COMMENTARY

NCI Funding Trends and Priorities in Physical Activity and Energy Balance Research Among Cancer Survivors

Catherine M. Alfano*, Shirley M. Bluethmann, Gina Tesauro, Frank Perna, Tanya Agurs-Collins, Joanne W. Elena, Sharon A. Ross, Mary O’Connell, Heather R. Bowles, Deborah Greenberg, Linda Nebeling

Affiliations of authors: Behavioral Research Program (CMA, SMB, GT, FP, TAC, MO, DG, LN) and Epidemiology and Genomics Research Program (IWE), Division of Cancer Control and Population Sciences, National Cancer Institute, Bethesda, MD; Nutrition Science Research Group (SAR) and Biometry Research Group (HRB), Division of Cancer Prevention, National Cancer Institute, Bethesda, MD.

*Current affiliation: American Cancer Society, Inc.

Correspondence to: Catherine M. Alfano, PhD, American Cancer Society, Inc., 555 11th Street NW Suite 300, Washington, DC 20004 (e-mail: catherine.alfano@cancer.org).

Abstract

There is considerable evidence that a healthy lifestyle consisting of physical activity, healthy diet, and weight control is associated with reduced risk of morbidity and mortality after cancer. However, these behavioral interventions are not widely adopted in practice or community settings. Integrating health behavior change interventions into standard survivorship care for the growing number of cancer survivors requires an understanding of the current state of the science and a coordinated scientific agenda for the future with focused attention in several priority areas. To facilitate this goal, this paper presents trends over the past decade of the National Cancer Institute (NCI) research portfolio, fiscal year 2004 to 2014, by funding mechanism, research focus, research design and methodology, primary study exposures and outcomes, and study team expertise and composition. These data inform a prioritized research agenda for the next decade focused on demonstrating value and feasibility and creating desire for health behavior change interventions at multiple levels including the survivor, clinician, and healthcare payer to facilitate the development and implementation of appropriately targeted, adaptive, effective, and sustainable programs for all survivors.

There were an estimated 14.5 million cancer survivors living in the United States in 2014 (1). This number is forecasted to increase substantially in the next decade because of the aging of the population and improved cancer survival rates (2,3). Numerous reports document that cancer survivors are at risk for recurrence, second cancers, and organ toxicities from treatment that may contribute to poor mental health and new or exacerbated comorbidities (4–8). Thus, research in the last decade has focused on identifying and mitigating these negative sequelae of cancer and supporting healthy living and healthy aging after cancer. There is now a considerable body of research suggesting a healthy lifestyle, including physical activity, healthy diet, and weight control, is associated with reduced risk of morbidity and mortality after cancer, while more limited research suggests activities to maintain muscle mass may also be helpful (eg, see [9–12] for reviews).

An Institute of Medicine report calls for lifestyle recommendations as a standard part of the cancer survivorship care plan to optimize health and well-being after cancer treatment (13). A recent position statement from the American Society of Clinical Oncology underscores the commitment of the oncology community to include strategies to promote exercise and weight control as part of survivorship care (14). As yet, these interventions are not widely available in clinical or community settings...
(15,16) and the ultimate goal of research efforts in this area must be to develop and implement appropriately targeted, adaptive, effective, and sustainable programs for all survivors. Providing research evidence necessary to integrate health behavior change interventions into standard survivorship care will take an understanding of the current state of the science, analysis of gap areas, and a coordinated research agenda for the future with focused attention in several priority areas. True understanding of the state of the science comes from the integration of synthesized published data (described in systematic reviews and meta-analyses) and, given possible publication bias, a description of the studies that are funded. To assist with the latter, this manuscript analyzes trends in the National Cancer Institute (NCI)-funded research portfolio from FY 2004 to 2014. It offers a prioritized research agenda to address critical gaps identified by the portfolio analysis to accelerate translation of scientific findings into care that improves the lives of cancer survivors.

