Delivering better cancer care
An overview of the Healthcare Delivery Research Program (HDRP)

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Health Systems & Interventions Research Branch
November 28, 2017
Roadmap

1. HDRP: Mission & organization
2. Types of research we support & how we support it
3. Grants: Some friendly reminders
4. Questions & discussion
Extramural research programs @ NCI

**DIVISION OF CANCER CONTROL AND POPULATION SCIENCES**
- Healthcare Delivery
  - Behavioral
  - Implementation Sci
  - Survivorship
  - Surveillance
  - Epi & Genomics

**DIVISION OF CANCER PREVENTION**
- Biometry
- Cancer biomarkers
- Community oncology & prevention trials
- Early detection
- Nutritional science

**DIVISION OF CANCER TREATMENT AND DIAGNOSIS**
- Cancer diagnosis
- Therapy evaluation
- Translational research
- Complementary & alternative

**DIVISION OF EXTRAMURAL ACTIVITIES**
- Scientific Review (in coordination with NIH Center for Scientific Review)
- Portfolio analysis, review

http://cancercontrol.cancer.gov/@NCICancerCtrl
Mission: Advance innovative research that reduces the burden of cancer by improving the delivery & outcomes of cancer-related care

Geiger AM et al. Evid-Based Oncol. 2016
What types of research do we support?
HDRP supports care delivery research across the cancer care continuum

- Observational research → targets for intervention
- Intervention research developing and testing care delivery interventions
- Patterns of care studies
- New measures and metrics

(Taplin et al., 2012)
Health systems & interventions research branch (HSIRB)

Mission: Advance observational and intervention research on structural, organizational, social, and behavioral factors that influence the delivery of cancer care -- from early detection through end of life

Observational & interventional research addressing:

- Care coordination & teamwork processes
- Team-based approaches to cancer care
- Transitions in care
- Shared decision making (e.g., HPV vaccination, genetic testing, long term surveillance)
- Multi-level interventions that improve care delivery & patient outcomes
- Interventions leveraging health information technology (HIT) or testing innovative HIT tools
4 Key tools HDRP uses to support research in these areas

- Funding research through grants, RFAs, etc.
- Developing & housing large data resources & measurement tools
- Supporting research networks
- Convening the extramural research community & key stakeholders
Investigator-Initiated Grants (Approximate)

Mechanisms

- Research Project (R01) = 67%
- Exploratory/Developmental (R21) = 20%
- Small (R03) = 7%
- Program Project (P01) = 1%
- Cooperative Agreement (U) = 5%

Cancer Control Continuum

- Prevention = 23%
- Detection = 30%
- Diagnosis = 3%
- Treatment = 30%
- Survivorship = 15%

Note: career awards are handled by the Center for Cancer Training, see http://www.cancer.gov/researchandfunding/cancer training
### Funding opportunities: Grant mechanisms – R01, R21, R03

https://cancercontrol.cancer.gov/funding_apply

<table>
<thead>
<tr>
<th>Research Project Grant (R01)</th>
<th>Exploratory/Developmental Grant (R21)</th>
<th>Small Grant Program (R03)</th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ Support a discrete, specified research project</td>
<td>▪ Supports new, exploratory, and developmental research projects</td>
<td>▪ Supports limited funding for a short period of time for a variety of types of projects,</td>
</tr>
<tr>
<td>▪ Most commonly used grant mechanism</td>
<td>▪ Sometimes used for pilot and feasibility studies</td>
<td>including: pilot or feasibility studies, collection of preliminary data, secondary analysis</td>
</tr>
<tr>
<td>▪ No specific dollar limit</td>
<td>▪ Preliminary studies are discouraged</td>
<td>of existing data, small, self-contained research projects, development of new research</td>
</tr>
<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>
<td>technology, etc.</td>
</tr>
<tr>
<td>▪ 3-5 years funding</td>
<td>▪ NCI does not participate in the NCI Parent/Omnibus R21 Announcement</td>
<td>▪ Limited to two years of funding</td>
</tr>
<tr>
<td>▪ NIH Omnibus/parent</td>
<td>▪ Look for program announcement in specific area</td>
<td>▪ Direct costs generally up to $50,000 per year</td>
</tr>
<tr>
<td>▪ Program announcement in specific area</td>
<td></td>
<td>▪ Not renewable</td>
</tr>
<tr>
<td>▪ Encourages applications from new &amp; early stage investigators</td>
<td></td>
<td>▪ NCI parent R03</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▪ Program announcement in specific area</td>
</tr>
</tbody>
</table>
## Examples of current HDRP funding opportunity announcements (FOA)

