CARING PILOT GRANTS

- Nine awards will be funded during the grant period
- The goal is for this internal pilot funding to serve as a foundation/model upon which future investigators will design and initiate research projects leading to externally funded awards and foster research collaborations across cancer centers.
- Each application must be accompanied by a letter of support from the institution of the investigator, and must discuss explicitly how CARG infrastructure resources (e.g. data, Core support) are needed to facilitate the next steps for the research.

<table>
<thead>
<tr>
<th>Pilot Grant</th>
<th>Year</th>
<th>Grant Support</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pilot Grant 1</td>
<td>2</td>
<td>$15,000</td>
<td>9/1/19-8/31/20</td>
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<tr>
<td>Pilot Grant 2</td>
<td>3</td>
<td>$20,000</td>
<td>2020-2021</td>
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<td>Pilot Grant 3</td>
<td>3</td>
<td>$20,000</td>
<td>2020-2021</td>
</tr>
<tr>
<td>Pilot Grant 4</td>
<td>3</td>
<td>$20,000</td>
<td>2021-2022</td>
</tr>
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<td>2021-2022</td>
</tr>
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<td>Pilot Grant 6</td>
<td>4</td>
<td>$20,000</td>
<td>2021-2022</td>
</tr>
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<td>Pilot Grant 7</td>
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<td>$20,000</td>
<td>2021-2022</td>
</tr>
<tr>
<td>Pilot Grant 8</td>
<td>5</td>
<td>$20,000</td>
<td>2022-2023</td>
</tr>
<tr>
<td>Pilot Grant 9</td>
<td>5</td>
<td>$20,000</td>
<td>2022-2023</td>
</tr>
</tbody>
</table>
CARinG Pilot Grant Process

RFA
- Request for Application Announcement – July 2020

LOI
- Letter of Intent Survey – August 2020
  - 19 LOIs submitted - 3 international LOIs = 16 LOIs Total

Application
- Pilot Grant Application – October 1, 2020
  - 6 applications received

Review
- Pilot Grant Review Session – October 30, 2020
  - 17 reviewers – first, secondary, statistical, patient advocate reviewers

Final Decision
- CARinG Advisory Board Meeting – November 20, 2020
## 2020 PILOT GRANT Awardees!

<table>
<thead>
<tr>
<th>Pilot Grant</th>
<th>Institution</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Melissa Loh</td>
<td>University of Rochester</td>
<td>A Telehealth Advance Care Planning Intervention for Older Patients with Acute Myeloid Leukemia and Myelodysplastic Syndrome</td>
</tr>
<tr>
<td>Katherine Clifton</td>
<td>Washington University in St. Louis</td>
<td>Evaluation of Loneliness and Social Isolation in Older Adults with Cancer</td>
</tr>
<tr>
<td>Sarah Wall</td>
<td>Ohio State University</td>
<td>Geriatric assessment with management for older adult hematopoietic cell transplant candidates</td>
</tr>
</tbody>
</table>
2020 CARinG Pilot Grant - List of Reviewers

- Gregory Abel
- Shabbir Alibhai
- Beverly Canin
- Eva Culakova
- Clark Dumontier
- Tomma Hargraves
- Chuck O'Shea
- Marianne Razavi
- John Simmons
- Enrique Soto
- Ishwaria Subbiah
- Can-Lan Sun
- Virginia Sun
- Mary Whitehead
- Melisa Wong
- Huiwen Xu
PILOT GRANT PRESENTATIONS
Development of a Personalized Discussion Prioritization Tool for Older Adults Considering Adjuvant Chemotherapy for Breast Cancer

Principal Investigators

Allison Magnuson, DO, MS
University of Rochester
Rochester, NY

Mina S. Sedrak, MD, MS
City of Hope,
Duarte, CA
Rationale

• Balancing risks and benefits of adjuvant chemotherapy for older adults is complex

• Tools are needed to help patients understand and prioritize their preferences, facilitate discussions with their oncologists

• Incorporating patient preferences to personalize oncology treatment decisions can improve outcomes
Gathering Patient-Specific Risk Predictors

Development and Validation of a Risk Tool for Predicting Severe Toxicity in Older Adults Receiving Chemotherapy for Early-Stage Breast Cancer

Allison Magnuson, DO; Mina S. Sedrak, MD; Cary P. Gross, MD; William P. Tew, MD; Heidi D. Klepin, MD; Tanya M. Wides, MD; Hyman B. Muss, MD; Efraim Dolan, MD; Rachel A. Freedman, MD; Tracey O’Connor, MD; William Dale, MD; Harvey J. Cohen, MD; Vani Katheria, MS; Anait Arsenyan, MS; Abrahm Levi, BS; Heeyoung Kim, MPH; Supriya Mohile, MD; Atri Hurria, MD; and Can-Lan Sun, PhD.
Gathering Patient-Specific Risk Predictors