**Methods**

**Portfolio Analysis Methods**

This analysis examined all awarded grants focused on physical activity, diet, weight, and body composition alone, or in combination, among cancer survivors identified through the internal NIH database of extramural grants. The analysis was limited to grants funded between fiscal years (FY) 2004 and 2014 for which NCI was the primary funder. Grant abstracts, project titles, and project-specific aims were searched for keywords by NCI program staff to determine whether grants met inclusion criteria. We identified the NCI portfolio of grants focused on physical activity, diet, weight, or body composition using the following search terms: physical activity, exercise, fitness, sedentary behavior(s), diet, dietary, nutrition, obesity, weight, fat mass, body mass index, body composition, and energy balance. Then these projects were searched to determine whether the studies focused on cancer survivors using the following search terms: survivor(s), survivorship, patients, quality of life, late effects, long-term effects, and newly diagnosed. To assess coding reliability, 10% of grants were randomly selected to be coded and discussed by NCI program staff. Few discrepancies were noted, and these were resolved through discussion until consensus was reached.

Grants included in this analysis assessed cancer survivors at any stage of the survivorship continuum (ie, newly diagnosed through long-term survivorship, with or without active disease). Included grants were either observational or interventions designed to increase health behaviors or test the effects of health behavior interventions on symptoms, quality of life, or clinical outcomes including survival. Grants focused exclusively on examining the relationships between physical activity, diet, weight, or body composition and cancer risk (etiology) were excluded. Given the focus on diet in the context of weight/energy balance and to be consistent with a prior NCI portfolio analysis in prevention and survivorship (17), we also excluded grants focused on dietary supplements or single nutrients. We further excluded training awards (ie, K, T, and F-award mechanisms), cancer center infrastructure grants, and conference grants. We also excluded grants focused on the sequelae of obesity (eg, insulin resistance) without measurement of physical activity, diet, weight, or body composition and those focused on cachexia or on physical therapy modalities (eg, swallowing exercises) that were not physical activity (aerobic, strength/resistance training, and/or flexibility) programs.

**Portfolio Coding and Analysis**

Data from grants that met inclusion criteria were abstracted and reviewed by NCI program staff members who administer this portfolio of research grants to examine trends over time in five categories (see Table 1). These were: 1) funding mechanism and response to specific funding announcements; 2) research area (physical activity, diet, weight, or body composition) components alone or in combination; 3) research design (observational vs intervention; translational research phase T0-T4 (18); study population; then for human studies, participant age, cancer and treatment type, time since diagnosis; mode of intervention delivery and timing of last outcome measure); 4) primary study exposures and outcomes; and 5) study team expertise and composition. To document the field of each investigator on the study team, highest degrees obtained from grant biosketches were categorized based on fields of study identified in the National Science Foundation’s Doctoral Record File (19).

We present trends between FY 2004 and 2014 in the portfolio of awarded grants according to these factors. Because of the small numbers of grants per year, trends (eg, increasing, stable over time) were determined descriptively rather than statistically.

**Portfolio Analysis Results**

**Trends in the NCI-Funded Portfolio Over Time**

The initial query of physical activity, diet, weight, and body composition terms yielded 1661 grants funded between FY 2004 and 2014. Limiting this list to grants that included the cancer survivor terms left 522 grants. However, 75% of those 522 were excluded (most were cancer etiology rather than survivorship), resulting in a portfolio of 129 grants with a focus on physical activity, diet, weight, and body composition among cancer survivors. Because four grants were multiproject grants, part of the Transdisciplinary Research on Energetics and Cancer (TREC) initiative (http://www.treescience.org/trec/default.aspx), the seven relevant projects contained within these four grants were coded separately. Thus, the portfolio analysis results presented here are for 132 distinct projects.

Awards were made to 55 distinct institutions and to 99 distinct principal investigators (PIs). Thirty-three percent of grants (n = 43) were awarded to new/early-stage investigators, similar to the National Institutes of Health (NIH) average of 39% (20). The majority of projects were human studies (n = 125); seven projects included animal components.

Overall, the trend from FY 2004 to 2014 shows increases in the number of funded grants focused on physical activity, diet, weight, and body composition over time (see Figure 1) until FY 2013 and 2014, when the NCI awarded fewer grants in this area consistent with reduced funding overall; however, the number of grants in any given year is relatively small. There was a spike in funding in FY 2009 corresponding to the increased NCI budget from the American Recovery and Reinvestment Act (ARRA).

