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

| Pilot Grant | <u>Year</u> | Grant Support | <u>Timeframe</u> |
|---------------|-------------|---------------|------------------|
| Pilot Grant I | 2 | \$15,000 | 9/1/19-8/31/20 |
| Pilot Grant 2 | 3 | \$20,000 | 2020-2021 |
| Pilot Grant 3 | 3 | \$20,000 | 2020-2021 |
| Pilot Grant 4 | 3 | \$20,000 | 2021-2022 |
| Pilot Grant 5 | 4 | \$20,000 | 2021-2022 |
| Pilot Grant 6 | 4 | \$20,000 | 2021-2022 |
| Pilot Grant 7 | 4 | \$20,000 | 2021-2022 |
| Pilot Grant 8 | 5 | \$20,000 | 2022-2023 |
| Pilot Grant 9 | 5 | \$20,000 | 2022-2023 |





CARinG Pilot Grant Process





2020 PILOT GRANT AWARDEES!

| Pilot Grant | Institution | Title |
|-------------------|------------------------------------|---|
| Melissa Loh | University of Rochester | A Telehealth Advance Care Planning Intervention for Older Patients with Acute Myeloid Leukemia and Myelodysplastic Syndrome |
| Katherine Clifton | Washington University in St. Louis | Evaluation of Loneliness and Social Isolation in Older Adults with Cancer |
| Sarah Wall | Ohio State University | Geriatric assessment with management for older adult hematopoietic cell transplant candidates |

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



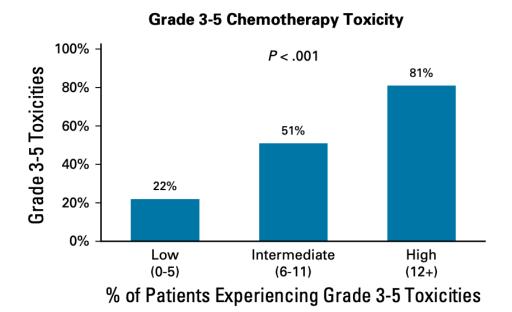
 Tools are needed to help patients understand and prioritize their preferences, facilitate discussions with their oncologists

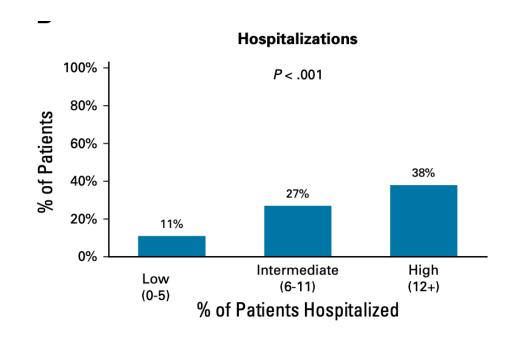
 Incorporating patient preferences to personalize oncology treatment decisions can improve outcomes

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, DO¹; Mina S. Sedrak, MD²; Cary P. Gross, MD³; William P. Tew, MD⁴; Heidi D. Klepin, MD⁵; Tanya M. Wildes, MD⁶; Hyman B. Muss, MD⁷; Efrat Dotan, MD®; Rachel A. Freedman, MD⁰; Tracey O'Connor, MD¹⁰; William Dale, MD²; Harvey J. Cohen, MD¹¹; Vani Katheria, MS²; Anait Arsenyan, MS²; Abrahm Levi, BS²; Heeyoung Kim, MPH²; Supriya Mohile, MD¹; Arti Hurria, MD²¬†; and Can-Lan Sun. PhD²





Gathering Patient-Specific Risk Predictors

- Relative Dose Intensity (RDI)
 - Relative dose intensity (RDI) = <u>Delivered Chemo Dose Intensity</u>
 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

Pilot Study

The <u>overall objective</u> 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

Laboratory Variables:

(Captured in Routine Blood Work)

- 1) Renal Function
 - -Creatinine Clearance
- 2) Hepatic Function
 - -Liver Function Tests
- 3) Hematologic Function
 - -WBC
 - -Hemoglobin

Tumor & Treatment Variables:

- 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

DECREASED RELATIVE DOSE INTENSITY (RDI<85%)

