these meetings, all care team members (care guides, social worker, marriage and family therapist, nurse, pharmacist and chaplain) will discuss the patient's story, health record, goals and plan of care. The purpose of the PSR is to come to a collective understanding of the patient's goals, values, wishes, needs and determine how to best match the personal and professional strengths of the team members to address them. They will also complete LifeCourse specific flow sheets in the EHR to document patient goals, wishes and story.

b. Surveys

- Care team members will be invited to complete burn-out surveys (approximately 30 minutes) at baseline and with follow-up surveys every 3 months. In addition, they will be invited to participate in semi-structured group interviews and semi-structured individual interviews which will be digitally audio recorded and led by the research team. Group interviews will be held once per month, and each team member will be invited to attend 2 group interviews per quarter. Individual interviews will occur once per quarter and will be scheduled as convenient for each care team member.

c. Observational Sub-Study

- Care team members will be observed with regard to demographic (identity) and functional (education) diversity in an observational study about how they interact in their teamwork with patients. The purpose of the observations is general, and will not rely on systematic observation codes to collect data. Rather, the purpose will be to gain an understanding about team member roles, jurisdictions, strengths and challenges in working with patients and each other as a team. Observation times may include team meetings, team travel for various work-related purposes, and may coincide with team members working with patients and/or families, either directly in person or over the phone. The focus of observations will be on team member roles, jurisdictions, strengths and challenges in working with each other, and in working with patients and / or caregivers. Care team members can decline observation at any time and PPTs and KFFs will give permission for observation.

6. Somali Listening Circles Sub-Study

i. Participants will attend a listening circle conducted by Allina Health and New American Academy. It will take approximately two hours and will include:

a. Project introduction & listening circle guidelines (30 Minutes)
b. Large group dialogue focused on comparing and contrasting life in Somalia with life in Minnesota (focused on topics like Family Support, Social Support) (30 minutes)
c. Large group dialogue focusing on challenges navigating the healthcare system. This discussion will focus both on the barriers/problems (communication, community resources) and the potential solutions (1 hour)

ii. The discussion will be recorded so it can be transcribed and translated in to English later.

XVII. Statistical Methods

A. The LifeCourse research team is interested in developing a parsimonious model that comprehensively evaluates and describes how clinical measures, patient experience, quality of care, and quality of life are related. LifeCourse will develop a multivariable approach to longitudinally evaluate contributions from individual-level and organizational-level factors associated with our primary and secondary outcomes; including linear, logistic, and Cox regression techniques. Standard univariate statistics will be used to produce descriptive measures of the sample, Chronbach's alpha, Exploratory and Confirmatory factor analysis to assess reliability and validity of survey measures. Structural Equation Modeling will be employed to determine if the data fits a priori theoretical model(s). A combination of the approaches above will help to assess the effectiveness of the LifeCourse intervention.

B. Qualitative Research Methods : The qualitative data analysis team will employ standard qualitative analysis methods. An inductive team-based approach, will be used to conduct thematic content analysis of the qualitative data. A list of inductively derived initial topcodes will be developed by the research team and serve as the codebook for initial coding of all data. The initial codes will be developed and confirmed through a consensus process after team members read and individually code a subset of interviews. In order to ensure reliability in application of codes as coding proceeds, a second coder from the team will review the coding for each transcript. Differences in coding interpretation will be resolved by consensus of the coders and discussed at a coding team meeting to ensure shared understanding of the use of codes.

XVIII. Data Collection Methods

All of the following will be used for data collection:

- Data banks, archives, medical records
- Existing registry
- Filming, video, or voice recording of subjects
- Paper, in-person and phone administered surveys
- Group and individual in-person interviewing

XIX. Protection

The following provisions will be in place to protect the subject's privacy:

A. Ensuring that the fewest number of individuals possible are aware of the subject's participation in the research
B. Ensuring that only personnel listed in the Personnel Information section of the IRB Application are present during the consent process.
C. Ensuring that the research activities are performed in as private a place as possible and that is acceptable to the participant and family.
D. Obtaining consent in a private conference room or area.
E. All study data collected will be password-protected and stored on shared drives or machines that are located at Allina Commons/UMN in a secured and locked facility.
F. Field staff will only access study data on Allina/UMN-owned, secured laptops, and will never store data locally.
G. All paper surveys, field notes and audio recorders will be transported directly to Allina Commons and will be stored in a locked cabinet within the secure facility.
H. Data collection surveys will not include participant Protected Health Information (PHI).
I. Once analysis data sets have been built from the EHR, all PHI will be stripped from the final data set.
    - Transmitted quantitative data to the University of Minnesota will be first de-identified and then encrypted.
J. LifeCourse will rely on a unique study identifier. A unique study identifier will be assigned to each participant for questionnaire data collection. The key will be stored on the shared drive. The documents will be password

protected, and a limited number of staff will have access to the documents. All data will be destroyed 3 years after the study ends.