Table 2 presents the overall trends in the NCI-funded portfolio over time, with specifics noted below:

**Trends by Funding Mechanisms**

Overall, almost 50% (n = 61) of funded grants were R01s, 29% were R21s (n = 37), and 18% were R03s (n = 23). Over FY 2004 to 2014, there was a trend toward more R01s and R21s and fewer R03s.
Most (n = 109/132) projects had a physical activity component, followed by a focus on weight (n = 62), diet (n = 59), and body composition (n = 24). Most projects (83%) that included diet, weight, or body composition components focused on multiple research areas (n = 75); however, 40% of the projects that included a physical activity component focused solely on physical activity (n = 42). During FY 2004 to 2014, there was an upward trend in the number of physical activity, diet, and weight control grants, until FY 2013 and 2014, when the numbers of funded grants decreased (see Figure 1). There were few projects on body composition across time.

**Trends in Research Design**

Among awards focused on physical activity, more experimental studies (n = 64) were funded than observational studies (n = 44), whereas the reverse was true for weight control studies (n = 36).
observational vs n = 26 intervention studies). For diet and body composition, approximately equal numbers of intervention and observational studies were funded. Across content areas, the trend toward increased funding for intervention studies over observational studies began in approximately 2009 (see Figure 2). All studies focused on T0-T2 (discovery and initial testing) phases. No T3 or T4 research (dissemination and implementation) was funded in this timeframe.

Most projects focused on breast cancer (n = 60), prostate cancer (n = 20), colorectal cancer (n = 18), and lung cancer (n = 6) survivors. A minority of grants focused on pediatric patients (n = 8) or adults over age 65 years (n = 6); no projects focused exclusively on adolescents or young adults, 16 targeted a specific race/ethnic group, and few projects targeted other special populations (eg, rural [n = 2], Spanish-speaking survivors [n = 1], etc.). Most (n = 83) studies were conducted with post-treatment survivors.

### Table 2. Trends in the NCI-funded grant portfolio over time*

<table>
<thead>
<tr>
<th>Domain</th>
<th>Trends by funding mechanisms</th>
<th>Trends by research area</th>
<th>Trends in research design: methodology</th>
<th>Trends in research design: study population</th>
<th>Trends in research design: intervention details (n = 72)</th>
<th>Trends in primary study exposures and outcomes: intervention studies</th>
<th>Trends in primary study exposures and outcomes: observational studies</th>
<th>Trends in study team expertise and composition</th>
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<tbody>
<tr>
<td></td>
<td>Consistently over 50% R01</td>
<td>Consistently more physical activity grants than weight, diet, or body composition</td>
<td>Physical activity grants: consistently more experimental than observational grants; weight control grants: consistently fewer experimental than observational grants</td>
<td>Stable across time: 46% breast cancer</td>
<td>Stable across time: 65% deliver interventions in person; 14% use mobile health technologies</td>
<td>Stable across time: physical activity was the most common exposure (71%) and the most common outcome (38%)</td>
<td>Stable across time: weight was the most common exposure (35%); survival was the most common outcome (30%)</td>
<td>Stable across time: 16 diverse fields of principal investigator expertise with psychology the most common</td>
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<td></td>
<td>Trend toward more R01s and R21s and fewer R03s</td>
<td>Increased number of physical activity, diet, and weight control grants until FY2013 and 2014; then all decreased with the NCI decrease in total grants</td>
<td>Trend toward more funding for experimental vs observational studies beginning in 2009</td>
<td>5% focus on adults age ≥ 65 y</td>
<td>19% measure maintenance at 9–12 mo post-treatment</td>
<td>Growth over time in grants focused on effects of physical activity and weight control intervention studies on biomarkers of prognosis among cancer survivors</td>
<td>Trend for increases in the number of principal investigators who were psychologists, epidemiologists, or physicians</td>
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<td>Observational (n = 60) vs intervention (n = 72) studies.</td>
<td>Trends in research design: study population</td>
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* FY = fiscal year; NCI = National Cancer Institute; T0-T2 = translation phase of research (T0: determinants/outcomes, T1: mechanism/preclinical studies/phase I-II trials, T2: phase III trials, T3: implementation/dissemination, T4: outcomes in real-world settings).
Among the intervention projects funded, 65% (n = 47) delivered an in-person intervention, followed by telephone-based (33%, n = 24) and print-based (19%, n = 14). Ten studies (14%) used mobile health (mHEALTH) technologies, such as a smartphone, to deliver interventions. Half (n = 14) of RCTs included only an immediate post-intervention time point; others assessed maintenance of behavior change at one to three months (15%, n = 4), four to eight months (20%, n = 6), or nine to 12 months (20%, n = 6) postintervention. No trends in these patterns over time were noted.