RDI = ratio of actual dose delivered to the intended dose

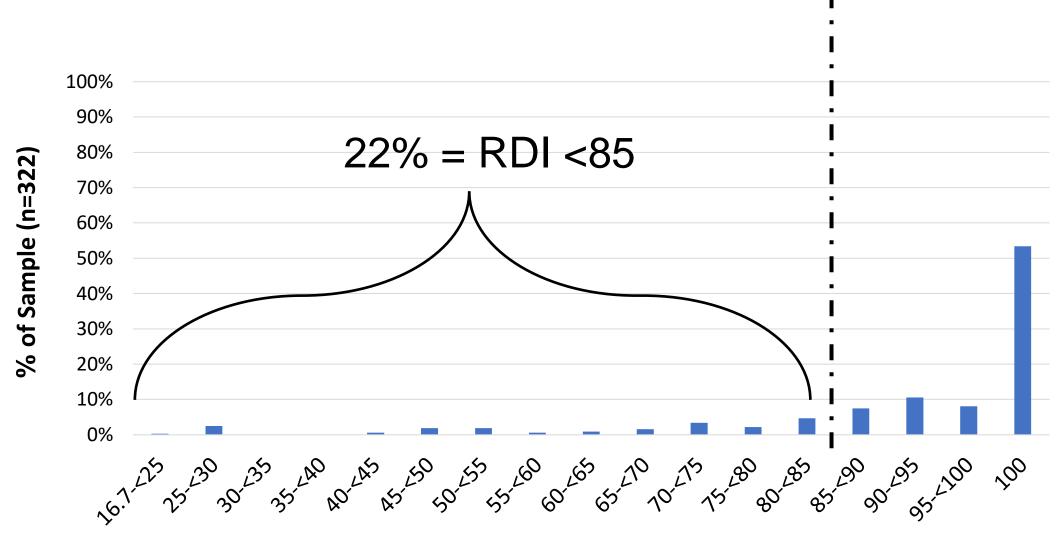


Geriatric Assessment Variables:

- 1) Functional Status
- 2) Comorbidity
- 3) Cognition
- 4) Psychological State
- 5) Social Activity and Support
- 6) Nutritional Status

PRIMARY OUTCOME

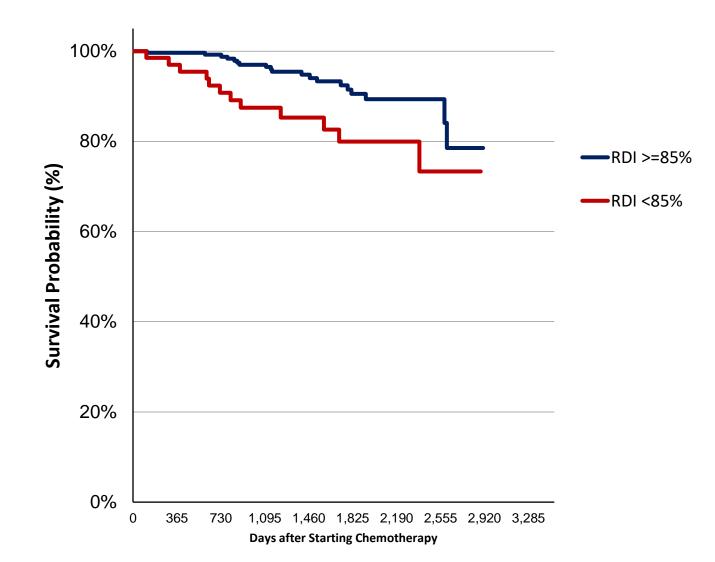
Aim 1 Results: Incidence



Aim 1 Results

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

| | OR (95% CI) | p-value |
|-------------------------------|------------------|----------|
| Age, years, | | |
| 65-75 | | |
| 76+ | 2.57 (1.12-5.91) | 0.03 * |
| AJCC Stage | | |
| 1 | | |
| 11/111 | 1.72 (0.83-3.56) | 0.15 |
| Chemotherapy Regimen | | |
| TC | | |
| Anthracycline-based/CMF | 3.47 (1.71-7.05) | 0.001 * |
| Pre-treatment organ function | | |
| Normal liver function tests | | |
| Abnormal liver function tests | 1.62 (0.67-3.88) | 0.28 |
| Kidney, GFR >60 | | |
| Kidney, GFR <=60 | 1.46 (0.77-2.78) | 0.25 |
| Performance Status | | |
| Physician-rated KPS >=90 | | |
| Physician-rated KPS <90 | 4.32 (1.98-9.42) | <0.001 * |
| Comorbidity | | |
| Cardiovascular disease, No | | |
| Cardiovascular disease, Yes | 2.27 (1.02-5.05) | 0.046 * |