1. Certificate of Confidentiality
   i. To help us protect participant privacy, we have obtained a Certificate of Confidentiality from the NIH on 3/31/2014. The researchers can use this Certificate to legally refuse to disclose information that may identify participants in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify participants, except as explained below.
   ii. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).
   iii. Participants should understand that a Certificate of Confidentiality does not prevent them or a member of their family from voluntarily releasing information about themselves or their involvement in this research. If an insurer, employer, or other person obtains their written consent to receive research information, then the researchers may not use the Certificate to withhold that information.
   iv. The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of child abuse and neglect, or harm to self or others.

XX. Monitoring

There will not be an independent Data Safety Monitoring Board for this study. LifeCourse will have quality assurance procedures established; the clinical site managers will oversee care team staff, and the research manager will oversee secondary outcomes data collection.

XXI. HIPAA

The HIPAA Privacy Rule establishes the right of an individual to authorize a covered entity, such as a health plan, health care clearinghouse or health care provider, to use and disclose his/her Protected Health Information (PHI) for research purposes. The Privacy Rule defines the elements of individual information that comprise PHI and establishes the conditions under which PHI may be used or disclosed by covered entities for research purposes. It also includes provisions to allow an individual's PHI to be disclosed or used in research without the person's authorization (i.e., IRB Waiver of HIPAA Requirement Authorization).

A. LifeCourse includes the use of PHI including the use of PHI from a covered entity outside of Allina. Study staff is working closely with Walker-Methodist and Augustana staff to coordinate these efforts and ensure the appropriate release forms are signed to cover both internal and external facilities including Data Usage, etc. Data from medical records will be used along with GSM (Geriatric Services of Minnesota) data to capture the whole patient story.
B. LifeCourse includes the use of a "limited data set" and has a data use agreement in place with the entity from which the data will be obtained as required by HIPAA.
C. The following identifiers will be recorded in association with the research data:
   1. Name
   2. Address (street, city, county, ZIP code)
   3. All elements of dates (except year) related to an individual (e.g., birth date, admission date, discharge date, etc.)
   4. Telephone and/or fax number
   5. Email address
   6. Medical record number(s)
   7. Health plan beneficiary number(s)

8. Account number(s)
9. Full face photographic images (and any comparable images)

D. Research data that contain subject identifiers will be disclosed to University of Minnesota investigators/staff and other professional consultants. This disclosure is included on the HIPAA Authorization signed by participants. All UMN team members have received CITI training and are aware of the PHI regulations of improper use and disclosure.

E. HIPAA Waiver/Alteration

1. PPTs
   - i. LifeCourse requests a HIPAA Waiver to enter potential patients' charts prior to enrollment in order to assess eligibility.
   - ii. Staff at partner sites will provide a list of potential patients based on the eligibility criteria.
   - iii. Later, the LifeCourse team will review the patient's EHR to determine if the patient is indeed eligible based on the eligibility criteria.
   - iv. Information may be reviewed by a team of LifeCourse clinicians, the principal investigator and a co-investigator. All individuals have received CITI training and are aware of the PHI regulations of improper use and disclosure.
   - v. LifeCourse needs a method to ensure potential patients are eligible for the study before approaching them and their families. It is not logistically practical to ask every patient in-person in order to determine eligibility and could cause emotional distress to ask patient's about their prognosis.
2. Care Team Observational Sub-Study
   - i. LifeCourse requests a HIPAA Waiver for care team observational research. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context.
   - ii. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
   - iii. The research could not practicably be carried out without the waiver or alteration; and
   - iv. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
   - v. Private or identifying data about care team members themselves will not be collected or recorded during observations.
   - vi. Observation research team member will discontinue observing if it is an expressed wish of a patient or a family member not to be part of the observations of teamwork.
   - vii. Data will not be used for performance review purposes.

XXII. Collaborative Research

Faculty members and staff from the University of Minnesota's Division of Health Policy & Management and other professional consultants are part of the research team for this initiative. These research experts are joining the internal research team to complement the expertise held by Allina investigators and to offer additional third-party evaluation expertise and objective feedback to the internal team. They will have access to and complete analysis of quantitative (See XXI.D.) and qualitative data. Team members will also participate in qualitative data collection efforts. The University of Minnesota's IRB will also review this study.

XXIII. Sponsor

Sponsor Name: Robina Foundation
Contact Name: Penny Hunt
Contact Title: Executive Director

Mailing Address: 80 South 8th St, 4900 IDS Center, Minneapolis, MN 55402
Contact's Phone Number: 612-333-2313
Contact's Email: info@RobinaFoundation.org
Award Amount: 9,666,454
Start Date: 01/01/2012
End Date: 12/31/2018

XXIV. Conflict of Interest

There is no conflict of interest by any investigator or staff member associated with LifeCourse. The Foundation funding this initiative has a vested interest in inducing transformative change in the healthcare delivery organization, not a vested interest in the outcome of a particular study. The outcome of the study will have no bearing on the professional success or the follow-up professional activities of any team members. The Principal Investigator team will meet weekly and will include conflicts of interest as a standing agenda item. In addition, the National Steering Committee for the project, comprised of external experts in this field, will advise and evaluate conflicts of interest as well. Finally, the organization's Chief Clinical Officer, who does not have a financial or professional stake in the external funding organization, will assume accountability for performance.