<table>
<thead>
<tr>
<th>Title</th>
<th>FOA Number (Mechanism)</th>
<th>Brief Description</th>
<th>Expiration Date</th>
<th>HDRP Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reducing Overscreening for Breast, Cervical, and Colorectal Cancers among Older Adults</td>
<td>PA-17-109 (R21) PA-17-110 (R01)</td>
<td>Promotes research designed to reduce overscreening among average risk adults</td>
<td>January 8, 2020</td>
<td>Erica Breslau 240.276.6773 <a href="mailto:breslaue@mail.nih.gov">breslaue@mail.nih.gov</a></td>
</tr>
<tr>
<td>Linking the Provider Recommendation to Adolescent HPV Vaccine Uptake</td>
<td>PAR-16-338 (R01) PAR-16-337 (R03) PAR-16-336 (R21)</td>
<td>Encourages research on how delivery system enhances or inhibits effectiveness of a provider's recommendation</td>
<td>July 6, 2019 (R01) July 17, 2019 (R03 and R21)</td>
<td>Sarah Kobrin 240-276-6931 <a href="mailto:kobrins@mail.nih.gov">kobrins@mail.nih.gov</a></td>
</tr>
<tr>
<td>Intervening with Cancer Caregivers to Improve Patient Health Outcomes and Optimize Health Care Utilization</td>
<td>PAR-16-317 (R01) PAR-16-318 (R21)</td>
<td>Funds interventions that support the success of informal cancer caregivers</td>
<td>April 12, 2019</td>
<td>Erin Kent 240-276-6776 <a href="mailto:kentee@mail.nih.gov">kentee@mail.nih.gov</a></td>
</tr>
<tr>
<td>Oral Anticancer Agents: Utilization, Adherence, and Health Care Delivery</td>
<td>PA-17-060 (R01) PA-17-061 (R21)</td>
<td>Funds development of models and strategies to improve safe and effective delivery of OAA to optimize clinical outcomes</td>
<td>January 8, 2020</td>
<td>Kathleen Castro 240-276-6834 <a href="mailto:castrok@mail.nih.gov">castrok@mail.nih.gov</a></td>
</tr>
</tbody>
</table>

[https://cancercontrol.cancer.gov/funding_apply.html#hdr]
FOA: Reducing overscreening for breast, cervical, and colorectal cancers among older adults
PA-18-005 (R01), PA-18-015 (R21)

- Promote research designed to reduce overscreening among average risk older adults

- Goals:
  - Understand factors that drive overuse
  - Develop and test interventions to reduce overuse

- Must:
  - Include screening rates as primary outcome
  - Address at least two contextual levels (individual, healthcare team, delivery system, or community)
  - Be grounded in conceptual framework

- HDRP Program Director: Erica Breslau (breslaue@mail.nih.gov)
- Preapplication webinar
FOA: Linking the provider recommendation to adolescent HPV vaccine uptake
PAR-18-008 (R01), PAR- 18-019 (R21), PAR-16-337 (R03)

- Encourages research on how delivery system enhances or inhibits effectiveness of a provider's recommendation

- Requirements
  - Primary data collection in clinical setting
  - Geographic areas where HPV vaccination low
  - Girls and boys ages 11 to 12 years
  - Consideration & measurement of characteristics at three levels (provider, patient/parent, and practice setting)

- Research requires expertise in cancer prevention, adult and childhood behavior, immunization promotion, and healthcare delivery

- HDRP Program Director: Sarah Kobrin (kobrins@mail.nih.gov)

- Preapplication webinar
FOA: Intervening with Cancer Caregivers to Improve Patient Health Outcomes & Optimize Healthcare Utilization
PAR-16-317 (R01), PAR-16-318 (R21)

