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Interventions to Improve the Quality of Life and Survivorship of Older Adults with Cancer: The Funding Landscape at NIH, ACS and PCORI

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A Hurria, S Mohile, and W Dale designed the conference schedule and speakers that generated original content for manuscript. All authors contributed to the manuscript concept as well as preparation, editing, and final review of the article.

Websites: (retrieved on October 29, 2015)

Department of Health and Human Services, Grants for Early Medical/Surgical Subspecialists' Transition to Aging Research (GEMSTAR) (R03) <http://grants.nih.gov/grants/guide/rfa-files/RFA-AG-16-015.html>

2008 Institute of Medicine Report, —Retooling for an Aging America: Building the Health Care Workforce (<http://iom.nationalacademies.org/Reports/2008/Retooling-for-an-Aging-America-Building-the-Health-Care-Workforce.aspx>)

National Cancer Institute. <http://www.cancer.gov/research/nci-role/extramural>

Department of Health and Human Services. Examination of Survivorship Care Planning Efficacy and Impact [R21] <http://grants.nih.gov/grants/guide/pa-files/PA-12-274.html>

Department of Health and Human Services. Examination of Survivorship Care Planning Efficacy and Impact [R01] <http://grants.nih.gov/grants/guide/pa-files/PA-12-275.html>

Department of Health and Human Services. Physical Activity and Weight Control Interventions Among Cancer Survivors: Effects on Biomarkers of Prognosis and Survival (R01): <http://grants.nih.gov/grants/guide/pa-files/PA-15-311.html#sthash.8eGmojZl.dpuf>

Department of Health and Human Services. Physical Activity and Weight Control Interventions Among Cancer Survivors: Effects on Biomarkers of Prognosis and Survival (R21): <http://grants.nih.gov/grants/guide/pa-files/PA-15-310.html#sthash.a5FfEz01.dpuf>

Department of Health and Human Services Caring for Caregivers and Patients: Revisiting the Research and Clinical Priorities for Informal Cancer Caregiving. <http://cancercontrol.cancer.gov/ocs/resources/icc-meeting.html>

PROMIS <http://www.nihpromis.org/?AspxAutoDetectCookieSupport=1%20-%202#21>. PCORI. <http://www.pcori.org/about-us>

PCORI What we've funded. <http://www.pcori.org/research-results>

PCORI. The PCORI Methodology Report. <http://www.pcori.org/assets/2013/11/PCORIMethodology-Report-Appendix-A.pdf>

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Abstract

Identifying knowledge gaps and research opportunities in cancer and aging research was the focus of a three-part conference series led by the Cancer and Aging Research Group from 2010 to 2015. The third meeting, featured representatives from the NIA, NCI, ACS and PCORI each of whom discussed research priorities and funding opportunities in cancer and aging at their respective agencies. This manuscript reports on the proceedings of that conference with a specific focus on funding priorities for interventions to improve the quality of life and survivorship of older adults with cancer. Helpful tips from each funder regarding writing a good research proposal are presented.

Keywords

Aging; Cancer; Older Adults; Frail; Funding; NIH; ACS; PCORI; Survivorship; Quality of Life

Introduction

The Cancer and Aging Research Group (CARG) is dedicated to advancing the care of older adults with cancer through evidence-based practice. Identifying knowledge gaps and research opportunities to provide this evidence was the focus of a three-part conference series from 2010 to 2015 funded by the National Institute on Aging (NIA) through a U13 cooperative conference grant. The third meeting, held in collaboration with the NIA and the National Cancer Institute (NCI), featured representatives from the NIA, NCI, American Cancer Society (ACS) and the Patient Centered Outcomes Research Institute (PCORI) each of whom discussed research priorities and funding opportunities in cancer and aging at their respective agencies (see Table 1). In general, discussions targeted opportunities that focused on supportive care, symptom management, and the quality of survivorship in older and/or frail adults with cancer. The primary purpose of this manuscript is to provide an overview of the information presented to assist scholars involved in geriatric oncology research in developing new funding applications. Tips for successful grantsmanship and common application pitfalls are also discussed.

National Institutes of Health (NIH)

The NIH is an agency of the US Department of Health and Human Services comprised of 27 institutes and centers, with a mission to improve health and well-being through health-related research. While we focus on content shared from representatives of NCI and NIA, many additional institutes support studies focused on older adults with cancer (for example, the National Institute of Nursing Research, NINR). Moreover, in recognition of the potential common mechanisms associated with aging that may underlie diverse chronic diseases, the trans-NIH Geroscience Interest Group (GSIG) was formed in 2011. The GSIG, whose members represent a number of different institutes, has as its goals to raise awareness concerning the role of aging biology in chronic disease; promote trans-NIH activities to meet the specific needs of the research community; develop public/private partnerships with scientific societies, industry and other institutions; and develop trans-NIH initiatives to encourage research on the basic biology of aging and its relation to chronic diseases of older adults. This initiative aligns with recognition of the imperative to conduct research on older adults and to examine aging mechanisms that may be amenable to prevention or amelioration across a variety of diseases including cancer.

