Multilevel Interventions in Cancer Care Delivery: Follow-up to Abnormal Screening Tests

PA-17-495

Healthcare Delivery Research Program
Division of Cancer Control and Population Sciences

https://healthcaredelivery.cancer.gov
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Webinar presenter

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Webinar Overview

1. Introduction
   - Division of Cancer Control and Population Sciences
   - Grant mechanisms

2. Funding Announcement Details
   - Goals of FOA
   - Areas of interest
   - Application dates
   - Select information

3. Questions
   - Questions about specific aims or grant application details will not be addressed
Background

Multilevel Interventions in Cancer Care Delivery: Follow-up to Abnormal Screening Tests

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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

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

- **HEALTH SYSTEMS & INTERVENTIONS**
  Observe and intervene on behavior and context

- **OUTCOMES**
  Evaluate and improve patient experiences and health outcomes

- **POPULATIONS**

- **CLINICIANS & DELIVERY SYSTEMS**

- **PATIENT**
How NCI funds grants

- Although most of our portfolio consists of investigator-initiated (unsolicited) grants, the Healthcare Delivery Research Program 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 Announcement (PAR)**
    - Program announcements with special receipt, referral, and/or review considerations

  - **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
NIH Research Project Grant (R01)

- Discrete, specified, and circumscribed research projects
- Most commonly used mechanism
- No specific dollar limit
  - Advance permission required for ≥$500K direct costs in any year
- Funding for 3-5 years

For more information: grants.nih.gov/grants/funding/funding_program.htm#RSeries
Funding Announcement Details

Multilevel Interventions in Cancer Care Delivery: Follow-up to Abnormal Screening Tests

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Multilevel interventions in cancer care delivery: Breakdowns occur at multiple points in the cancer screening process

Cancer Control Continuum

Risk Assessment → Detection → Diagnosis → Cancer or Precursor Treatment → Survivorship → End-of-Life-Care

Outcomes

Risk Status
Clinical Status
Functional Status
Quality of Life
Satisfaction
Mortality
Quality of Death

Failure to Screen
Failure to Detect
Failure to Follow-up
Failure to Treat
Purpose of Funding Announcement: PA-17-495

- Develop and test multilevel interventions to improve the follow-up of abnormal screening tests in breast, cervical, colorectal and lung cancers.
Funding Announcement: Goals

Test interventions to improve the follow-up of abnormal screening in one or more ways

- Measure effects of interventions at every level of healthcare system
- Compare single versus multilevel interventions

Advance the science of multilevel interventions

- Intervention effects must be measured at multiple levels
- Establish standardized and/or complementary measures of effect at individual, provider team and organization levels
- Standardize analyses of intervention effects on individuals, provider teams, and organizations
Definition-1

**Multilevel Interventions:** Are interventions that occur at two or more levels of individuals, clinical teams, healthcare systems and/or community settings and measure outcomes at three or more of these levels.
Definitions-2

Levels include -

- **Individuals**: Patients, caregivers and family members, providers.

- **Clinical teams**: Two or more providers including primary and specialty care, support staff.

- **Healthcare system**: Collection of primary and specialty care providers and support staff, medical facilities, and organizational structures.

- **Community setting**: Environments in which the process of delivering healthcare reflects approaches followed by providers whose primary responsibilities are patient care (e.g., Federally Qualified Health Centers).
Definitions-3

- **Abnormal screening test:** Includes any clinical indications (either a true or false-positive result) from a screening test or examination that suggests the need for further evaluation to determine the presence or absence of disease.

- **Follow-up to abnormal screening test:** Diagnostic procedures recommended, ordered, performed or received to accomplish this goal.
Complexity of healthcare delivery

Intra-Level Information Flow: Test Delivery and Screening Follow-up

Providers, Clinical Teams (People)

Patients and Caregivers (People)

Healthcare System (Organizations)

Inter-Level Information Flow: Test Delivery and Screening Follow-up

W.H. Rouse, 2010
Examples of Multilevel Interventions and Measurement of Effect on Patient, Provider Team and Organization

- **Single level intervention** (Individual provider, team roles, attitudes or behaviors)
  - Intervene: Provider Team

- **Two-level intervention** (Patient Navigator and provider team functioning, leadership, communication with multispecialty clinical team)
  - Intervene: Patient Navigator and Provider Team

- **Multilevel intervention** (Organizational leadership and culture)
  - Intervene: Automated Reminders for Patient, Provider Team that Engages Organizational Involvement in the Context of Care

**Required:**
Intervene at **two** or more level and measure intervention impact at **three** or more levels
Science Supported by Funding Announcement

- *Intervene at two or more levels*
- Hypothesized *interactions among all levels*
- *Measurement* of baseline and *outcomes* at *multiple* levels
- Identify and analyze potential outcome moderators and mediators
- Analysis to test for hypothesized interactions
- Documentation of *four* endpoints:
  1. Initiation of the diagnostic evaluation
  2. Completion of the diagnostic evaluation
  3. Report of results to the referring provider
  4. Report of results to the patient with the abnormal screening test
Considerations

- **Multilevel research:**
  - Evolving area of complex science that necessitates ambitious studies

- **Measurement:**
  - Anchoring constructs, measures, interventions conceptually or theoretically

- **Principal Investigators:**
  - Developing multilevel experience
## Select Application Information: PA-17-495

**Standard dates apply**

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<th>Cycle 1</th>
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<td>Application due date (new R01)</td>
<td>Feb 5</td>
<td>June 5</td>
<td>Oct 5</td>
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<td>Scientific Merit Review</td>
<td>June-July</td>
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<td>Advisory Council Round</td>
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<td>Earliest Project Start Date</td>
<td>Sept or Dec</td>
<td>April</td>
<td>July</td>
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Read the funding announcement carefully!

- Earliest Start Date: **Standard dates apply**
- Expiration Date: **01/08/2020**
- Start the process early! Allow time for registration in the System for Award Management, eRA Commons, and Grants.gov
NIH Might Consider Your Human Subjects Research to be a Clinical Trial

Does your study...

✓ Involve one or more human subjects?
✓ Prospectively assign human subject(s) to intervention(s)?
✓ Evaluate the effect of intervention(s) on the human subject(s)?
✓ Have a health-related biomedical or behavioral outcome?

If “yes” to ALL of these questions, your study is considered a clinical trial

Unsure how to answer the questions? We have a tool that can help! https://grants.nih.gov/ct-decision/
Resources

- Today’s webinar and FAQ will be posted on our website: https://healthcaredelivery.cancer.gov/media
- Connect with your HDRP Program Director, Dr. Breslau early!
  - Check the FOA for contact information
  - Staff listing: https://healthcaredelivery.cancer.gov/about/staff
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Questions

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Thank you!

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