Trends in Primary Study Exposures and Outcomes: Intervention Studies
The 72 intervention studies had 24 distinct exposures and 24 distinct outcomes identified in the primary aims. Physical activity was the most frequent exposure (n = 51, 71%). The most frequent outcomes were physical activity (n = 27), diet (n = 14), weight control (n = 16), symptoms (n = 16; eg, fatigue), and physical health-related quality of life (n = 12). These were stable across time.

Because 61 of these 72 interventions had a physical activity component, we looked specifically at these projects. Of these, the most common outcomes were physical activity behavior (n = 27), weight control (n = 15), symptoms (n = 14), physical health-related quality of life (n = 11), diet (n = 10), and biological indicators (eg, from blood) of immunological or endocrine function, or DNA damage (n = 8).

Given NCI interest in grants testing the effects of physical activity and weight control intervention studies on biomarkers of prognosis among cancer survivors, we specifically analyzed this portfolio. NCI has funded 10 such studies between FY 2007 and 2014. Five of these 10 were submitted in response to targeted funding opportunities NCI issued in 2012 to encourage this science and were funded in FY 2014. Of these 10, four target physical activity alone, whereas six target weight with diet or diet+physical activity. The most common outcomes are biomarkers of glucose metabolism (n = 5) or inflammation (n = 4). One related observational study was funded in response to NCI’s Provocative Questions initiative (PQA2: How does obesity contribute to cancer risk?).

Trends in Primary Study Exposures and Outcomes: Observational Studies
The 60 observational studies had 23 distinct outcomes and 18 distinct exposures identified in the primary aims. Weight was the most frequent exposure (n = 21, 35%) followed by physical activity (n = 16) and biological indicators (eg, from blood) of immunological or endocrine function or DNA damage (n = 15). Survival was the most frequent outcome (n = 18, 30%) followed by patient-reported symptoms (eg, fatigue n = 9) and health-related quality of life (n = 8).

Trends in Study Team Expertise and Composition
Of the 99 distinct PIs, the majority of awardees (67%, n = 67) held a PhD as their primary degree, 14% held an MD only, 12% held both a MD and a PhD, and 7% of degrees were classified as other. Sixteen diverse fields of study were identified from the principal investigator’s biosketch. Psychology was the most prevalent field (27%), followed by epidemiology (20%). Over time, there was an increase in numbers of psychologists, epidemiologists, and physicians as PIs. Teams were multidisciplinary: The average number of different disciplines represented on grants was four, and 83% of grants included a physician on the team.

The number of disciplines per team did not change over time. However, there was a trend for more kinesiology, nutrition science, basic science, and epidemiology experts to be included on teams. Psychologists and physicians were well represented on teams across the years.

Regarding multisite collaboration, 5% of grants (n = 6) utilized the multi-PI mechanism. However, there was ample evidence of multisite collaboration: While 50% of the grants identified one performance site, 25% identified two performance sites and 25% identified three or more sites. These trends were stable over time.

Research Agenda for 2015–2025
The results of this portfolio analysis of survivorship studies funded between FY 2004 and 2014 demonstrate growth in this research area, especially in intervention research. Despite this major investment in science, interventions are not widely available for all survivors who need them and there is no ongoing science to test the implementation and dissemination of programs. Further, few studies are designed to provide the data needed for policy makers and healthcare payers to consider reimbursement for these interventions. The data from this portfolio analysis point to critical gap areas and inform a prioritized research agenda for the next decade. It focuses on demonstrating value and feasibility and creating desire for health behavior change interventions at multiple levels, including the survivor, clinician, and healthcare payer. Filling these critical research gaps will facilitate the creation of efficacious interventions that are translated into standard survivorship care.