The NIH supports a variety of independent investigator awards (R series), career development awards (K series), research training (T and F series) and program center grants (P series). Refer to Table #5 for definitions of key funding announcements from NIH. The majority of funded R01 and R21 studies are independent investigator-initiated original research proposals received under the ‘omnibus’ or ‘parent’ funding announcements and not submissions in response to designated or targeted calls for applications. Research topics, however, should be relevant to the specific Institute or Center to which the investigator applies.

The cornerstone of the NIH grant review process is the peer review mechanism. Grants submitted to the NIH go to the Center for Scientific Review which, with few exceptions

(e.g., grants in response to an RFA), coordinates the study sections or review groups that evaluate applications for their scientific merit. Major review criteria include overall impact, significance, innovation, approach, expertise and experience of the research team, and the quality of the research environment. Additional review criteria include protection of human subjects (and vertebrate animals if included), as well as inclusion of women and minorities.

National Institute on Aging (NIA)

The NIA “leads the federal government in conducting and supporting research on aging and the health and well-being of older people” (<https://www.nia.nih.gov/about/mission>). Among the many scientific foci at the intersection of clinical aging research and cancer is expanding attention to non-disease-specific outcomes—particularly functional outcomes—because of the potential adverse impact of cancer and its treatment on daily function. Resilience, the ability to respond appropriately to stressors at all levels from molecular to individual, may be an important framework in which to study cancer treatment approaches and their outcomes. Moreover, interventions aimed at enhancing resilience may reduce vulnerability to adverse effects of cancer and its treatment in older adults. In addition, cancer may occur in the setting of multiple chronic conditions in older adults, which may impact cancer decision-making and outcomes, quality of life, and overall survival. Understanding the interplay at multiple levels among cancer, its treatment, and aging processes is warranted.

As part of its mission to support development of scientists in aging research, the NIA sponsors a special grant program called GEMSSTAR, or Grants for Early Medical/Surgical Specialists’ Transition to Aging Research (see RFA-AG-16-015 for the most recent competition). GEMSSTAR is targeted primarily at early-stage physician-scientists seeking to bridge their medical or surgical specialty with aging research. This grant program is typically a first independent NIH research award, which provides support for investigator effort, project costs, and other research expenses. Successful candidates include in their investigative team senior collaborators with geriatrics or gerontology expertise, and propose separately funded professional development plans to enhance the investigator’s skills and knowledge in aging research. In addition to grant support, GEMSSTAR awardees also participate in regular grantee conferences to promote research career advancement and provide scientific networking opportunities both within and beyond awardees’ clinical specialty. The GEMSSTAR program seeks to address recommendations in the 2008 Institute of Medicine Report, “Retooling for an Aging America: Building the Health Care Workforce (<http://iom.nationalacademies.org/Reports/2008/Retooling-for-an-Aging-America-Building-the-Health-Care-Workforce.aspx>)”.

National Cancer Institute (NCI)

The mission of the NCI is to develop the knowledge base that will reduce the burden of cancer (<http://www.cancer.gov/research/nci-role/extramural>). Focusing specifically on extramural funding opportunities speakers at the conference highlighted NCI-led priorities in cancer survivorship and the development of resources to examine patient reported outcomes (PROs) and evaluate cancer care delivery. The focus on cancer survivorship includes the priority of studying survivorship issues in older adults, the largest population of cancer survivors, yet an understudied group. This includes an emphasis on studies that examine

post-treatment care pathways (Examination of Survivorship Care Planning Efficacy and Impact PA-12-274 and PA-12-275; <http://grants.nih.gov/grants/guide/pa-files/PA-12-274.html> and <http://grants.nih.gov/grants/guide/pa-files/PA-12-275.html>), promotion of healthy lifestyles and their potential contribution to disease morbidity and mortality (Energy Balance PA-15-311 and PA-15-310; <http://grants.nih.gov/grants/guide/pa-files/PA-15-311.html> and <http://grants.nih.gov/grants/guide/pa-files/PA-15-310.html>), and examining and intervening on the impact of a cancer diagnosis on informal caregivers (<http://cancercontrol.cancer.gov/ocs/resources/icc-meeting.html>).