• Relative Dose Intensity (RDI)
  
  • Relative dose intensity (RDI) = \( \frac{\text{Delivered Chemo Dose Intensity}}{\text{Planned Chemo Dose Intensity}} \)

  • Patients with early stage breast cancer treated with a low (<85%) RDI of adjuvant chemo have inferior outcomes

  • Data on the incidence, risk factors, and significance of low RDI in older women are inconsistent and limited

Hryniuk JCO 1984
Bonadonna NEJM 1995
Lyman JCO 2003
Ladwa Clin Breast Ca 2018
Wildiers Crit Rev Onc 2011
Pilot Study

The overall objective of this pilot proposal is to develop and test a technology-mediated Discussion Prioritization Tool (DPT) for older adults with breast cancer considering adjuvant chemotherapy.

• **Aim 1:** Conduct a secondary analysis of patients enrolled on NCT01472094 to determine the association between clinical factors and reduced RDI of a prescribed chemotherapy regimen.

• **Aim 2:** Develop a DPT to include personalized information regarding risk of chemotherapy toxicity and risk of reduced RDI, and evaluate the usability of the DPT in ten older adults considering adjuvant chemotherapy for breast cancer.
Aim 1 Methods

**Sociodemographic Variables:**
1) Patient Age
2) Race/Ethnicity
3) Education
4) Marital Status
5) Living Companion
6) Employment

**Tumor & Treatment Variables:**
1) Breast Cancer Stage
   - Disease Subtype
2) Planned Chemotherapy Intensity
   - Drugs, Dose, Schedule, Duration
   - WBC Growth Factors
3) Treatment Setting
   - Neoadjuvant
   - Adjuvant
4) Radiation Prior to Chemotherapy
5) Prior Chemotherapy

**Laboratory Variables:** *(Captured in Routine Blood Work)*
1) Renal Function
   - Creatinine Clearance
2) Hepatic Function
   - Liver Function Tests
3) Hematologic Function
   - WBC
   - Hemoglobin

**Geriatric Assessment Variables:**
1) Functional Status
2) Comorbidity
3) Cognition
4) Psychological State
5) Social Activity and Support
6) Nutritional Status

**DECREASED RELATIVE DOSE INTENSITY (RDI < 85%)**
RDI = ratio of actual dose delivered to the intended dose

**PRIMARY OUTCOME**
Aim 1 Results: Incidence

22% = RDI <85
Aim 1 Results

Multivariable odds ratios for baseline characteristics in relation to low RDI among older women with HER2 negative EBC

<table>
<thead>
<tr>
<th>OR (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age, years</strong></td>
<td></td>
</tr>
<tr>
<td>65-75</td>
<td>2.57 (1.12-5.91)</td>
</tr>
<tr>
<td>76+</td>
<td></td>
</tr>
<tr>
<td><strong>AJCC Stage</strong></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>1.72 (0.83-3.56)</td>
</tr>
<tr>
<td>II/III</td>
<td></td>
</tr>
<tr>
<td><strong>Chemotherapy Regimen</strong></td>
<td></td>
</tr>
<tr>
<td>TC</td>
<td>3.47 (1.71-7.05)</td>
</tr>
<tr>
<td>Anthracycline-based/CMF</td>
<td></td>
</tr>
<tr>
<td><strong>Pre-treatment organ function</strong></td>
<td></td>
</tr>
<tr>
<td>Normal liver function tests</td>
<td>1.62 (0.67-3.88)</td>
</tr>
<tr>
<td>Abnormal liver function tests</td>
<td></td>
</tr>
<tr>
<td>Kidney, GFR &gt;60</td>
<td>1.46 (0.77-2.78)</td>
</tr>
<tr>
<td>Kidney, GFR &lt;=60</td>
<td></td>
</tr>
<tr>
<td><strong>Performance Status</strong></td>
<td></td>
</tr>
<tr>
<td>Physician-rated KPS &gt;=90</td>
<td>4.32 (1.98-9.42)</td>
</tr>
<tr>
<td>Physician-rated KPS &lt;90</td>
<td></td>
</tr>
<tr>
<td><strong>Comorbidity</strong></td>
<td></td>
</tr>
<tr>
<td>Cardiovascular disease, No</td>
<td>2.27 (1.02-5.05)</td>
</tr>
<tr>
<td>Cardiovascular disease, Yes</td>
<td></td>
</tr>
</tbody>
</table>