Aim 2 Methods

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 at 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

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 dayto-day activities

and



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

During the treatment my Quality of Life would be:



Relatively unchanged

Select

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-today abilities

and



Be hospitalized due to side effects

During the treatment my Quality of Life would be:



Significantly worse than it is right now

Select

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-today abilities

and



Be hospitalized due to side effects

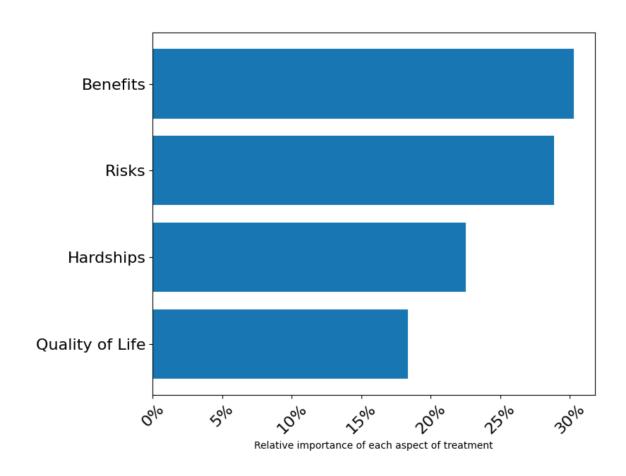
During the treatment my Quality of Life would be:

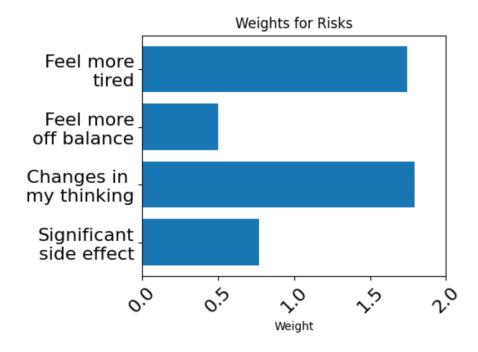


Relatively unchanged

Select

Aim 2: Results





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

| Number of Items |
|-----------------|
| |
| 8 |
| 4 |
| 8 |
| 20 |
| 12 |
| 6 |
| 1 |
| 1 |
| N/A |
| |
| 4 |
| |

^t 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

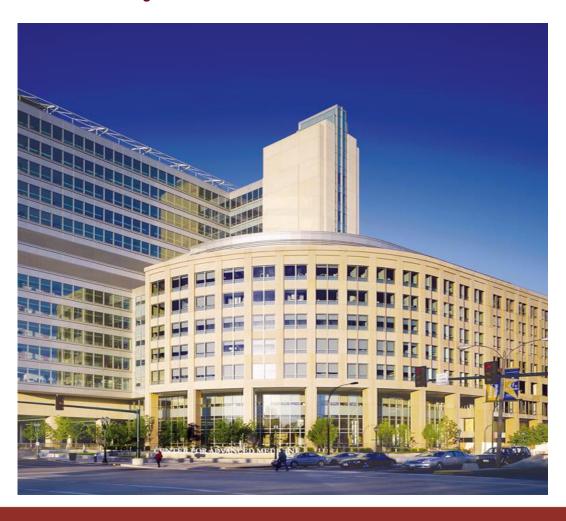
Innovation:

- 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





End-of-Life Experience in AML & MDS

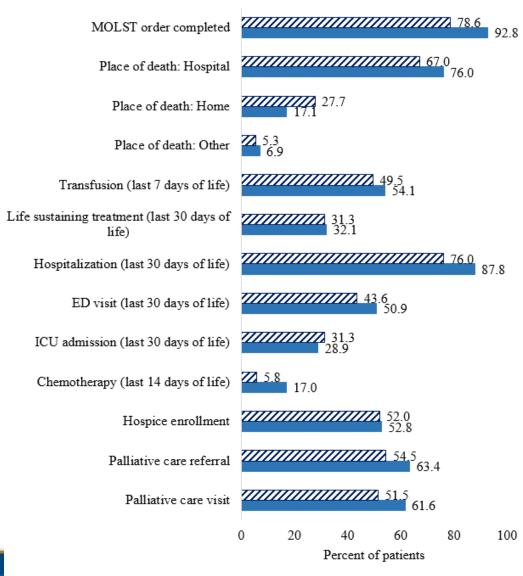
Compared to solid tumors:

- 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

Odejide et al. J Clin Oncol. 2016 Odejide et al. J Oncol Pract. 2014 Rao et al. J Clin Oncol. 2019



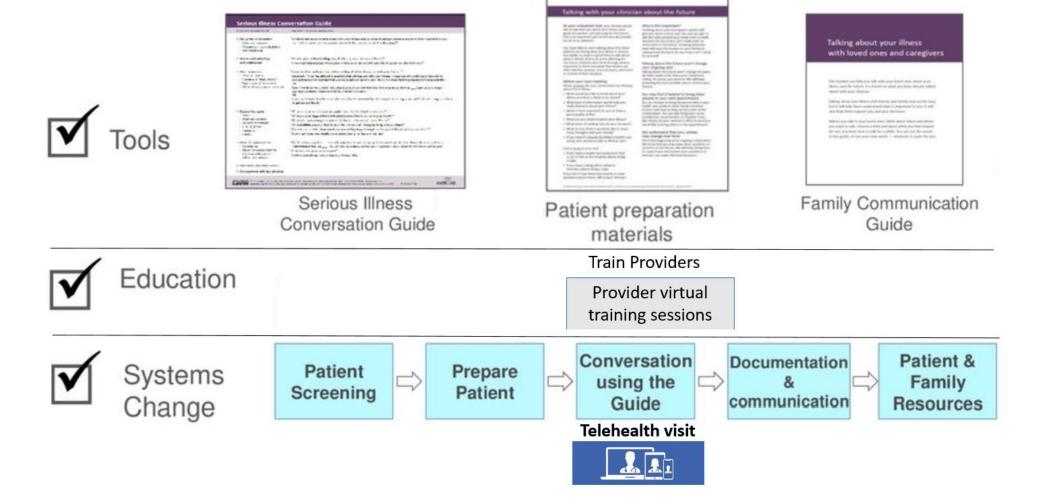
End-of-Life Metrics in AML & MDS



- 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





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



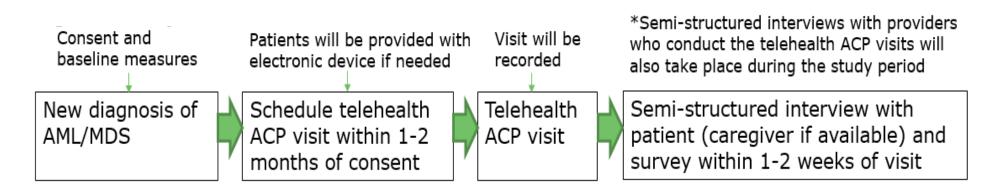


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Themes

- •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)