- Funds interventions that support the success of informal cancer caregivers, as measured by:
  1. **Improved patient health**: Physical and psychosocial outcomes, QOL
  2. **Improved caregiver well-being**: Lower burden, higher capacity, and QOL
  3. **Optimized healthcare utilization**: Improved oral medication adherence; reduced ER visits, hospitalization and hospital readmissions; lower infection rates; use of supportive/ palliative care service; caregiver use of health care services & cancer support services

- Studies must target adult cancer patients/survivors
- Special consideration for studies targeting medically underserved & under-represented patient-caregiver populations
- HDRP Program Director: Erin Kent ([kentee@mail.nih.gov](mailto:kentee@mail.nih.gov))
- Preapplication webinar
Four moonshot FOAs with relevance to HDRP research
(https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative/funding)

Approaches to identify and care for individuals with inherited cancer syndromes (U01, RFA-CA-17-041)

   Deadline: Jan 9, 2018; preapplication webinar

Research centers improving management of symptoms across cancer treatments (UM1, RFA-CA-17-042)

   Deadline: Jan 17, 2018; preapplication webinar

Analyzing and interpreting clinician and patient adverse event data to better understand tolerability (U01, RFA-CA-17-052)

   Deadline: Jan 17, 2018; next webinar Dec 13

Accelerating colorectal cancer screening and follow-up through implementation science (UG3/UH3, RFA-CA-17-038)

   Deadline: Jan 18, 2018; preapplication webinar
4 Key tools HDRP uses to support research in these areas

- Funding research through grants, RFAs, etc.
- **Developing & housing large data resources & measurement tools**
- Supporting research networks
- Convening the extramural research community & key stakeholders
HDRP Data & Research Resources

https://healthcaredelivery.cancer.gov/initiatives/

Publicly Accessible Data

- Medical Expenditure Panel Survey: Experiences with Cancer Survivorship Supplement (MEPS)
- National Health Interview Survey (NHIS) Cancer Control Supplement (CCS)
- SEER-CAHPS Linked Data Resource
- SEER-Medicare Linked Database
- SEER-MHOS Linked Data Resource

Measurement Tools

- HealthMeasures
- Multidisciplinary Treatment Planning (MTP) Questionnaire
- Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE™)

Consumer Assessment of Healthcare Providers and Systems (CAHPS) for Cancer Care
4 Key tools HDRP uses to support research in these areas

- Funding research through grants, RFAs, etc.
- Developing & housing large data resources & measurement tools
- **Supporting research networks**
- Convening the extramural research community & key stakeholders
Examples of HDRP supported research networks

- Population-based Research to Optimize the Screening PRocess (PROSPR)
  - Goal: Increase understanding of healthcare system, provider, and individual factors that affect the quality of cancer screening in the U.S. & ultimately improve the cancer screening process
  - Cervical, colorectal, and lung cancers

- NCI Community Oncology Research Program (NCORP)
  - Goal: Practice transformation
  - Study clinically important and sustained modification of the structures and processes of cancer care delivery to improve clinical outcomes, enhance patient experiences, and optimize value
  - Research Bases (7) lead study development & provide infrastructure
  - Community sites (34) and Minority and Underserved sites (12) inform study development & conduct work
4 Key tools HDRP uses to support research in these areas

- Funding research through grants, RFAs, etc.
- Developing & housing large data resources & measurement tools
- Supporting research networks
- **Convening the extramural research community & key stakeholders**
Convening the research community
https://healthcaredelivery.cancer.gov/media/

- Joint ASCO-NCI Teams in Cancer Care Delivery Workshop
  - 19 case studies & 4 editorials published in special issue of the Journal of Oncology Practice (Vol 12, No 1, Nov 2016)

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

- Virtual speaker series (e.g., Healthcare teams cyber discussion series)

- Pre-application webinars
Applying for funding: Some friendly reminders

- Read entire funding announcement carefully
- Talk with a Program Officer before submitting & after review
  - Pre-application: Identify staff appropriate for your idea(s) through mentors, peers, published literature, meetings, web pages, etc.
    https://healthcaredelivery.cancer.gov/about/staff/
- Avoid jargon and abbreviations
- Write a clear, concise stand-alone summary of your project & get feedback early
- Emphasize potential direct impact
  - How could/will the proposed work influence how care is delivered & related patient or population health outcomes?
  - How will this work advance the science of cancer care delivery?
NIH Policies for Clinical Trials

Does your study...