NCI has also led efforts to improve assessment of outcomes for older cancer patients. An NCI-led NIH-wide Roadmap project supported the development of the Patient Reported Outcomes Measurement Information System (PROMIS) bank of self-report tools (<http://www.nihpromis.org/?AspxAutoDetectCookieSupport=1#2>). Components of this toolkit are designed to permit assessment of individuals. Measures have been tested among older cancer survivors and are publicly available for use in clinical studies. In a complementary effort, NCI supported the development of the Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE)(1).

PRO-CTCAE was developed as a companion to clinician ratings of toxicity using the Common Terminology Criteria of Adverse Events (CTCAE), the internationally accepted system for grading adverse treatment effects in cancer clinical trials. Of the nearly 800 toxicities included in the CTCAE, approximately 10% are subjective symptoms such as pain, fatigue and nausea that are best evaluated by gathering information directly from patients. The PRO-CTCAE was specifically designed to capture symptomatic adverse treatment effects from the patient's perspective. The PRO-CTCAE item library is comprised of 124 PRO items reflecting 78 symptom terms, with each term assessed relative to one or more attributes, including presence/absence, frequency, severity, and/or interference with usual or daily activities. It includes items that capture the full range of symptomatic treatment effects that may be experienced across a variety of disease sites and cancer treatment modalities. PRO-CTCAE may have a role in studies to optimize treatment dosage and schedule, and to improve supportive management in older adults receiving cancer treatment. As the experience of adverse events is known to be associated with poorer physical function and comorbidity, studies examining the use of PROs to improve clinical outcomes for older adults receiving cancer treatment are a critical priority(2). In an ongoing NCI-funded project, investigators are examining the use of PRO-CTCAE, together with other patient-reported outcomes and comprehensive geriatric assessment, to promote early detection and optimal supportive care management in an effort to improve treatment tolerability in older adults initiating treatment for a solid malignancy(2) (ClinicalTrials.gov Identifier: NCT02054741).

In addition to PRO tools, the NCI is investing in research infrastructures that provide broader access to older adult cancer patients and survivors. The NCI Community Oncology Research Program (NCORP) is a national network of investigators, cancer care providers, and academic and community organizations. The NCORP network supports the conduct of multisite clinical trials and cancer care delivery research in diverse populations in a network of community-based oncology centers across the US. The community network provides

access to diverse populations, including minority and underserved patients, receiving cancer care in real-world settings. As the majority of older adults receive cancer care in the community setting, the NCORP infrastructure provides an ideal setting to conduct cancer clinical trials, as well as symptom management and cancer care delivery research with older adults during and following cancer treatment(3–5). Research in this network is aimed at reducing cancer risk and incidence; improving cancer care outcomes; expanding access to oncology clinical trials and cancer care delivery studies; and reducing cancer disparities (<http://ncorp.cancer.gov/>).

American Cancer Society

ACS is the nationwide, community-based voluntary health organization dedicated to preventing cancer, saving lives, and diminishing suffering from cancer through research, education, advocacy and service. Research is prominent in the Society's mission and is essential to their goal of creating a world with less cancer and more birthdays. ACS's mission priority areas include: lung cancer/tobacco control, preventing cancer through nutrition and physical activity, colorectal cancer control, breast cancer control, improving access to health care, and improving cancer treatment and patient care. Improved treatment, care and access to care are areas that resonate with geriatric oncologists; however, all priority areas have a potential fit with researchers interested in cancer and aging.

ACS is the largest private, not-for-profit funder of cancer research in the United States and has funded research for nearly 70 years. ACS has both intramural and extramural research departments. The Intramural Research Program staff conduct original cancer research in epidemiology, surveillance, health behavior, and health economics. The department also produces important resources for researchers including the annual Cancer Facts and Figures report, the more recently developed biennial Cancer Treatment and Survivorship Facts and Figures report, and the Cancer Atlas(6, 7) (<http://canceratlas.cancer.org/>). However, the majority of the research budget, 79% (\$95.5 million in CY2014), goes toward funding external researchers. For more information on current funding breakdown by areas of research or by cancer type see the ACS website (<http://www.cancer.org/research/currentlyfundedcancerresearch/index>).