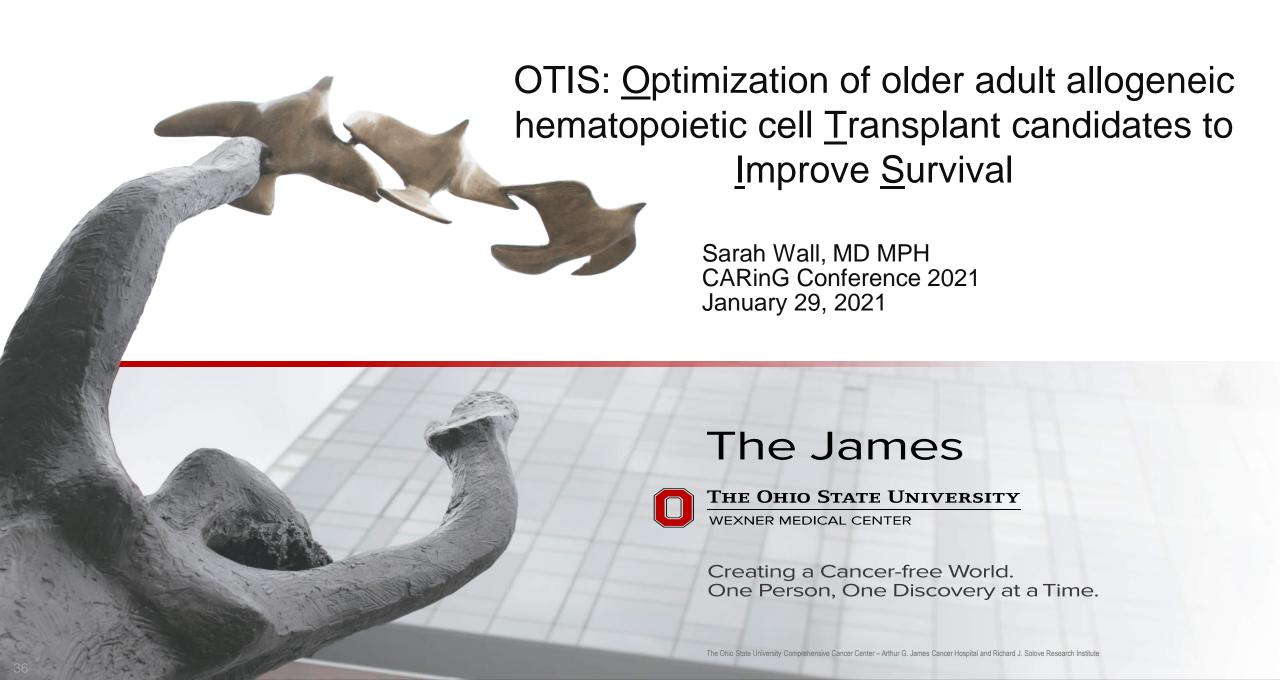
Providers will undergo training prior to enrolling patients

Measures: Enrollment and retention rates, usability, EOL indications, other PROs

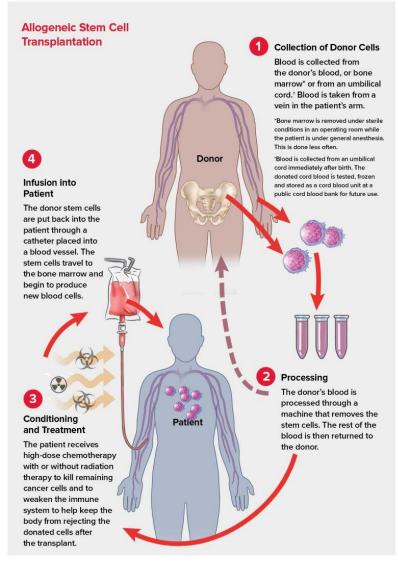




MEDICINE of THE HIGHEST ORDER



Background – What is allogeneic hematopoietic cell transplant?



"Immune System Transplant"

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

Basics:

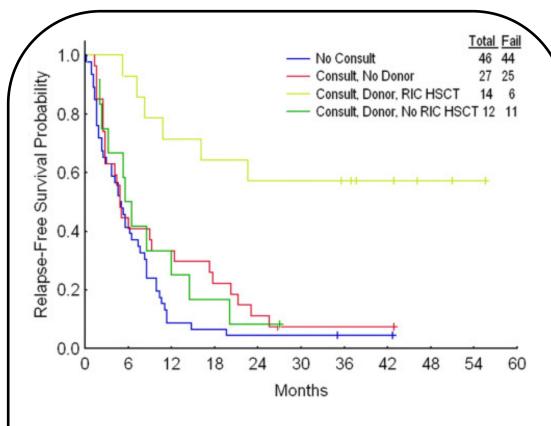
- Only potentially curative therapy for many blood cancers
 - Primary cause of death after transplant = relapse
- Definitely toxic!
 - Short and long-term complications
- Quality of life is unquestionably impacted
 - At least 3-6 months for all recipients
 - Anticipate lifelong effects

THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

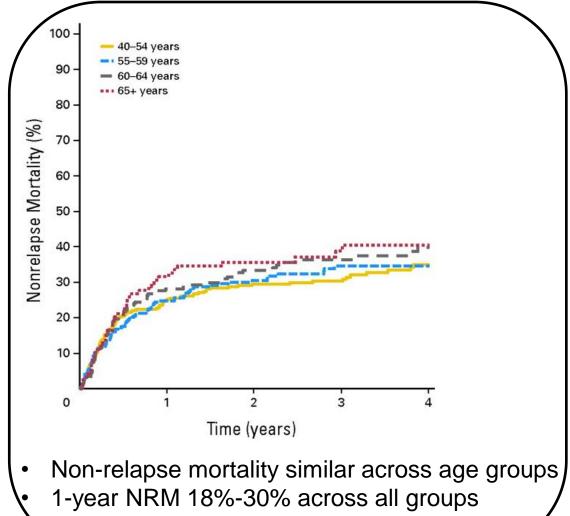
The James

From Leukemia & Lymphoma Society, © Fran Millner 2018

Background – Is allo-HCT too toxic for older adults?

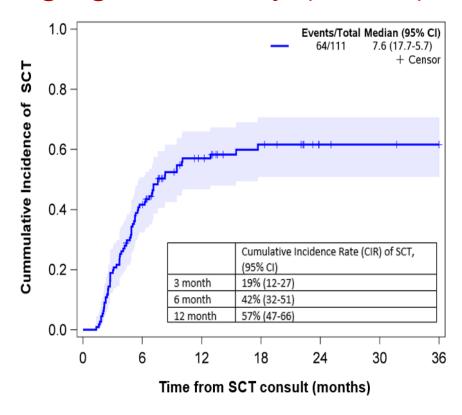


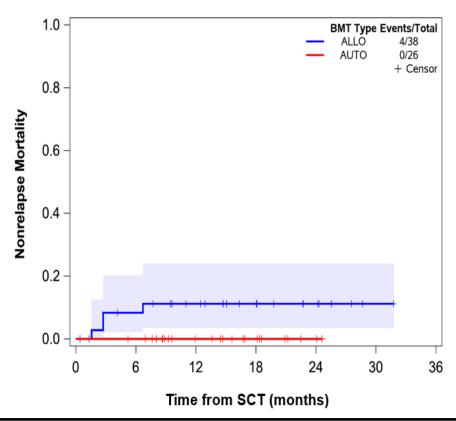
- 46% of patients > 50 years old with AML in CR were not referred for transplant consult
 - 30% "too ill", 46% reason unknown Estey E, et al. Blood, 109 (2007), pp. 1395-1400





Solution – Geriatric Assessment with Optimization in the Cancer and Aging Resiliency (CARE) Clinic at The James

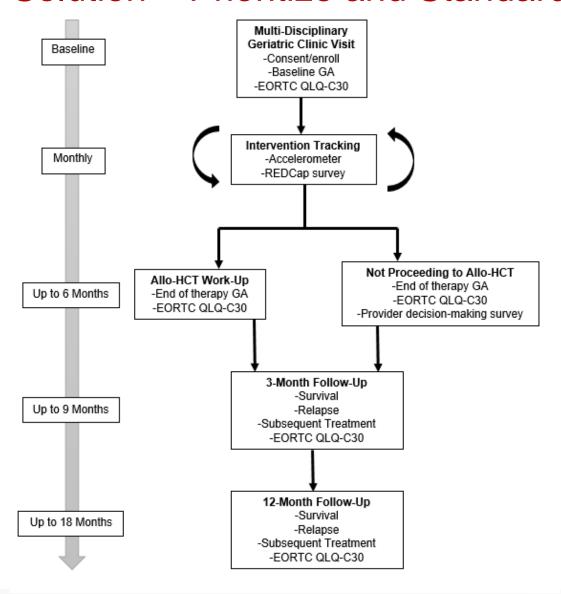




Mini Nutritional Assessment: Normal nutrition associated with improved OS compared to malnourished



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

| Domain | Tools | |
|----------------------|---|--|
| Physical Function | 6-minute walk test (6MWT) | |
| | Short physical performance battery (SPPB) | |
| Nutrition | Mini nutritional assessment (MNA) | |
| | Weight & BMI | |
| | Albumin | |
| Medication Adherence | Pharmacist-led medication review (BEERS criteria, adherence, patient knowledge) | |
| Cognition | Montreal cognitive assessment (MoCA) | |
| Mental Health | PHQ-9 and GAD-7 | |
| | Transplant evaluation rating scale (TERS) | |



Geriatric Optimization! Prescription

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



Thank You

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