✓ Involve one or more human subjects?
✓ Involve one or more interventions?
✓ Prospectively assign human subject(s) intervention(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 & case studies that can help: https://grants.nih.gov/ct-decision/
Implications: Due dates Jan 25, 2018 & onward

- Proposals including clinical trials must be submitted to a funding opportunity announcement that specifically allows for clinical trials
  - “Clinical trial required” or “clinical trial optional”
  - New review criteria & guidance for clinical trial applications (NOT-OD-17-118)
Last 2 reminders…

- New NIH grant application forms (NOT-OD-17-062)
  - Due dates Jan 25, 2018 & onward: Use NIH FORMS-E grant application forms & instructions
  - Consolidates human subjects, inclusion enrollment, and clinical trial information into a single form
    
    PHS Human Subjects and Clinical Trials Information Form

- Requesting study section or areas of scientific expertise needed to review your application?

  Cover Letter

  PHS Assignment Request Form
In closing

- Thank you for your attention & participation!
- Today’s goal: 30K foot overview & where to find more
- Many resources at your disposal…including program directors
- Junior faculty & students…want more on grant writing & administration?

  NIH Regional Seminars on Program Funding & Grants Administration
  
  
  May 2-4, 2018, Washington, DC
  
  Additional 2018 dates TBD soon!
Healthcare Delivery Research Program – Paul Jacobsen, PhD

Meet the Healthcare Delivery Research Program’s Associate Director, Paul Jacobsen, PhD!

Dr. Jacobsen joined HDRP in September 2016 to lead the program towards its mission of advancing innovative research to improve the delivery of cancer-related care. The vision of HDRP is optimal health outcomes for individuals, families, and communities affected by cancer.

https://healthcaredelivery.cancer.gov

@NCICareDelivRes
Questions & discussion

Sallie.weaver@nih.gov
Extra slides
SEER-Medicare Health Outcomes Survey Linkage (SEER-MHOS)

- Combines SEER cancer registry data (NCI) and Medicare Health Outcomes Survey data (CMS)
  - SEER – program of cancer registries that collect clinical, demographic and cause of death information for persons with cancer
  - MHOS -- information about the health-related quality of life (HRQOL) of Medicare Advantage Organization (MAO) enrollees
- Data available for 15 cohorts of MHOS data (baseline and follow-up) covering data collection years 1998-2014
- Investigators are required to obtain approval in order to obtain the data
HealthMeasures http://www.healthmeasures.net/

HealthMeasures consists of four precise, flexible, and comprehensive measurement systems that assess physical, mental, and social health, symptoms, well-being and life satisfaction; along with sensory, motor, and cognitive function.

Sign up for HealthMeasures updates and newsletter here
Get tailored email updates and join the HealthMeasures dialogue

PROMIS® short form measures have recently been examined for measurement equivalence in ethnically and socio-demographically diverse populations of cancer patients.
Read more in Psychological Test and Assessment Modeling.

PROMIS®
Self-reported and parent-reported measures of global, physical, mental, and social health for adults and children in the general population and those living with a chronic condition

Neuro-QoL
Self-reported and proxy-reported measures of physical, mental, and social health for adults and children living with a neurological condition

ASCQ-MeSM
Self-reported measures of physical, mental, and social health for adults living with sickle cell disease

NIH Toolbox®
Performance tests of cognitive, motor, and sensory function and self-reported measures of emotional function for adults and children in the general population and those living with a chronic condition
Public Data Resources on Cancer Patient Quality and Health Outcomes

**SEER-MHOS**
Linkage of the following data sources:
1. Cancer registry data (SEER)
2. Patient survey on health status/outcomes (MHOS)


**SEER-CAHPS**
Linkage of the following data sources:
1. Cancer registry data (SEER)
2. Patient survey on experiences of care (Medicare CAHPS®)
3. Healthcare claims data (Medicare)

[https://healthcaredelivery.cancer.gov/seer-cahps/](https://healthcaredelivery.cancer.gov/seer-cahps/)
SEER-MHOS Linked Data Resource