The Extramural Grants Department is organized into six program areas. Research proposals in cancer and aging can potentially fit in any of these programs. Details on each program are available on the ACS website. Here, we highlight three programs that are most relevant to the conference focus on survivorship and quality of life. The *Clinical Cancer Research, Nutrition, and Immunology* program focuses on investigations including basic, preclinical, clinical, and epidemiological studies and seeks to fund research on new modalities for cancer prevention, diagnosis and treatment. In addition, the program seeks to improve understanding of cancer-related inflammatory responses, immunosurveillance, and the use of the immune system for cancer prevention and therapy. The program also focuses on exposome links to cancer and increased understanding of the effects of nutrition and the environment on cancer prevention, initiation, progression and treatment. The *Cancer Control and Prevention Research* program, focuses on the development and testing of interventions to influence health behaviors and health care delivery. Research projects in this program

focus on cancer risk reduction and delivery of high quality health promotion, screening, early detection and treatment services. The program also includes projects directed at health services, outcomes and policy research to assess the effectiveness of interventions and impact of policies on access to care, quality of care, and costs of cancer care. Special emphasis is placed on health equity research addressing disparities in disadvantaged groups, and social determinants of health that drive inequities. The *Health Professional Training in Cancer Control* program aims to accelerate the wide application of research findings in cancer prevention and control by increasing the number of nursing and social work clinicians, and researchers and physicians with expertise and career commitment to cancer control. By contacting the Program Director who orchestrates the individual program early in the application process, applicants can receive advice at all stages of the grant process; from application development, to responding to reviewer comments, to expanding collaborative relationships and improving grantsmanship skills.

ACS has multiple funding mechanisms that include both training and research project support. A full list of available research grant mechanisms and health professional training awards can be found on the ACS website [www.cancer.org/research]. A recent change now allows Intramural Researchers at ACS to serve as collaborators on a grant application. ACS research grants primarily focus on early investigators and can fund research across the cancer continuum in aging. *Mentored Research Scholar Grants* (MRSRG) provide support for mentored investigator-initiated research and training (up to \$135,000/year direct costs for five years including up to \$10,000/year for the mentor; indirect costs may be up to 8%) to full-time clinical, cancer control or cancer prevention researchers in the first four years of their initial faculty appointment. An example of a currently funded MRSRG relevant to cancer and aging is by Dejana Braithwaite, PhD, MS titled “Breast Cancer Screening and Outcomes: Role of Comorbidity.”

Research Scholar Grants (RSG) fund independent investigators within the first six years of their independent careers to conduct research (up to \$165,000/year direct costs up to 4 years; indirect costs may be up to 20%). Examples of currently funded RSGs relevant to cancer and aging include “Identifying Key Telomerase Activity Patterns in Human Cells” by Bradley Stohr, MD, PhD and “Control of Telomere Recombination in Human Cells” by Lifeng Xu, PhD. For more information on currently funded projects see <http://www.cancer.org/research/currentlyfundedcancerresearch>.

Health equity is a priority area in the Cancer Control and Prevention Research Program. Investigators proposing health equity research have expanded eligibility and may apply for funding while at any career stage. Furthermore, investigators proposing population-based health equity research in psychosocial, behavioral, health policy, or health services research may propose up to 5 years and up to \$400,000 per year in direct cost. A strong argument can be made that older adults represent a potential health disparity population in the realm of cancer care due to the long standing pattern of underrepresentation of older cancer patients in cancer-related clinical research(8, 9); further, older compared to younger survivors experience a greater impact from cancer and cancer treatment(s) on their functioning levels due to higher numbers of comorbidities and age-related disabilities commonly present before the cancer diagnosis(10, 11).

There are also two current Requests for Applications (RFAs), or research initiatives with dedicated funding, that are open to any stage investigator. The *Pilot and Exploratory Projects in Palliative Care of Cancer Patients and their Families* RFA supports investigators performing pilot and exploratory research studies that test interventions, develop research methodologies, and explore novel areas of research in palliative care of cancer patients and their families. The *Role of Health Policy and Health Insurance in Improving Access to and Performance of Cancer Prevention, Early Detection, and Treatment Services* RFA calls for research assessing the impact of changes in national, state, and/or local policy and the response to these changes by healthcare systems, insurers, payers, communities, practices, and patients.

The peer review process at the ACS is very similar to the peer review process at the NIH. Applications are assigned to a Peer Review Committee of on average 12 to 25 experts plus up to three stakeholders, individuals without formal training as a scientist or health professional but someone who has a strong personal interest in advancing the effort to control and prevent cancer through research and training. There is also strong representation by clinicians on review panels. All application are assigned to at least two reviewers who provide a comprehensive critique and rate the scientific merit and overall impact the proposed research. Applications are evaluated based on some or all of the following criteria depending on the specific award: (a) significance, (b) cancer relevance, (c) novelty or importance, (d) approach, (e) the productivity and promise of the investigator and study team, and (f) the research or training environment. In addition, mentored and training grant reviews include evaluation of the mentoring team and training plan. Unfunded RSG and MRSRG applications can be revised and resubmitted up to two times.