A. The research project does not involve a drug, device, or biological invented by research personnel or immediate family members.
B. The research project sponsor has not paid research personnel or immediate family members for consulting or advising.
C. Research personnel and immediate family members will not receive special compensation or increased compensation if the research generates a favorable outcome.
D. Research personnel and immediate family members will not receive any money, gift, or anything of monetary value above and beyond the actual costs of enrollment, conduct of the research, and reporting on the results, including, but not limited to, referral fees, recruitment bonuses, and an enrollment bonus for reaching an accrual goal or similar types of payments.
E. Research personnel and immediate family members do not hold any intellectual property rights or interests (e.g., patents, copyrights, licensing agreements) related to the research project or the sponsoring company.

XXV. Allina Health

2925 Chicago Avenue
Minneapolis, MN 55407

A. Qualifications of Investigators

Eric Anderson, Principal Investigator

Dr. Anderson has been involved in end-of-life interdisciplinary care for nearly 30 years. This has included helping start a rural hospice research project in the pre-Medicare Hospice Benefit days, serving as a hospice medical director since 1986, and full time palliative medicine since 2001. As Allina's Inpatient Palliative Care Medical Director, Dr. Anderson helped develop inpatient Palliative Care services at five metro hospitals serving the 19-county area of eastern Minnesota. He continues to see inpatients at United Hospital in St. Paul. Overall, the integrated Allina palliative care, home care, and hospice research projects have a combined daily census of 1,500. In addition to his clinical practice, Dr. Anderson teaches interdisciplinary palliative care to diverse groups of students at the University of Minnesota School of Health Sciences Center for Spirituality and Healing. Dr. Anderson received his medical training at University of California San Diego and the University of Minnesota. He pursued additional study with Dr. Robert Twycross and the Harvard Program for Palliative Care Education and Practice. He is board certified in both Internal Medicine and Palliative Medicine. Dr. Anderson will devote 60% of his time to the project. He will serve as the clinical lead for the Principal Investigator team and will have authority and accountability around partnerships with primary care and specialty providers, development of the supportive care plan, design of the assessment and reassessment visits and associated clinical measurements, patient population selection, and clinical leadership for Supportive Care Case Managers.

Heather Britt, Research Co-Investigator

Heather Britt is a behavioral epidemiologist, strategic thinker and implementer, and catalyst for research and innovation at Allina. She is the Director of the Division of Applied Research. Dr. Britt was an integral part of the inception and development of the Center for Healthcare Innovation broadly, as well as a key participant in the initial design teams that launched the Heart of New Ulm and the Backyard Initiative. In her current role, Dr. Britt facilitates research agendas and collaboration conversations, participates actively in research teams, and seeks to grow and position the unit appropriately within the organization. She works across all clinical communities, but has a special interest in the work done by and the potential inherent within the Clinic and Community Division. She has a vested interest in the redesign of primary care and the way in which large systems move towards micro change in a variety of ways. Prior to joining the Center for Healthcare Innovation, Dr. Britt was the Manager of Survey Measurement within the Measurement and Analysis department at Allina. In that role, she facilitated and implemented patient experience and other survey efforts necessary for the organization. Before Allina, Dr. Britt was a Prevention Research Scientist with the Minnesota Department of Education's Safe and Healthy Learners team (the "Prevention Unit"), following time as a Researcher at the Urban Coalition, a community based organization focused on research and advocacy with low-income communities and communities of color. Dr. Britt holds a BS in biology from Cornell University, an MPH in health behavior and health from the University of North Carolina at Chapel Hill, and a PhD in epidemiology from the University of Minnesota.

Sandra Schellinger, Care Model Co-Investigator

Sandy Schellinger has over 25 years of nursing experience focusing on the care of patients and families with chronic progressive illness. Her nursing degrees were obtained at the University of Minnesota and at Metropolitan State University for her Masters of Nursing Science. Sandy is AANP board certified as an Adult Nurse Practitioner. Currently, Sandy is the research project development manager for advance

care planning for the Allina Health System. Sandy provides hospice and palliative care consult for Allina patients and families and is also a National Faculty Member and Instructor for the Respecting Choices: First Steps and Disease Specific Advance Care Planning Facilitator training. Ms. Schellinger will devote 75% of her time to the project in the design period and 50% of her time to the project during enrollment, implementation and analysis. She will serve as the operational lead for the Principal Investigator team and will have authority and accountability around hiring of Supportive Care Case Managers, staff and care team training and development, creation and implementation of electronic health record tools, and project implementation.