Survivor-Level Agenda
To facilitate the uptake of physical activity, diet, and weight control interventions among all survivors who need them, the top research priority is to create interventions that are feasible for diverse survivors and with outcomes that are meaningful to them. Regarding diversity, most studies were conducted with homogenous samples; eg, mostly breast cancer, limited age range, little attention to rural, lower socioeconomic, or race/ethnic minority survivors who may need different interventions. Research is needed to engage a wider variety of survivors, especially older adults who constitute the majority of cancer survivors, to understand how to create interventions that are relevant, meaningful, and feasible for them. One step to make the interventions meaningful would be to test the effects of these interventions on outcomes relevant to survivors. For example, in this portfolio analysis, only a minority of grants targeted symptoms that survivors may be struggling with; whereas nearly 80% of the intervention studies targeted behavior (physical activity, diet) or weight loss as the primary outcome. Given the number of studies that have demonstrated cancer survivors can successfully change their behavior (eg [21]), future research must go beyond testing this question. Dosing studies are needed testing how much of which intervention (eg, minutes of aerobic activity or percent weight loss) is needed for specific survivor-relevant outcomes such as managing comorbid conditions without medications or improving fatigue or decreasing risk of recurrence. This knowledge could incentivize survivors to make meaningful changes in health behaviors. Future research must also determine whether there are variations in the type and dose of intervention needed by characteristics such as age, cancer/treatment type, functional status, comorbidities, or genetic factors. Given the small number of RCTs that included long-term follow-up of participants, a final component of creating more
meaningful interventions is making sure they focus on how to sustain healthy changes over time.

Even meaningful interventions will not be implemented widely if they are not feasible for survivors to do in settings that can sustain them. This portfolio analysis found that most studies conducted in-person interventions, whereas only 10 studies used mHEALTH such as smart phones. In a recent meta-analysis on physical activity interventions in survivors, while interventions with more intense supervision and monitoring of participants had higher effect sizes, moderate levels of supervision were enough (21). Supervised, in-person interventions are likely required for some research questions (eg, testing intervention dose-response, interventions in medically compromised patients). However, to create feasible interventions with high dissemination potential, there is a pressing need to learn from the in-person interventions and test how to conduct these interventions in home, community-based, and low-resource settings using technology like smart phones where it can facilitate intervention access.

Clinician-Level Agenda
We need to create value for these interventions among clinicians from oncology and primary care and referral pathways so that clinicians can easily refer cancer survivors to safe and effective interventions. Two research priorities will facilitate these goals. First, studies of the underlying biology of how health behavior interventions improve health and well-being in cancer survivors will help clinicians understand which survivors to refer for which interventions. For example, does a clinician need to advise a postmenopausal breast cancer survivor to lose 10% of her body weight or is the goal actually about determining the intervention dose needed to help her reduce inflammation to normal levels to improve symptoms, comorbidities, and prognosis? Animal models may be particularly useful to study these mechanisms: Given how rare animal studies are in this area, grants are needed that are designed to translate the results of animal studies into human trials with cancer survivors. Additionally, in this era of evidence-based medicine, increasing the rigor of lifestyle interventions and the systematic reviews and meta-analyses of this work will help increase acceptance of these interventions.

Second, clinicians need effective programs in a variety of settings to which they can refer their cancer survivors. Studies are needed to test best practices for facilitating quick referral to these programs so that busy clinicians find this referral no more burdensome than ordering standard lab tests. Additionally, a system of feedback to the prescribing clinician needs to be created from these interventions for assessment of intervention efficacy and additional referral if necessary.

Healthcare Payer-Level Agenda
A fourth research priority is to collect the data needed to make the case for reimbursement of these programs by healthcare payers. Given that much of survivorship care occurs in primary care, one critical vehicle for reimbursement is the US Preventive Services Task Force (USPSTF) recommendation. Under the Patient Protection and Affordable Care Act, interventions for which the USPSTF assigns an A or B rating (www.uspreventivestaskforce.org/Page/Name/grade-definitions) must be covered by new insurance policies or plans without cost sharing (ie, deductibles). Leaders from the National Institutes of Health and the Agency for Healthcare Research and Quality (AHRQ) have articulated the types of data that studies should collect to facilitate USPSTF review of behavioral interventions, noting that studies included in the systematic reviews conducted by the AHRQ’s Evidence-based Practice Centers for the USPSTF must be high quality (22). Specifically, the USPSTF needs evidence on: 1) the effects of the intervention according to the symptoms or risk status of the participants (eg, varying intervention efficacy for survivors with different symptoms or comorbidities); 2) feasibility of referral from primary care to a behavioral counseling intervention; 3) the dose of intervention delivered and dose-response studies; 4) the independent contribution of specific intervention components in multicomponent interventions (eg, diet+exercise); 5) adverse events to evaluate potential harm; 6) the use of standardized measures to facilitate pooling data across studies; and 7) effects of interventions on health outcomes or intermediate biometric indicators where these are acceptable alternatives to health outcomes (22). This last point underscores the need for interventions to go beyond investigating the effects on behavior change: Clinical endpoint studies showing effects of these interventions on prognosis and other health outcomes in cancer survivors are needed to pave the way for third-party reimbursement for these programs. Health services research is needed to demonstrate cost effectiveness and value added to busy clinics and a stressed healthcare budget (eg, in increasing medication adherence or decreasing the burden of comorbidities). Some studies addressing these research gaps will require large multi-institution collaborations to facilitate rapid recruitment and potentially lengthy follow-up. The NIH leadership has recognized the need for funding large, lengthy studies with clinical endpoints (22). The NCI has a mechanism for conducting phase III trials through the National Clinical Trial Network/National Community Oncology Research Program Research Bases. Conducting trials through this mechanism is required if the study cannot be completed in a five-year period (see NIH notice NOT-CA-13-012) as it leverages infrastructure and investigator expertise already in place for oncology treatment trials. Filling the research gaps above will allow for the USPSTF and other policy-making groups to evaluate these interventions for possible reimbursement. With a clear reimbursement structure, academic research-industry partnerships could be leveraged to create effective interventions based on good science that can be scaled up, managed, and sustained by industry.