Patient-Centered Outcomes Research Institute

Authorized by Congress in 2010, PCORI is an independent nonprofit, non-governmental organization that funds comparative effectiveness research (CER). PCORI uses a contract mechanism to fund CER studies that conduct patient-centered outcomes research (PCOR) to address real-world questions about what works best for patients based on their unique circumstances and concerns and focuses on outcomes that are most important to patients. As stated in its mission, “PCORI helps people make informed healthcare decisions, and improves healthcare delivery and outcomes, by producing and promoting high-integrity, evidence-based information that comes from research guided by patients, caregivers, and the broader healthcare community.” A unique component of this agency is the strong emphasis on engaging patients, caregivers and other key stakeholders in all phases of the research process. (<http://www.pcori.org/about-us>)

PCORI has identified the following five national research priorities that are addressed by its five scientific programs: 1) Assessment of Prevention, Diagnosis and Treatment Options, 2) Improving Healthcare Systems, 3) Communication and Dissemination Research, 4) Addressing Disparities, and 5) Accelerating Patient-Centered Outcomes Research and Methodological Research. As of August 2015, PCORI has funded 440 projects totaling more than \$1 billion addressing its five national priorities in a variety of settings including geriatric oncology.

Periodic PCORI funding announcements (PFAs) are released over three cycles every year under two different mechanisms. First, each scientific program releases a broad PFA, emphasizing the unique research priorities of the program. These PFAs by definition are broad in scope and primarily seek investigator-initiated applications. All the programs fund studies with a maximum of \$1.5 million in direct costs over a three year period of performance. In addition, the Improving Healthcare Systems program also supports large applications up to \$5 million in direct costs over a 5 year period. Second, the “Pragmatic Clinical Studies to Evaluate Patient-Centered Outcomes” (PCS) is another funding mechanism which supports large pragmatic studies that compare two or more alternatives for addressing prevention, diagnosis, treatment, or management of a disease or symptom; improving healthcare system-level approaches to managing care; or for eliminating health or healthcare disparities. Unlike the broad PFAs, the PCS PFA outlines specific research topics that PCORI is interested in funding. Through this mechanism, investigators can request up to \$10 million in direct costs over a five year period. “A Pragmatic Trial to Improve Colony Stimulating Factor Use in Cancer” led by Scott D. Ramsey, MD, PhD at the Fred Hutchinson Cancer Research Center is one exemplary oncology study recently funded through the PCS mechanism.

In addition to the periodic PFAs, PCORI may also solicit applications for one-time, adhoc, targeted PFAs that focus on high priority research questions that may be specific to a disease condition, patient population, or type of intervention. For example, PCORI and the NIA have collaborated to fund a five-year, \$30 million national study to prevent injurious falls among community-dwelling older adults.

Regardless of the funding mechanism, PCORI adheres to a strict set of unique requirements for all funded CER contracts. They must meaningfully engage patients and other stakeholders throughout the research process, adhere to the PCORI Methodology Standards, and include well-articulated comparators with established efficacy or effectiveness. PCORI will not fund studies proposing to test the efficacy of a new intervention, develop new instruments, perform a cost effectiveness analysis, or conduct bench science. Inclusion of any of the aforementioned components will automatically deem the proposal nonresponsive, and therefore, not fundable. All funding opportunities and resources for applicants including application guidelines and templates are posted on the PCORI website. Public abstracts of all funded studies are also available for reference on the website. Table #4 was assembled to provide successful grantsmanship tips for research submitted for PCORI funding.

PCORI Merit Review is a multi-phase process that includes evaluation of Letters of Intent (a limited number are invited for full application submission); review of full applications by multi-stakeholder panels that include scientists (topic specific experts, methodologists, and statisticians), patients and caregivers, and other relevant stakeholders; and final approval by the Board of Governors during a publicly-available teleconference. Applications are reviewed against the following criteria (excluding methods proposals): 1) impact of the condition on the health of individuals and populations, 2) potential for the study to improve health care and outcomes, 3) technical merit, 4) patient-centeredness, and 5) patient and stakeholder engagement.

Funding opportunities at PCORI are consistent with a clinical research focus of geriatric oncology. For example, discussions during the conference concluded that more CER is needed to match clinical treatments for older and/or frail adult cancer patients with their individual needs and preferences, especially when two or more equally efficacious options are available. PCORI's unique mission and requirement of involving patient stakeholders in all phases of the research process is consistent with geriatric oncology values to enhance the patient's and caregiver's voices in defining their goals of care and priorities. Exemplary studies funded by PCORI exploring these issues include "Improving Advanced Cancer Patient-Centered Care by Enabling Goals of Care Discussions" led by Nina Bickell, MD, MPH of the Mount Sinai School of Medicine; "Tools and Information to Guide Choice of Therapies in Older & Medically Infirm Patients with Acute Myeloid Leukemia" led by Mohamed Lotfy Sorrow, MD, MS of the Fred Hutchinson Cancer Research Center, and "Improving Communication for Chemotherapy: Addressing Concerns of Older Cancer Patients and Caregivers" led by Supriya Mohile, MD, MS of the University of Rochester.

As of August 2015, PCORI has funded 50 scientific projects in cancer totaling \$132 million; cancer studies form the largest disease-specific PCORI-funded portfolios. These studies have focused on all aspects of the cancer continuum from prevention, screening, diagnosis, treatment, post-treatment survivorship, and end-of-life. Despite a well-developed cancer portfolio, the elderly and individuals with multiple chronic conditions remain priority patient populations of interest to PCORI and investigators are encouraged to pursue PCORI funding for CER studies in geriatric oncology.

Conclusion and Summary

Research priorities, funding mechanisms, and review processes for the NIH (NIA & NCI), ACS, and PCORI were presented with a specific focus on opportunities relevant for interventions to improve quality of life and survivorship for older/ frail adults with cancer. The intersection of aging and cancer, and efforts to improve the delivery of supportive, rehabilitative, and survivorship care to older adults are an important priority for all three agencies. Regardless of the source of funding, a cardinal tenant is that to receive funding, a research proposal needs a good idea that is well written, follows agency guidelines and stands up to rigorous peer review. Readers are encouraged to review the helpful tips for writing a good research proposal and common application problems provided in tables. While content on specific funding announcements is included here, readers are reminded that many initiatives are time-limited, and new funding announcements are continually being released. As an additional resource we have included funding announcements which are posted on the Cancer and Aging Research Group (CARG) website in Table #6. The CARG website is updated regularly, and readers are encouraged to visit the website for the most up to date announcements that may be relevant.

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References

1. Basch E, Reeve BB, Mitchell SA, Clauser SB, Minasian LM, Dueck AC, et al. Development of the National Cancer Institute's patient-reported outcomes version of the common terminology criteria for adverse events (PRO-CTCAE). *J Natl Cancer Inst.* 2014 Sep.106(9) PubMed PMID: 25265940. Pubmed Central PMCID: PMC4200059. Epub 2014/10/01. eng.
2. Ngeow J, Leong SS, Gao F, Toh CK, Lim WT, Tan EH, et al. Impact of comorbidities on clinical outcomes in non-small cell lung cancer patients who are elderly and/or have poor performance status. *Crit Rev Oncol Hematol.* 2010 Oct; 76(1):53–60. PubMed PMID: 19939700. Epub 2009/11/27. eng. [PubMed: 19939700]
3. Lloyd Wade J 3rd, Petrelli NJ, McCaskill-Stevens W. Cooperative Group Trials in the Community Setting. *Semin Oncol.* 2015 Oct; 42(5):686–692. PubMed PMID: 26433550. Epub 2015/10/05. eng. [PubMed: 26433550]
4. McCaskill-Stevens W, Lyss AP, Good M, Marsland T, Lilenbaum R. The NCI community oncology research program: what every clinician needs to know. American Society of Clinical Oncology educational book / ASCO American Society of Clinical Oncology Meeting. 2013 PubMed PMID: 23714464. Epub 2013/05/30. eng.
5. Kent EE, Mitchell SA, Castro KM, DeWalt DA, Kaluzny AD, Hautala JA, et al. Cancer Care Delivery Research: Building the Evidence Base to Support Practice Change in Community Oncology. *J Clin Oncol.* 2015 Aug 20; 33(24):2705–2711. PubMed PMID: 26195715. Pubmed Central PMCID: PMC4559611. Epub 2015/07/22. eng. [PubMed: 26195715]
6. American Cancer Society. Cancer Facts & Figures 2015. Atlanta: 2015.
7. American Cancer Society. Cancer Treatment and Survivorship Facts & Figures 2014–2015. Atlanta: 2014.
8. Dale W, Mohile SG, Eldadah BA, Trimble EL, Schilsky RL, Cohen HJ, et al. Biological, clinical, and psychosocial correlates at the interface of cancer and aging research. *J Natl Cancer Inst.* 2012 Apr 18; 104(8):581–589. PubMed PMID: 22457474. Pubmed Central PMCID: PMC3328422. Epub 2012/03/30. eng. [PubMed: 22457474]
9. Hurria A, Dale W, Mooney M, Rowland JH, Ballman KV, Cohen HJ, et al. Designing therapeutic clinical trials for older and frail adults with cancer: U13 conference recommendations. *J Clin Oncol.* 2014 Aug 20; 32(24):2587–2594. PubMed PMID: 25071116. Pubmed Central PMCID: PMC4129504. Epub 2014/07/30. eng. [PubMed: 25071116]
10. Mohile SG, Xian Y, Dale W, Fisher SG, Rodin M, Morrow GR, et al. Association of a cancer diagnosis with vulnerability and frailty in older Medicare beneficiaries. *J Natl Cancer Inst.* 2009 Sep 2; 101(17):1206–1215. PubMed PMID: 19638506. Pubmed Central PMCID: PMC3937788. Epub 2009/07/30. eng. [PubMed: 19638506]
11. Hewitt M, Rowland JH, Yancik R. Cancer survivors in the United States: age, health, and disability. *J Gerontol A Biol Sci Med Sci.* 2003 Jan; 58(1):82–91. PubMed PMID: 12560417. Epub 2003/02/01. eng. [PubMed: 12560417]

Table #1

Websites for Detailed Information

Websites for Information	Home Page	Funding Home Page
NCI	http://www.cancer.gov/	http://www.cancer.gov/grants-training
NIA	https://www.nia.nih.gov/	https://www.nia.nih.gov/research
PCORI	http://www.pcori.org/	http://www.pcori.org/funding-opportunities
ACS	http://www.cancer.org/index?_ga=1.142319415.403530104.1432132574	http://www.cancer.org/research/applyforaresearchgrant/index
CARG	http://www.mycarg.org/	http://www.mycarg.org/grant_opportunities

Table #2**Top Ten Tips for Successful Grantsmanship for NIH and ACS Applications**

Top Ten Tips	
1.	DO YOUR HOMEWORK: Go online and look for relevant funders and funding announcements.
2.	DO NOT WAIT for an RFA (set aside funding) or a specific FOA: If there is a gap in the science and you have a good idea to pursue prepare an application. Let the science guide your application. Do not contort your application to a funding announcement that does not really fit.
3.	TALK TO YOUR PROGRAM OFFICER: Talk early, often and after the review if your application did not fare well. Prior to review, ask the Program Officer whether your ideas are of interest to the funder, and who might be the best champion for this work. Review the study section rosters and consider which study sections have on their panel reviewers with the requisite expertise to evaluate the application's merits.
4.	FOLLOW DIRECTIONS: For requested format, content, receipt dates, etc.
5.	START EARLY: Be willing to write and rewrite your application.
6.	WRITE WITH THE REVIEWER IN MIND: Remember that scientific peer review is you. Most reviewers want to be your advocate, but your job is to convince these individuals that what you want to do is exciting, important, well-thought out, and that you are the right person/team to do it.
7.	CRITIQUE: Obtain peer review and critique prior to submission.
8.	PERSISTENCE: The majority of applications received are NOT funded on the first submission.
9.	MULTIPLE FUNDERS: Do not send your bright ideas to only one funder (i.e., do not put all your eggs in one basket). Funding sources such as foundations, charitable organizations, patient advocacy groups, and professional societies can be an important source of funding for pilot studies.
10.	FOCUS AND SIMPLIFY: Ensure that your aims are connected, focus around a well-defined question or theme, and proceed logically toward your short- and long-term research goals. When in doubt, simplify your aims.

Table #3**Most Common Application Problems for NIH and ACS Submissions**

Significance:	
▪	Absence of an acceptable scientific rationale
▪	Low likelihood for substantial impact
Approach:	
▪	Questionable reasoning in experimental approach
▪	Uncritical approach; failure to mention potential limitations
▪	Diffuse, superficial, or unfocused research plan
▪	Lack of sufficient methodological detail
▪	Lack of knowledge of published relevant work
▪	Unrealistically large amount of work
▪	Uncertainty concerning future directions
Innovation:	
▪	Lack of new or original ideas
▪	Lack of innovative methodologies or approach
Investigators:	
▪	Lack of experience in the essential methodology
▪	Lack of evidence of previous collaboration among key study members (more important for larger studies than for smaller or exploratory/developmental studies)
Environment:	
▪	Lack of institutional resources necessary to accomplish the proposed work

Table #4**Top Ten Tips for Successful Grantsmanship and Ten Common Mistakes to avoid for PCORI Applications**

Successful PCORI Letters of Intent (LOIs) and Applications	
1. Test intervention(s) with established efficacy or that are in widespread common use	<ul style="list-style-type: none"> Cite prior studies that establish the efficacy of the proposed intervention(s); or describes pilot data. Efficacy or pilot data from a similar established intervention <i>may</i> be considered. If the intervention to be tested in the CER trial is in widespread use with limited established efficacy data, widespread use must be clearly demonstrated with significant evidence.
2. Propose a CER study and articulate clear comparators	<ul style="list-style-type: none"> The interventions (or comparators) being tested in the study must be well-articulated. PCORI is especially interested in head-to-head comparisons of different interventions; usual care may be an acceptable comparator if it is justified and specifically described.
3. Measure patient-centered outcomes identified by patients themselves as important	<ul style="list-style-type: none"> The outcomes being evaluated are important to patients, in addition to other key stakeholders.
4. Outline strong, specific research design	<ul style="list-style-type: none"> The research design must be appropriate for the study. Provide clear and detailed information on the comparators, target population, sample size and associated power analyses, anticipated effect size, recruitment and enrollment plans, and primary and secondary outcomes. The sample size should be large enough to facilitate tests of heterogeneity of treatment effects across multiple subgroups
5. Engage patients, caregivers and other key stakeholders throughout the research process	<ul style="list-style-type: none"> The study's engagement plan should clearly outline plans to meaningfully engage patients, caregivers and other key stakeholders throughout the entire duration of the study.
6. Account for the real-world environment (account for barriers, but also leverage opportunities)	<ul style="list-style-type: none"> Account for the real-world environment in which the research is to be conducted. This means that potential barriers for conducting the study are described and addressed and plans to leverage opportunities (e.g., changes in reimbursement) are described.
10. Common Mistakes to Avoid When Submitting a LOI or Research Application to PCORI	
1.	The LOI or application addresses a research question of potential interest to PCORI, but does not translate the idea into a well-articulated CER study.
2.	The plans for patient and stakeholder engagement as described in the application are limited and inadequate.
3.	The LOI or application proposes an intervention that is likely to have limited impact on outcomes that matter to patients.
4.	The LOI or application proposes to develop the intervention during the study, or to conduct a feasibility or acceptability study.
5.	The LOI or application lacks critical scientific information including limited discussion on the study design, lack of well-specified power calculations, or unclear recruitment and enrollment plans.
6.	The LOI or application proposes a study that exceeds the maximum duration and/or direct costs of the award as outlined in the PFA.
7.	The proposed study duplicates work already funded by PCORI. Applicants should check the PCORI funded awards section of the PCORI website to ensure their study is not redundant with existing awards.
8.	A formal cost effectiveness analysis is included in the proposed study. Note, general estimates of total cost to the system, or out of pocket costs to patients are acceptable but a formal cost effectiveness analysis is not.
9.	Usual care is proposed as a comparator but the elements of usual care are not clearly defined.
10.	The proposed study focuses on developing clinical guidelines.

Table #5

NIH Categories of Funding Opportunity Announcements (FOAs)

Funding Announcement	Definitions
Program Announcement (PA)	Broad scope, usually no set aside funds.
Program Announcement with Set-Aside (PAS)	Broad scope, usually recurring; set aside funds ; review considerations vary.
Program Announcement with special Receipt, Referral, and/or Review considerations (PAR)	Broad scope, usually no set-aside funds; special receipt, referral, and/or review considerations .
Request for Application (RFA)	Focused scope; usually one time, set-aside funds; special receipt, referral, and review considerations.

Table #6

Funding Opportunities from Cancer and Aging Research Group Website:

PROGRAM ANNOUNCEMENTS THAT MAY BE RELATED TO CANCER AND AGING RESEARCH

Advancing the Science of Geriatric Palliative Care (R01)
<http://grants.nih.gov/grants/guide/pa-files/PA-13-354.html>

Advancing the Science of Geriatric Palliative Care (R21)
<http://grants.nih.gov/grants/guide/pa-files/PA-13-355.html>

Advancing the Science of Geriatric Palliative Care (R03)
<http://grants.nih.gov/grants/guide/pa-files/PA-13-356.html>

Testing Interventions for Health-Enhancing Physical Activity (R01)
<http://grants.nih.gov/grants/guide/pa-files/PA-14-315.html>

Developing Interventions for Health-Enhancing Physical Activity (R21/R33)
<http://grants.nih.gov/grants/guide/pa-files/PA-14-321.html>

Self-Management for Health in Chronic Conditions (R01)
<http://grants.nih.gov/grants/guide/pa-files/PA-14-344.html>

Behavioral Interventions to Address Multiple Chronic Health Conditions in Primary Care (R01)
<http://grants.nih.gov/grants/guide/pa-files/PA-14-114.html>

Grants for Early Medical/Surgical Subspecialists' Transition to Aging Research (GEMSSTAR) (R03)
<http://grants.nih.gov/grants/guide/rfa-files/RFA-AG-16-015.html>

Conference Grants to Advance Collaborative Research on Aging Biology (R13)
<http://grants.nih.gov/grants/guide/pa-files/PA-15-265.html>

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