Survival Probability (%)

Days after Starting Chemotherapy

- RDI >=85%
- RDI <85%
Conjoint Analysis (CA)

- CA is a method to elicit decision-making preferences
  - assess the relative importance that patients place on different aspects of care by asking patients to make a series of trade-offs between competing options
  - helps patients become more aware of options for discussion, while revealing their priorities to their physicians
  - decision-making elements should be tailored the target population

- Preliminary data: use of CA to develop a decision tool
  - Qualitative data from older adults with breast cancer considering adjuvant chemotherapy was collected at Rochester to inform the attributes levels (aspects) that are important in decision making
  - These themes were used to develop a Discussion Prioritization Tool (DPT), a web-based platform

Aim 2 Methods
Attributes

• Attributes identified in qualitative work

  • Benefit of therapy
    • Recurrence risk
    • Survival
    • Worry/distress

  • Hardship
    • Risk of hospitalization
    • Burden on support system

• Side effects of therapy
  • Fatigue
  • Falls/balance
  • Cognition
  • Risk of treatment toxicity

• Quality of life
Aim 2:

Results

**Treatment 1**

The treatment would:

- Decrease my worry about the cancer

But the treatment may also cause me to:

- Feel more tired and limit my day-to-day activities

and

- Need more help from others for day-to-day activities

During the treatment my Quality of Life would be:

- Relatively unchanged

**Treatment 2**

The treatment would:

- Decrease my worry about the cancer

But the treatment may also cause me to:

- Have changes in my thinking that limit my day-to-day abilities

and

- Be hospitalized due to side effects

During the treatment my Quality of Life would be:

- Significantly worse than it is right now

**Treatment 3**

The treatment would:

- Increase the number of years that I am likely to live

But the treatment may also cause me to:

- Have changes in my thinking that limit my day-to-day abilities

and

- Be hospitalized due to side effects

During the treatment my Quality of Life would be:

- Relatively unchanged
Aim 2: Results

- Benefits
- Risks
- Hardships
- Quality of Life

Relative importance of each aspect of treatment

Weights for Risks
- Feel more tired
- Feel more off balance
- Changes in my thinking
- Significant side effect
Conclusions

• In older women with early breast cancer treated with neo/adjuvant chemotherapy, 1 in 5 received RDI <85%, which was related to inferior survival.

  • Factors associated with suboptimal RDI were identified prior to initiation of chemotherapy

• We have developed a discussion prioritization tool, incorporating personalized information about treatment priorities and risk factors for treatment toxicity and reduced RDI.
Thank you!

Questions/Feedback?
Evaluation of Loneliness and Social Isolation in Older Adults with Cancer

2020 CARinG Pilot Grant Award

Katherine Clifton, MD
January 29, 2021
Background

- **Loneliness:** subjective feeling of separation from others
  - Risk factor for depressive symptoms, functional decline and mortality¹
- **Social Isolation:** absence of interpersonal interactions
  - Patients with cancer who experience social isolation have worse outcomes²
- **February 2020: NASEM Consensus Study Report³**
  - Identify, prevent, and mitigate the adverse health impacts of social isolation and loneliness
- **COVID-19 Pandemic:** Previous in-person interventions to combat social isolation and loneliness no longer feasible
- **ESMO May 2020:** Prolonged isolation may be detrimental for older adults with cancer⁴
- Stay-at-home orders associated with health anxiety, financial worry, and loneliness⁵
- High rates of stress and symptom burden during pandemic in cancer patients⁶

**Aims**

- **AIM 1:** Assess loneliness and social isolation during the COVID-19 pandemic in older adults with cancer.

- **AIM 2:** Adapt an intervention to address loneliness in older adults with cancer during the COVID-19 pandemic for the future.
Methods

• **Design:**
  • cross-sectional study
  • surveys completed by telephone and one in-person assessment

• **Sample size:**
  • 100 participants

• **Inclusion Criteria:**
  • Age ≥ 65
  • Receiving active systemic treatment
  • Anticipated to receive ongoing care at Siteman Cancer Center

• **Exclusion Criteria:**
  • Anticipated duration of cancer treatment < 3 months
  • Unable to participate in a telephone interview due to significant hearing impairments or lack of telephone access
  • Dementia diagnosis
Methods

CARG Cores:

- **Analytics Core:**
  - advisory role for statistical analysis

- **SCOREBoard:**
  - feedback on the development of an intervention to combat loneliness in older adults

