Intervening with Cancer Caregivers to Improve Patient Health Outcomes and Optimize Health Care Utilization

PAR-19-352 (R01); PAR-19-355 (R21)

Healthcare Delivery Research Program
Division of Cancer Control and Population Sciences

https://healthcaredelivery.cancer.gov
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Using WebEx and webinar logistics

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- Closed captioning is available by selecting the Media Viewer Panel on the right hand side of your screen
- This webinar is being recorded
Outline

- Background
- FOA Details
- Questions
  - Note: questions about specific aims or grant application details will not be addressed
Background

Healthcare Delivery Research Program
Organizational Chart of Extramural Divisions at NCI

Division of Cancer Control and Population Sciences
  Behavioral Research Program
  Epidemiology and Genomics Research Program
    Healthcare Delivery Research Program
    Surveillance Research Program
    Office of the Director

Division of Cancer Biology

Division of Cancer Prevention

Division of Cancer Treatment and Diagnosis

Office of the Director
  Center for Cancer Training
  Center for Global Health
  Center to Reduce Cancer Health Disparities
  Office of HIV and AIDS Management
HEALTHCARE DELIVERY RESEARCH PROGRAM
Advancing innovative research to improve the delivery of cancer-related care.

HEALTHCARE ASSESSMENT
Assess utilization, access, diffusion, and effectiveness in community settings

HEALTH SYSTEMS & INTERVENTIONS
Observe and intervene on behavior and context

OUTCOMES
Evaluate and improve patient experiences and health outcomes
Informal Cancer Caregiving
Informal Caregivers: Who are they?

- Individuals that assist family members/friends by providing care which is:
  - typically uncompensated
  - usually in the home setting
  - involves significant efforts for extended time
Informal Caregivers: What do they do?

- Caregiving can require demanding tasks, including:
  - Monitoring for side effects
  - Managing symptom burden
  - Treatment decision-making
  - Care coordination
  - Triage
  - Administering medication
  - Technical medical tasks
  - Managing patient’s financial and social obligations
Cancer caregiving

- Unique aspects of caregiving in the context of cancer
  - Multi-modal therapies
  - High burden of care
  - Cancer care continuum
  - Recurrence, and fear of recurrence
Research and Priorities in Cancer Caregiving

Cancer Caregiving Report
National Alliance for Caregiving
National Cancer Institute
Cancer Support Community

NCI and NINR Workshop

Caring for Caregivers and Patients: Revisiting the Research and Clinical Priorities for Informal Cancer Caregiving

Sponsored by the National Cancer Institute and the National Institute for Nursing Research
May 4-5, 2016
NCI Shady Grove TE400

NCI Planning Committee: Co-chairs Erin Kent (NCI), Julia Rowland (NCI)
Wen-Ying Sylvia Chou (NCI/NCPP SBP), Kristin Litzeinman (NCI/NCPP SBP),
Ann O’Mara (NCI/NCPP), Nomineeke Sheilbume (NCI/NCPP SBP)

Key Recommendations

- Expanding Assessment of Prevalence and Burden
- Integrating caregivers into the healthcare system
- Maximizing the Positive Impact of Technology
- Improving Interventions
Previous (Expired) FOA: Intervening with Cancer Caregivers

- PAR-18-246 and PAR-18-247 (previously PAR-16-317/318)
- Focused on interventions that examine strategies to support cancer caregivers to improve patient and caregiver outcomes
- Nine awards funded (4-R01s, 1-R37, 4-R21s)
Current FOA Details
Intervening with cancer caregivers to improve patient & caregiver health outcomes and optimize healthcare utilization PAR 19-352/355

**Purpose:** Support interventions that examine strategies to provide caregivers with training, promote coping skills, and ultimately help them manage their care.

Outcomes of interventions should aim to:

1. Improve patient health
2. Improve caregiver well-being
3. Optimize healthcare utilization
### Grant mechanisms – R01 and R21

<table>
<thead>
<tr>
<th>NIH Research Project Grant (R01)</th>
<th>NIH Exploratory/Developmental Grant (R21)</th>
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<tbody>
<tr>
<td>Supports a discrete, specified, and circumscribed research project</td>
<td>Supports new, exploratory, and developmental research projects</td>
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<tr>
<td>Most commonly used grant program</td>
<td>May be used for pilot and feasibility studies</td>
</tr>
<tr>
<td>No specific dollar limit</td>
<td>Combined budget for direct costs for the two-year project period usually may not exceed $275,000</td>
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<tr>
<td>▪ Advance permission required for $\geq$500K direct costs in any year</td>
<td>▪ Up to 2 years of funding</td>
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<tr>
<td>▪ 3-5 years of funding</td>
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For more information: grants.nih.gov/grants/funding/funding_program.htm#RSeries
Application requirements

- Interventions must be delivered at least to the caregiver, though can also be delivered to the patient/care recipient.

