Intervening with Cancer Caregivers to Improve Patient Health Outcomes and Optimize Health Care Utilization (R01, R21)

Healthcare Delivery Research Program
Division of Cancer Control and Population Sciences

https://healthcaredelivery.cancer.gov
Webinar presenters

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Using WebEx and webinar logistics

- Submit questions at any time during the presentation. Type into the Q&A feature on the right of the interface and press “submit”
  - 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
  - Questions about specific aims or grant application details will not be addressed
Background

Healthcare Delivery Research Program
NCI DCCPS organizational structure

Division of Cancer Control and Population Sciences (DCCPS)

- Healthcare Delivery Research Program (HDRP)
- Behavioral Research Program (BRP)
- Epidemiology and Genomics Research Program (EGRP)
- Surveillance Research Program (SRP)

https://healthcaredelivery.cancer.gov
HEALTHCARE DELIVERY RESEARCH PROGRAM
Advancing innovative research to improve the delivery of cancer-related care

POPULATIONS

HEALTHCARE ASSESSMENT
Assess utilization, access, diffusion, and population-based outcomes

CLINICIANS & DELIVERY SYSTEMS

HEALTH SYSTEMS & INTERVENTIONS
Observe and intervene on behavior and context

PATIENT

OUTCOMES
Evaluate and improve patient experiences and health outcomes
How we fund grants

- Although most of our portfolio consists of investigator-initiated (unsolicited) grants, HDRP also supports grant applications in specific areas of interest
  - Requests for Applications (RFA)
    - Identifies the specific receipt date(s), the estimated amount of funds earmarked for the initiative, the number of awards likely to be funded, and any specific criteria for scientific peer review; applications received in response to a particular RFA are reviewed by an Institute’s Scientific Review Group
  - Program Announcements (PA)
    - Most PA applications are submitted with a standing receipt date and are reviewed with all other applications received at that time using standard peer-review processes
  - Program Announcement (PAR)
    - Program announcements with special receipt, referral, and/or review considerations
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>▪ Support a discrete, specified, and circumscribed research project</td>
<td>▪ Supports new, exploratory, and developmental research projects</td>
</tr>
<tr>
<td>▪ Most commonly used grant program</td>
<td>▪ Sometimes used for pilot and feasibility studies</td>
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<tr>
<td>▪ No specific dollar limit</td>
<td>▪ Preliminary studies are discouraged</td>
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<tr>
<td>▪ Advance permission required for ≥$500K direct costs in any year</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>▪ 3-5 years funding</td>
<td>▪ Up to 2 years funding</td>
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For more information: grants.nih.gov/grants/funding/funding_program.htm#RSeries
Background

Informal Cancer Caregiving
Informal Caregivers

- Individuals that assist family members/friends by providing care which is:
  - typically uncompensated
  - usually in the home setting
  - involving significant efforts for extended time

- 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-specific caregiving

- Unique aspects of caregiving in the context of cancer
  - Rapid deterioration of health
  - High burden of care
  - Multi-modal therapies
  - Cancer care continuum
  - Recurrence, and fear of recurrence
For the vast majority of respondents, being diagnosed with cancer caused distress. The impact of cancer on their family was most often reported as being extremely stressful. In all aspects of life mentioned in this survey, respondents aged 25 to 54 years were significantly more likely than those aged 55 years and older to report being highly or extremely distressed.

### Cancer-Related Distress

<table>
<thead>
<tr>
<th>Aspect</th>
<th>25-54 Years Old (n=267)</th>
<th>55 and Older (n=238)</th>
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<tbody>
<tr>
<td>The impact of your cancer on your family</td>
<td>48%*</td>
<td>20%</td>
</tr>
<tr>
<td>How you feel physically</td>
<td>42%*</td>
<td>13%</td>
</tr>
<tr>
<td>Finances</td>
<td>40%*</td>
<td>19%</td>
</tr>
<tr>
<td>Ability to work</td>
<td>39%*</td>
<td>16%</td>
</tr>
<tr>
<td>Ability to do things you love to do</td>
<td>38%*</td>
<td>14%</td>
</tr>
<tr>
<td>How long you expect to live</td>
<td>35%*</td>
<td>14%</td>
</tr>
</tbody>
</table>

*Indicates statistically greater at 90% confidence level

11. How distressed (anxious, extremely upset, or in emotional pain, for example) have you been due to the impact cancer has had on the following aspects of your life?
Cancer-specific caregiving

Main findings:

- ~2.8 million adults serving as a caregiver to an adult with cancer in the U.S.
- Average time per week caring: 32.9 hours
- 43% performing complex medical/nursing tasks without any prior preparation
- 50% reporting high emotional stress
- 25% reporting high levels of financial strain


http://www.caregiving.org/cancer/
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, 2015
NCI Shady Grove TE406

NCI Planning Committee: Co-chairs Erin Kent (NCI), Julia Rowland (NCI)
Wen-Ying Sylvia Chou (NCI/DCCPS/BRP), Kristin Litzelman (NCI/DCCPS/BRP),
Ann O’Mara (NCI/DCP), Nonniekaye Shelburne (NCI/DCCPS/EGRP)

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

Erin E. Kent, PhD, MS; Julia H. Rowland, PhD; Laurel Northouse, PhD, RN; Kristin Litzelman, PhD;
Wen-Ying Sylvia Chou, PhD, MPH; Nonniekaye Shelburne, MS, CRNP, AOCN; Catherine Timura, PhD, MPhi;
Ann O’Mara, PhD, RN, MPH; and Karen Huss, PhD, RN

Kent et al., 2016, Cancer, PMID: 26991807
Key Recommendations

- Expanding Assessment of Prevalence and Burden
- Improving Interventions
- Maximizing the Positive Impact of Technology
- Integrating caregivers into the healthcare system
Selected Recommendations

- Prioritize health outcomes of interest, define constructs, and harmonize measures
- Examine effects of interventions on patient and caregiver outcomes, health care utilization, and cost-effectiveness.
- Increase the inclusion of diverse populations
- Replicate interventions that show some benefit and attend to fidelity and dose
Intervening with cancer caregivers to improve patient & caregiver health outcomes and optimize healthcare utilization: PAR-16-317 (R01), PAR-16-318 (R21)

- Fund interventions that support the success of informal cancer caregivers for adult cancer patients, as measured by the following outcomes:
  1. Improved patient health
  2. Improved caregiver well-being
  3. Optimized healthcare utilization

FOA Details

Informal Cancer Caregiving
Application requirements

- Study design must consist of a behavioral or healthcare delivery intervention with random assignment and a control group.
- R21s need not consist of a double-arm RCT; applications submitted as R21s can propose to develop and test acceptability and feasibility.
- Interventions must be delivered at least to the caregiver, though can also be delivered to the patient/care recipient.
- 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.
- Only studies conducted with patients ages 21 and over at diagnosis are eligible.
Application requirements

Outcomes:

- At least one cancer patient-level health outcome (behavioral, physical, and/or psychosocial morbidity)
- At least one caregiver-level outcome (behavioral, psychosocial, and/or physical)
- At least one healthcare utilization/health system-level outcome related to care delivery, program implementation, and/or sustainability
Application requirements

- Adjunct mixed-methods and/or qualitative studies to determine the most effective components of interventions are encouraged in the context of the above study designs.
- Development and testing of assessment instruments to evaluate cancer caregiving.
- Special consideration will be given to applications that target underrepresented and/or medically underserved populations.
Research strategy

- Describe the proposed project using the standard sub-sections (Significance, Innovation, and Approach).
- The description must address all the specific aspects listed below.
  - 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.
Specific review criteria

- 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:
  - Does the research team include 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?
Read the FOAs very carefully!

- PAR-16-317 (R21); PAR-16-318 (R01)

- Application Due Dates:
  - October 10, 2017; April 11, 2018; October 10, 2018; April 11, 2019

  - Note the special review submission dates and that there are only 2 submission dates per year, including resubmissions (A1s)

- Letter of Intent: Not required, but encouraged, one month prior

- Start the process early! Allow time for registration in the System for Award Management, eRA Commons, and Grants.gov
Resources

- Today’s webinar and FAQ will be posted on our website: https://healthcaredelivery.cancer.gov/media
- Connect with your Program Directors early!
- Check the FOA for contact information
Additional resources

https://healthcaredelivery.cancer.gov/caregiving/

National Academies of Medicine Study of Caregiving for Older Adults (September, 2016)

https://videocast.nih.gov/

National Institute of Nursing Research Meeting (August, 2016)
Summary:

- Intervening with cancer caregivers to improve patient & caregiver health outcomes and optimize healthcare utilization


- Fund interventions that support the success of informal cancer caregivers for adult cancer patients, as measured by the following outcomes:
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Questions?
Please type your questions in the Q & A section on WebEx

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