- **Communication Core:**
  - disseminate findings in publication form

---

<table>
<thead>
<tr>
<th>Measures</th>
<th>Number of Items</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Quantitative</strong></td>
<td></td>
</tr>
<tr>
<td>G-8 geriatric screening tool</td>
<td>8</td>
</tr>
<tr>
<td>PROMIS Bank v2.0 Emotional support – Short Form</td>
<td>4</td>
</tr>
<tr>
<td>PROMIS Bank v2.0 Social Isolation – Short Form</td>
<td>8</td>
</tr>
<tr>
<td>UCLA loneliness scale</td>
<td>20</td>
</tr>
<tr>
<td>Medical Outcomes Study (MOS) social support survey</td>
<td>12</td>
</tr>
<tr>
<td>Short Blessed Test</td>
<td>6</td>
</tr>
<tr>
<td>Timed up and go test*</td>
<td>1</td>
</tr>
<tr>
<td>Trails B test*</td>
<td>1</td>
</tr>
<tr>
<td>Medication review*</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Qualitative</strong></td>
<td></td>
</tr>
<tr>
<td>Open-ended questions to better understand the impact of the COVID-19 pandemic on loneliness and gain insights for planning of a potential future intervention</td>
<td>4</td>
</tr>
</tbody>
</table>

* In-person assessment
Conclusions

• Social isolation and loneliness were prevalent in older adults prior to the COVID-19 pandemic
  • Assessing these domains in older adults with cancer during the pandemic is important

• Innovation:
  • Telephone interviews eliminate potential patient exposure to COVID-19 and allows recruitment while maintaining physical distancing.
  • Adapting alternatives to in-person meetings for older adults is innovative beyond the pandemic as older adults may have difficulty with transportation and mobility.
  • Use of community stakeholders, including patient advocates, who can bring unique perspectives to help adapt an effective intervention to combat loneliness

• Next Steps:
  • Implementation of intervention to combat loneliness and social isolation
Thank you!

• Mentor:
  • Dr. Tanya Wildes

• CARG Leadership Team
  • Dr. William Dale
  • Dr. Heidi Klepin
  • Dr. Supriya Mohile

• Questions?
  • K.Clifton@wustl.edu
A Telehealth Advanced Care Planning Intervention for Older Patients with Acute Myeloid Leukemia and Myelodysplastic Syndrome

Melissa (Kah Poh) Loh, MBBCh BAO

Senior Instructor

Division of Hematology/Oncology

@MelissaLoh21
End-of-Life Experience in AML & MDS

Compared to solid tumors:

- More likely to die in the hospital
- Receive emergency department care or hospitalization
- Receive aggressive care including chemotherapy at the EOL
- Incur greater costs over this time frame
- Less likely to be enrolled in hospice care


@MelissaLoh21
End-of-Life Metrics in AML & MDS

- 36% completed MOLST >30 days prior to death (vs. 51% ≤30 days before death and 13% never)

- Early completion had decreased
  - Inpatient death
  - Transfusion (last 7 days)
  - Chemo admin (last 14 days)
  - LST use
  - Hospitalization
  - ICU admission

- Early completion had higher hospice use
Serious Illness Care Program

Tools
- Serious Illness Conversation Guide
- Patient preparation materials
- Family Communication Guide

Education
- Train Providers
  - Provider virtual training sessions

Systems Change
- Patient Screening
- Prepare Patient
- Conversation using the Guide
- Documentation & communication
- Patient & Family Resources

Telehealth visit

@MelissaLoh21
Goal, Aims, and Study Design

**Aim 1:** To incorporate telehealth into an evidence-based ACP intervention that is adapted for older patients suffering from AML and MDS utilizing qualitative interviews with patients, their caregivers, and oncology providers

  Study Design: Qualitative Study

**Aim 2:** To assess the feasibility and usability of the adapted telehealth-delivered ACP intervention in a single-arm pilot study of 20 older patients with AML and MDS.

  Study Design: Single-arm pilot study

**Long-term goal:** To improve ACP access, patient-reported outcomes, and EOL care in older patients with AML and MDS via a telehealth-delivered ACP intervention
Inclusion Criteria

Patients (N=5-10)
1. Age ≥60 years
2. AML or MDS (Newly diagnosed for Aim 2)
3. Able to provide informed consent

Caregivers (N=5-10)
Selected by patient

Oncology providers (Pall care providers for Aim 1)
1. Oncologists, advanced care practitioners (APPs), and nurses (N=5-10 each)
2. Cared for at least one patient age ≥70 years with AML/MDS in the past year
3. Wilmot Cancer Institute and its affiliated community centers
Themes