Cross-Cutting Agenda Issues: Technology
Accelerating the pace of turning scientific results into care for cancer survivors can be facilitated through effective use of electronic health (eHEALTH) and mHEALTH technologies. Few research found minorities are more likely to turn to smart phones and electronic health (eHEALTH) and mHEALTH technologies. Pew research found minorities are more likely to turn to smart phones and use technology with this population who may have vision impairments or tremors and find current smart phone-based intervention difficult to use. Technology also could be used to build, adapt, and evaluate these multicomponent interventions (23). Given the large number of cancer survivors over the age of 65 years, future research must test methods to effectively use technology with this population who may have vision impairments or tremors and find current smart phone-based intervention difficult to use. Technology also could be used to facilitate clinicians’ referral of survivors into these programs. Progress in the health behavior change interventions could then
be noted in the electronic medical record to facilitate feedback to the prescribing clinician and assessment of ongoing needs.

**Cross-Cutting Agenda Issues: Observational Studies**

Although much of the research on the next decade’s research agenda is intervention research, there are still key questions that need to be answered with observational studies. Cohorts could be leveraged to look at rare/understudied cancers and populations, study combinations of multiple exposures and actual use patterns, and uncover unanticipated relationships. Integrating cohorts with big data from wearable/environmental sensors may uncover novel relationships, eg, the potential effects of physical activity on late effects. Careful examination of observational data can also prevent the development of ineffective or wrongly targeted interventions.

There are several limitations to the methods of our portfolio analysis. First, we include NCI-funded studies, which is an incomplete picture of studies funded in this area. Second, the specific search terms used to query the grant database for grants on cancer survivors may have resulted in some grants being overlooked if investigators did not use any of the keywords in the abstracts, titles, or aims. Third, the process of determining inclusion and exclusion required judgment that could have biased the results; however, our procedure required consensus of a small team of authors (CA, GT, and SB) for inclusion and exclusion decisions, mitigating this concern. The focus on dietary patterns and energy balance and thus exclusion of diet studies focused on single foods or nutrients eliminated many grants from this portfolio analysis, and results cannot be generalized to that body of work. Finally, the decision to code only the abstracts, titles, or aims. Third, the process of determining inclusion and exclusion required judgment that could have overlooked if investigators did not use any of the keywords in the abstracts, titles, or aims. Third, the process of determining inclusion and exclusion required judgment that could have biased the results; however, our procedure required consensus of a small team of authors (CA, GT, and SB) for inclusion and exclusion decisions, mitigating this concern. The focus on dietary patterns and energy balance and thus exclusion of diet studies focused on single foods or nutrients eliminated many grants from this portfolio analysis, and results cannot be generalized to that body of work. Finally, the decision to code only the exposure(s) and outcome(s) listed in Aim 1 of the project as “primary” means that these results capture only a fraction of the exposures and outcomes actually investigated by these projects. However, we believe this analysis does present a cohesive picture of the primary focus of these grants.

In conclusion, translating the research on lifestyle interventions into the standard of care for cancer survivors will take a coordinated effort by researchers, survivors, and clinicians and effective public-private partnerships. Working together on the research agenda presented here will help to overcome barriers at the survivor, clinician, and healthcare payer levels and lead to appropriately targeted, adaptive, effective, and sustainable programs for all survivors.

**References**