- Applications should focus on caregivers of patients ages 21 and over at diagnosis (see RFA-CA-19-033 for interventions focused on caregivers of pediatric cancer populations).

- Patients must be at point of diagnosis forward on the cancer control continuum. Studies conducted with patients in active treatment, transitioning into survivorship, with advanced cancer, or at end-of-life are acceptable.
Application requirements

Outcomes must focus on the following areas:

- **At least one** cancer patient health outcome (behavioral, physical, and/or psychosocial morbidity)
- **At least one** caregiver well-being outcome (behavioral, psychosocial, and/or physical)
- **At least one** healthcare utilization outcome
Application considerations

 Research projects should aim to identify intervention components that make them effective (e.g., conceptual framework, timing of and content of intervention, intervention mode and dosage)

 Investigators are encouraged to consider sustainability and scalability in the development, design, and testing of interventions

 Transdisciplinary approaches that foster collaboration of diverse stakeholders (e.g., clinicians, researchers, caregivers) is encouraged

 Studies targeting or expanding inclusion of medically or minority underserved patient-caregiver populations are encouraged
Application considerations

- Use of randomized controlled trials and/or pragmatic trial designs is strongly encouraged
- Applications may include mixed-methods approaches to determine the most effective components in the context of the intervention
- Applications may or may not include the development and testing of tools to evaluate caregiving, although the focus should be on the development and testing of an intervention
Applications not appropriate for this FOA

- Applications focusing on caregivers of pediatric populations
- Applications proposing observational research only
- Applications focused on cancer patients or survivors only (do not include a caregiver population)
Research strategy

- **Specific aspects to be addressed:**
  - A clear definition of the target cancer patient/caregiver population, as well as indication of how the project addresses persistent and salient problems for the specified population
  - Inclusion of a research team with appropriate caregiving science and health services expertise
  - A description of how the intervention will balance improvements targeted in all 3 outcome areas: (1) healthcare utilization; (2) caregiver well-being; and (3) patient health
  - A strategy for how the intervention, if successful, will be appropriately disseminated
Review criteria specific to this FOA

- **Significance:**
  - Does the project address persistent and salient challenges that the targeted cancer patient/caregiver population faces? How amenable is the proposed intervention for dissemination/implementation?

- **Investigator:**
  - How strong is the research team, including representation of appropriate caregiving and health services expertise (broadly construed)?

- **Approach:**
  - Does the intervention appropriately balance improvements targeted in all three outcome areas: (1) health care utilization; (2) caregiver well-being; and (3) patient health?
Application Requirements: Clinical Trials

- NIH requirements for clinical trials research applications were updated in January 2018. Please note the following policies:
  - Application form now consolidates all Human Subjects and Clinical Trial related information into one place and also expands information required for clinical trials applications (FORMS-E)
  - Investigators and staff must receive training in Good Clinical Practice
  - All sites participating in multi-site studies research will use a single IRB
  - All NIH-funded clinical trials are expected to register and submit results to Clinicaltrials.gov

- Information about the NIH Clinical Trial Requirements: [https://grants.nih.gov/policy/clinical-trials.htm](https://grants.nih.gov/policy/clinical-trials.htm)
Application Requirements: Budget

- Budget should reflect the actual needs of the proposed project
- R01: Advance permission required for ≥$500K direct costs in any year
- R21: The combined budget for direct costs for the two-year project period may not exceed $275,000. No more than $200,000 may be requested in any single year.
Resources

- Read the FOA carefully:
  

- Application Due Dates:
  
  - PAR-19-352 (R01): New, Renewal, and Resubmissions due 10/17/19; thereafter standard due dates apply
  
  - PAR-19-355 (R21): New submissions due 10/16/19; Resubmissions due 11/16/19; thereafter standard due dates apply

- Webinar and FAQ will posted on our website:
  
  https://healthcaredelivery.cancer.gov/media

- Connect with us early:
  
  Scientific contact: Michelle Mollica; michelle.mollica@nih.gov
Summary

- PAR-19-352; PAR-19-355: Intervening with cancer caregivers to improve patient & caregiver health outcomes and optimize healthcare utilization (R01/R21)

- Purpose: Support interventions that examine strategies to provide caregivers with training, promote coping skills, and ultimately help them manage their care
Questions?
Please type your questions in the Q & A section on WebEx

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