Surveillance, Epidemiology and End Results – Medicare Health Outcomes Survey

- Over 140,000 SEER-linked Medicare Advantage (HMO) beneficiaries*
- Over 2 million beneficiaries without cancer
- Baseline and follow-up survey, spaced two years apart, proportion with surveys before and after dx

Survey includes:
- Health-related quality of life (SF-36, VR-12)
- Activities of daily living
- HEDIS effectiveness of care
- Patient-reported outcomes relevant for older adults with cancer

*No healthcare claims available in SEER-MHOS of medical care; Part D prescription drug claims under investigation though a feasibility study

Rich data source on cancer patient reported health outcomes

https://healthcaredelivery.cancer.gov/seer-mhos/
SEER-CAHPS Linked Data Resource

Surveillance, Epidemiology and End Results – Consumer Assessment of Healthcare Providers and Systems

- Over **205,000** cancer respondents
- More than **724,000** non-cancer respondents
- Medicare **claims** allow examination of aspects of healthcare utilization

CAHPS survey includes subscales such as:
- Doctor Communication
- Getting Needed Care
- Getting Care Quickly
- Care Coordination

https://healthcaredelivery.cancer.gov/seer-cahps/
CAHPS for Cancer Care Surveys

Consumer Assessment of Healthcare Providers and Systems

- **Surveys** developed and tested with funding from the AHRQ, NCI, and California Health Care Foundation
- Released in June, 2017
- May be assessed at independent community oncology practices and cancer centers, **or used in research studies**

NEW measures that enable cancer-specific assessment of care experiences

Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE™)

This site was designed to provide you with information about the PRO-CTCAE, a patient-reported outcome measurement system developed by the National Cancer Institute to capture symptomatic adverse events in patients on cancer clinical trials.

The site includes an overview of the methods used to develop this measurement system, and resources and references for further information.

- What is PRO-CTCAE?
- How Do I Use PRO-CTCAE?
- Overview
- Instrument
- Permission to Use
- Build a Custom Form
- Development Team
- PRO-CTCAE Scientific Leadership at NCI
- Resources
- Frequently Asked Questions
Population-based Research to Optimize the Screening Process (PROSPR) II

- **Goal**: increase understanding of healthcare system, provider, and individual level factors that affect the quality of cancer screening in the U.S. to improve the cancer screening process.
- Includes cervical, colorectal, and lung cancers
- Focus on how factors affect variations in populations with diverse racial/ethnic, socioeconomic, and healthcare access characteristics
Goal = PRACTICE TRANSFORMATION

Clinically important and sustained modification of the structures and processes of cancer care delivery to improve clinical outcomes, enhance patient experiences, and optimize value*

Scientific Activities

- Research Bases (7) lead study development & provide infrastructure
- Community sites (34) and Minority and Underserved sites (12) inform study development & conduct work
- DCCPS/HDRP provides vision and guides direction
NCORP Community Site, M/U Community Site and Research Bases Geographic and Organizational Diversity

- Investigators (4,025)
- Components/Subcomponents (938)

**Community Sites (34)**
- Distributed network (25)
- Integrated System (7)
- Small Network (2)

**MU Community Sites (12)**
- Academic (8)
- Non-Academic (4)

**Research Bases (7)**

Updated: May 2017
### Examples of NCORP CCDR Studies (as of 8/8/17)

<table>
<thead>
<tr>
<th>Study ID (Add’l Funding)</th>
<th>Study Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>SWOG S1417CD</td>
<td>Implementation of a Prospective Financial Impact Assessment Tool in Patients with Metastatic Colorectal Cancer</td>
</tr>
<tr>
<td>SWOG S1415CD (PCORI)</td>
<td>A Pragmatic Trial to Evaluate a Guideline-Based Colony Stimulating Factor Standing Order Intervention (TRACER)</td>
</tr>
<tr>
<td>COG ACCL15N1CD</td>
<td>Improving the use of Evidence-Based Supportive Care Clinical Practice Guidelines in Pediatric Oncology</td>
</tr>
<tr>
<td>Alliance A191402CD (NIMHD R01)</td>
<td>Testing Decision Aids to Improve Prostate Cancer Decisions for Minority Men</td>
</tr>
</tbody>
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