- EOL care as it relates to older patients with AML and MDS
- Barriers and challenges to ACP and MOLST completion
- Potential solutions and ideas
- Experience with telehealth interventions
- Support and concerns for the proposed intervention
- Components of the intervention that are important to them
- Opinions about the intervention (e.g., delivery, format)
Study Procedures and Measures (Aim 2)

• Providers will undergo training prior to enrolling patients

• Measures: Enrollment and retention rates, usability, EOL indications, other PROs
OTIS: Optimization of older adult allogeneic hematopoietic cell Transplant candidates to Improve Survival

Sarah Wall, MD MPH
CARinG Conference 2021
January 29, 2021
“Immune System Transplant”

- **Rationale:**
  - Cancer cell immortality due to immune system evasion
  - Replace ineffective immune system with healthy donor

- **Basics:**
  - Only *potentially* curative therapy for many blood cancers
  - Primary cause of death after transplant = relapse
  - *Definitely* toxic!
    - Short and long-term complications
  - Quality of life is *unquestionably* impacted
    - At least 3-6 months for all recipients
    - Anticipate lifelong effects

---

From Leukemia & Lymphoma Society, © Fran Millner 2018
Background – Is allo-HCT too toxic for older adults?

- 46% of patients > 50 years old with AML in CR were not referred for transplant consult
  - 30% “too ill”, 46% reason unknown

- Non-relapse mortality similar across age groups
- 1-year NRM 18%-30% across all groups
Mini Nutritional Assessment: Normal nutrition associated with improved OS compared to malnourished
Solution – Prioritize and Standardize

- Prioritize
  - Recruitment is key
  - All patients with transplant-eligible diagnosis

- Standardize the Individualization
  - Apply same GA to all patients
  - Provide prescription for all domains
  - Solicit feedback routinely
# Geriatric Assessment

<table>
<thead>
<tr>
<th>Domain</th>
<th>Tools</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical Function</td>
<td>6-minute walk test (6MWT)</td>
</tr>
<tr>
<td></td>
<td>Short physical performance battery (SPPB)</td>
</tr>
<tr>
<td>Nutrition</td>
<td>Mini nutritional assessment (MNA)</td>
</tr>
<tr>
<td></td>
<td>Weight &amp; BMI</td>
</tr>
<tr>
<td></td>
<td>Albumin</td>
</tr>
<tr>
<td>Medication Adherence</td>
<td>Pharmacist-led medication review (BEERS criteria, adherence, patient knowledge)</td>
</tr>
<tr>
<td>Cognition</td>
<td>Montreal cognitive assessment (MoCA)</td>
</tr>
<tr>
<td>Mental Health</td>
<td>PHQ-9 and GAD-7</td>
</tr>
<tr>
<td></td>
<td>Transplant evaluation rating scale (TERS)</td>
</tr>
</tbody>
</table>
## Geriatric Optimization! Prescription

<table>
<thead>
<tr>
<th>Domain</th>
<th>GO! Prescription Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Physical Function</strong></td>
<td>Referral for outpatient physical therapy if warranted</td>
</tr>
<tr>
<td></td>
<td>Self-administered activity with specified frequency</td>
</tr>
<tr>
<td><strong>Nutrition</strong></td>
<td>Add supplemental nutrition with specified frequency if warranted</td>
</tr>
<tr>
<td></td>
<td>Caloric intake or meal frequency task</td>
</tr>
<tr>
<td></td>
<td>Daily fluid intake task</td>
</tr>
<tr>
<td><strong>Medication Adherence</strong></td>
<td>Adherence improvement task(s)</td>
</tr>
<tr>
<td></td>
<td>Referral for discussion of additional pharmacotherapy or de-prescribing</td>
</tr>
<tr>
<td><strong>Cognition</strong></td>
<td>If MOCA ≤ 20, referral for dementia evaluation with neuropsychological testing battery</td>
</tr>
<tr>
<td></td>
<td>If MOCA 20-25, referral to transplant social worker for evaluation of caregiver plan and additional education</td>
</tr>
<tr>
<td></td>
<td>If MOCA ≥ 26, no intervention warranted</td>
</tr>
<tr>
<td><strong>Mental Health</strong></td>
<td>If PHQ or GAD &gt;15, discuss pharmacologic intervention and referral to psychosocial oncology</td>
</tr>
<tr>
<td></td>
<td>If PHQ or GAD 5-14, discuss referral to psychosocial oncology</td>
</tr>
<tr>
<td></td>
<td>If PHQ of GAD &lt;5, coping with transplant tip sheet</td>
</tr>
</tbody>
</table>
Thank You

To learn more about Ohio State’s cancer program, please visit cancer.osu.edu or follow us in social media: