



NIH Pathways to Prevention (P2P) Program
April 27, 2023

A Report From the Federal Partners Meeting of the NIH P2P Workshop: Nutrition as Prevention for Improved Cancer Health Outcomes



National Institutes of Health
Office of Disease Prevention

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Sponsored by:

National Institutes of Health
Office of Disease Prevention
National Cancer Institute
National Institute on Aging
Office of Nutrition Research
Office of Dietary Supplements

Eunice Kennedy Shriver National Institute of Child Health and Human Development

Introduction

The Pathways to Prevention (P2P) program of the National Institutes of Health (NIH) Office of Disease Prevention (ODP) uses an unbiased, evidence-based process to identify research gaps in a scientific area of broad public health importance. The goals of the P2P process are to synthesize and interpret the current evidence, identify research gaps, shape a research agenda, and develop an action plan. In July 2022, NIH convened the P2P Workshop: Nutrition as Prevention for Improved Cancer Health Outcomes. See Background below. This workshop was co-sponsored by ODP, the National Cancer Institute (NCI), National Institute on Aging (NIA), Office of Nutrition Research (ONR), Office of Dietary Supplements (ODS), and *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD). An independent panel reviewed the systematic evidence review and workshop presentations and made recommendations for moving the field forward, which are included in the independent panel report published in the *Journal of the National Cancer Institute (JNCI)*.¹ A link to this report as well as other reports generated from this workshop may be found on the [workshop webpage](#).

On April 27, 2023, ODP convened a meeting with representatives from federal government agencies (the Federal Partners) to identify strategies to address the recommendations in the independent panel report (see Appendix A for the list of attendees). This document summarizes the discussions and action items identified at the Federal Partners Meeting.

Background

Malnutrition reportedly occurs in up to 70–75% of people diagnosed with cancer, although the prevalence of the condition varies by cancer type, individual, and social factors. Cancer and

¹ Hiatt RA, Clayton MF, Collins KK, et al. [The Pathways to Prevention \(P2P\) Program: Nutrition as Prevention for Improved Cancer Outcomes](#) [published online ahead of print, 2023 May 22]. *Journal of the National Cancer Institute*. 2023;djad079. doi:10.1093/jnci/djad079.

cancer treatment can have nutrition-related side effects and nutrition impact symptoms, including nausea, appetite and taste changes, and fatigue, which make it hard for people with cancer to eat well and absorb nutrients from food. People who have upper gastrointestinal tract, head, neck, lung, blood, gynecological, or colorectal cancers are more likely to suffer from malnutrition. People with cancer who have excess weight or obesity are also at greater risk for complications related to poor nutrition.

Cancer-associated malnutrition may be preventable. Studies have shown that interventions such as medical nutrition therapy can reduce weight loss, maintain strength, support cancer treatment, and improve quality of life.

While malnutrition is common among people with cancer, nutritional screening and interventions are not standard parts of outpatient cancer care in the United States (U.S.). There are no national clinical guidelines to prevent or treat cancer-associated malnutrition before or during cancer treatment, and currently there is a lack of high-quality evidence about how nutritional interventions affect cancer health outcomes. Health care providers and decision-makers need high-quality research on cancer-associated malnutrition screening, nutritional support and therapies, and a comprehensive review of the evidence to inform development of clinical guidelines for preventive care.

Workshop Key Questions

To address this complex issue, ODP, NCI, NIA, ONR, ODS, and NICHD co-sponsored the P2P Workshop: Nutrition as Prevention for Improved Cancer Health Outcomes. The workshop sought to address four Key Questions (KQ) and one Contextual Question:

KQs 1 and 2: Effects of Nutritional Interventions Before and After Cancer Treatment	In adults diagnosed with cancer who have or are at risk for cancer-associated malnutrition, what is the effect of nutritional interventions prior to (KQ1) or during (KQ2) cancer treatment in preventing negative treatment outcomes such as effects on dose tolerance, hospital utilizations, adverse events, and survival? Do the effects of nutritional interventions on preventing the negative outcomes associated with cancer treatment vary by cancer type, treatment type (chemotherapy, radiation, surgery), stage of disease, across the lifespan, or across special populations?
KQ 3: Effects of Nutritional Interventions on Side Effects and Quality of Life	In adults diagnosed with cancer who have or are at risk for cancer-associated malnutrition, what is the effect of nutritional interventions prior to or during cancer treatment on associated symptoms such as fatigue, nausea and vomiting, appetite, physical and functional status (e.g., frailty), and quality of life? Do the effects of nutritional interventions on preventing the negative outcomes associated with cancer treatment vary by cancer type, treatment type (chemotherapy, radiation, surgery), stage of disease, across the lifespan, or across special populations?

KQ 4: Effects of Intentional Weight Loss Before or During Cancer Treatment	In adults with cancer who have overweight or obesity, what is the effect of nutritional interventions intended for weight loss prior to or during cancer treatment in preventing negative treatment outcomes such as effects on dose, hospital utilizations, adverse events, and survival?
Contextual Question: Cost Effectiveness	What evidence is available on the cost effectiveness of nutritional interventions for preventing negative outcomes associated with cancer treatment?

Systematic Evidence Review

A systematic evidence review of the scientific literature, guided by the KQs, was conducted by the University of Minnesota's Evidence-based Practice Center, through a contract with the Agency for Healthcare Research and Quality (AHRQ) and was published in the *JNCI Cancer Spectrum*.² The purpose of the systematic evidence review was to inform the P2P workshop by providing an understanding of the evidence base for nutrition interventions delivered prior to or during cancer treatment for preventing and treating negative cancer and cancer treatment-related outcomes among individuals with or at risk for malnutrition. The review resulted in an "evidence map" of the existing literature and highlighted these main findings:

- Two decades of randomized trial evidence of over 180 studies on nutrition interventions for adults prior to and/or during cancer treatment focused on the use of dietary supplements, nutrition support (including oral nutrition supplements), and the route or timing of nutrition interventions within gastrointestinal and head and neck cancers.
- Studies focused on evaluating changes in weight/body composition, adverse events, length of hospital stay, and quality of life.
- Among studies with a high volume of literature, which predominately examined dietary supplements and nutrition support in gastrointestinal and head and neck cancers, 10% (n=10) were rated as low risk of bias (higher quality), 39% (n=39) medium risk of bias, and 51% (n=51) as high risk of bias (lower quality).
- Low- and medium-risk-of-bias studies reported mixed results on the effect of nutrition interventions across outcomes for cancer and cancer treatment (detailed in the evidence summary results below).
- Few (5%, N=8) studies reported a formal cost-effectiveness analysis or provided costs detailed by intervention component; generally, these studies reported only overall costs from inpatient non-U.S. settings.

² Parsons HM, Forte ML, Abdi HI, et al. [Nutrition as prevention for improved cancer health outcomes: a systematic literature review](https://doi.org/10.1093/jncics/pkad035). *JNCI Cancer Spectrum*. 2023;7(3)pkad035. doi:10.1093/jncics/pkad035. PMCID: PMC10290234.

- Future research would benefit from a detailed assessment of a subset of studies in this evidence map; that subset would include studies focused on priorities and interventions most relevant to specific stakeholders (e.g., oncologists, dietitians, researchers, policymakers, and individuals with cancer). Future studies could then be specifically designed to evaluate the main outcomes of interest relevant for clinical practice.
- Future research would also benefit from the creation of standardized taxonomies for interventions and outcomes as well as more rigorous design and reporting of nutrition interventions.

Limitations

The methods used for the systematic review provided a detailed evidence map of the current state of literature on nutrition interventions, highlighting not only concentrations of literature but also gaps in intervention types. The reviewers chose purposefully broad definitions of nutrition interventions, thereby increasing the scope, breadth, and heterogeneity of the included literature in order to better assess the range and depth of available evidence. This decision allowed for demonstration of the diffuse literature set on the topic and highlighted the predominantly low quality of studies where there were concentrations of similar intervention types. However, this required focusing on high level directionality of intervention effects across a broader range of nutrition interventions rather than looking for more detailed, precise estimates of intervention effects. Overall, this approach allowed for high level mapping of the evidence across KQs by patient, intervention, comparator, and outcome categories. It also revealed evidence gaps for future research.

Independent Panel Report

A unique feature of every P2P workshop is the involvement of a multidisciplinary, independent panel comprised of non-federal representatives who have attested that they hold no scientific or personal conflicts with the subject matter of the P2P workshop for which they have volunteered their service. Independent panel members were vetted for potential conflicts of interest. Panel members were charged with writing the independent panel report that (1) summarized the key findings and research needs outlined in the systematic evidence review and discussed at the workshop; and (2) provided a set of recommendations to move the field forward. The independent panel report includes a conceptual framework, overall recommendations for the field and specific recommendations related to the KQs (see Appendix B).

Federal Partners Meeting

ODP convened a meeting on April 27, 2023, with Federal Partners to discuss ways of addressing the recommendations of the independent panel. The objectives of the Federal Partners Meeting were to discuss (1) federal agency perspectives and alignment with panel recommendations; (2) general comments, observations and collaboration opportunities shared by Federal Partners; (3) prioritized activities and new ideas; and (4) next steps for implementing recommendations and potential collaborations across agencies to set the stage for future activities. Representatives from NCI, ONR, NICHD, and ODS led the discussion of federal agency research needs and opportunities, panel recommendations, and next steps for the field.

1. Federal Agency Perspectives and Alignment with Panel Recommendations: Current and Future Efforts in Nutrition and Cancer Health Outcomes

1a. Panel Recommendations Related to Screening in Nutritional Risks

Screening in Nutritional Risk
<i>Independent Panel Recommendations</i>
Screening for nutritional status, risk, and body composition using validated and standard measurement approaches with defined cut points to identify malnutrition should be routinely integrated throughout the care process and across all cancer care settings (Panel Recommendation 3; KQs 1, 2, 3)
Improved screening methods to identify loss of muscle volume or function that can occur even in the presence of obesity. Reliance on edema-dependent markers and body mass index (BMI) alone is ineffective (Panel Recommendation 10; KQ 4)

Federal Partners described the following current and future efforts underway related to screening in nutritional risks:

- **NCI's Automated Software for Point-of-Care Testing to Identify Cancer-Associated Malnutrition:** This [Small Business Innovation Research \(SBIR\)](#) program (PHS 2024-1) supports the development of an automated nutrition screener that combines questionnaire-based tools that capture changes in appetite and unintentional weight loss with diagnostic imaging that assesses muscle and adipose tissue.
- **The U.S. Department of Veterans Affairs (VA) is supporting four related grants and projects:**
 - Preserving Physical Function in Older Adults with Cancer: Impact of an Optimizing Nutrition Intervention Applied Before and After Surgery
 - Nutritional (High Protein) Perihabilitation in Older Veterans Undergoing Surgery
 - The Relationship Between Sarcopenia and Chemotherapy Toxicity in Patients with Cancer
 - The Feasibility of a Sarcopenia Screening and Treatment Protocol for Veterans in a VHA Cancer Center

1b. Panel Recommendations Related to Nutrition Interventions

Nutrition Interventions
<i>Independent Panel Recommendations</i>
Rigorous, well-designed nutritional intervention studies conducted in the U.S. in adults diagnosed with cancer who are at risk for or have definite cancer-associated malnutrition to allow for comparisons across studies (Panel Recommendation 1; KQs 1, 2, 3, 4)
Large nutrition intervention studies to evaluate the efficacy of common interventions on improving important outcomes such as cancer treatment tolerance, health care resources utilization, treatment-limiting side effects, survival, and quality of life (Panel Recommendation 7; KQs 1, 2, 3)

Nutrition Interventions
<i>Independent Panel Recommendations</i>
Studies examining malnutrition across a larger variety of cancer diagnoses, and in outpatient settings. Pragmatic studies embedded in clinical practice or mirroring real world clinical care will help to address issues inherent to both vulnerable populations and varied settings (Panel Recommendation 2; KQs 1, 2, 3, 4)
Studies that integrate dietitians and their expertise into the health care team and that are powered to examine the impact of nutrition interventions on cancer outcomes (e.g., cancer treatment tolerance, health care resources utilization, treatment-limiting side effects, survival, and quality of life) by cancer type, treatment type, wasting status, comorbidity status, and across the lifespan (Panel Recommendation 6; KQs 1, 2, 3)

Federal Partners described the following current and future efforts underway related to nutrition interventions:

- **The VA's Preserving Physical Function in Older Adults with Cancer:** This study, also noted above for screening, examines the impact of nutritional interventions using high-protein, HMB, and vitamin D in older Veterans recently diagnosed with cancer who are preparing for a surgical resection.
- **The VA's Nutritional (High Protein) Perihabilitation in Older Veterans Undergoing Surgery:** This study, also noted above for screening, aligns with Panel Recommendations 2 and 6, which the VA views as high priority.
- **The VA also supported or is supporting four other related grants and projects:**
 - Vitamin D3 Supplementation for Low-Risk Prostate Cancer: A Randomized Trial
 - Prophylactic vs Reactive Feeding Tube Placement in Veterans with Head and Neck Cancer Receiving Chemoradiotherapy: The PRETUBE Trial
 - The Impact of Registered Dietitian Staffing and Nutrition Practices in High-Risk Cancer Patients Across the Veteran's Health Administration
 - Diet Modulation of the Gut Microbiome During Treatment with Immune Checkpoint Inhibitors
- **NCI is supporting five related grants and projects:**
 - Bridging the Gap: This grant evaluates why and how to implement lifestyle programs for patients with cancer into routine clinical oncology care.
 - Every Day Counts: This grant evaluates a lifestyle program for women with metastatic breast cancer.
 - Impact of Web-Based Lifestyle Interventions on Prostate Cancer Prognosis: This grant delivers a lifestyle intervention via the internet as adjuvant therapy to standard prostate cancer.
 - Novel Randomized Controlled Trials of Vitamin D Supplementation in Patients with Colorectal Cancer: Impact on Survival and Biology: This grant examines if vitamin D supplementation improves survival and influences several neoplastic pathways that can be exploited as biomarkers of efficacy and targets for novel treatment strategies.

- *A Mobile-Support Program to Facilitate Nutritional Caregiving in Head and Neck Cancer:* This grant uses a needs assessment planning tool and pilot-tests a nutrition-focused mobile support system (mSupport) to manage nutritional needs and concerns during the initial recovery period.
- **The Centers for Medicare & Medicaid Services' (CMS) Enhancing Oncology Model:** This five-year model is scheduled to begin in July 2023 with oncology physician group practices and other payers offering innovative payment strategies that promote high-quality, person-centered, equitable care to Medicare fee-for-service beneficiaries undergoing chemotherapy treatment. While the payment flexibility is based on provider discretion, CMS is currently creating guidance for participants and welcomes input.
- **The Department of Defense (DOD) Congressionally Directed Medical Research Programs (CDMRP) through the Translational Research Partnership Award (TRPA) mechanism** has awarded Remote Malnutrition Monitoring After Surgery for Pancreatic Cancer Patients (HT9425-23-1-0514 and HT9425-23-1-0515), which will conduct a pilot clinical trial to investigate the use of a telehealth intervention to manage nutrition after surgery.
- **The Centers for Disease Control and Prevention's (CDC) Prevention Research Centers,** a network of 26 academic research centers that study how people and their communities can reduce the risk for chronic diseases, include research on physical activity and nutrition.

1c. Panel Recommendations Related to Mechanistic Studies

Mechanistic Studies
<i>Independent Panel Recommendations</i>
Examination of biological mechanisms that would assist in designing approaches such as dietary restriction versus supplementation for specific patients with cancer with respect to age, ethnicity, and sex as well as for differing types of cancer diagnoses and treatments (Panel Recommendation 5; KQs 1, 2)
Greater diversity among cancer diagnoses and inclusion of those with differing body composition prior to and during treatment to better understand the relationships among physiologic muscle wasting and deterioration and cancer treatment and suggest optimal timing for nutritional intervention, screening, and support. This might be accomplished by creating large biobanks of both host and tumor specimens and body composition data to understand mechanisms leading to muscle abnormalities (Panel Recommendation 9; KQs 1, 2, 4)

Federal Partners described the following current and future efforts underway related to mechanistic studies:

- **DOD/CDMRP highlighted three metabolic and biological profile grants:**
 - Idea Development Award (W81XWH-22-1-1019) will identify metabolic profiles, metabolites, and lipids that are associated with pancreatic cancer and seek to identify metabolites associated with diabetes and their association with pancreatic cancer.
 - Idea Development Award (W81XWH-22-1-0911) will investigate diet-driven epigenomic changes in mouse models of metastasis and mechanisms that promote metastasis in obesity and fatty liver disease, and the association with pancreatic cancer metastasis.

- TRPA (W81XWH-22-1-1021 and W81XWH-22-1-1022) will identify biological profile(s) for obese versus healthy weight African American and non-Hispanic White patients with pancreatic cancer.
- **The VA is supporting two related projects:**
 - [Pharmacogenomics Action for Cancer Survivors \(PHASER\)](#): This program, which obtains blood samples and prescribes medications based on genetics, may be applied to research in this area.
 - The VA Precision Oncology Program’s biobank helps provide targeted cancer care based on genetic profiles (i.e., tumor, bone marrow, or blood samples, DNA, pharmacogenetics) and different types of proteins and are used to understand genetic responses and how well current therapies, tumor-targeted therapies, and immunotherapies will work on the many types of solid tumors and blood cancers.
- **NIH and the U.S. Department of Agriculture (USDA) National Institute of Food and Agriculture’s (NIFA) Food Specific Molecular Profiles and Biomarkers of Food and Nutrient Intake, and Dietary Exposure (PAR-15-024)** promotes research on food specific molecular signatures and biomarkers of dietary consumption.
- **NCI is supporting two related grants and projects:**
 - Time-Restricted Eating and Cancer: Clinical Outcomes, Mechanisms, and Moderators; Vitamin D and Follicular Lymphoma (NCT04722341) examined an intermittent fasting regimen and found anti-cancer effects such as decreased IGF-1 levels, reduced oxidative stress, upregulated antioxidant defenses, and enhanced autophagy.
 - [CANCAN \(Cancer Cachexia Action Network\)](#), cofounded with Cancer Research UK, is a virtual institute that unites and funds the global research community to promote an understanding and reverse cachexia and declining performance status in patients with cancer.

1d. Panel Recommendations Related to Body Composition/Weight Management

Body Composition/Weight Management
<i>Independent Panel Recommendations</i>
Studies that will disentangle age from cancer-related sarcopenia and cachexia (Panel Recommendation 8; KQs 1, 2)
More direct measures of adiposity and muscle mass to add rigor to the investigation of the relationships between body composition and outcomes of different types of cancer treatment. Prospective studies exploring the role of body composition in predicting dose-limiting toxicities and the relationship between dose modification and clinical outcome to lay a foundation for more customized treatment dosing and timing (Panel Recommendation 11; KQ 4)

Body Composition/Weight Management
<i>Independent Panel Recommendations</i>
Research on weight and cancer outcomes to consider a patient's disease trajectory and body composition changes across time (Panel Recommendation 12; KQs 1, 2, 4)
Randomized controlled dietary interventions that incorporate intentional weight loss before and during cancer treatment designed to address variables such as timing, rate, and mode of weight loss that may influence outcomes (Panel Recommendation 13; KQ 4)
Since evidence supports physical activity during cancer treatment as beneficial in managing quality of life, its potential to minimize loss of lean body mass during weight loss warrants its inclusion in weight loss intervention trials. Interventions that test physical activity with and without weight loss to provide insight for optimal treatment of people who have overweight or obesity (Panel Recommendation 14; KQ 4)

Federal Partners described the following current and future efforts underway related to body composition and weight management:

- **NCI's Exercise and Nutrition Interventions to Improve Cancer Treatment-Related Outcomes (ENICTO) in Cancer Survivors:** This consortium of four research sites and a coordinating center is designed to advance an understanding of how exercise and nutrition interventions may affect both outcomes and quality of life during cancer treatment.
- **NCI is also supporting four grants** related to Panel Recommendations 13 and 14:
 - Prolonged Nightly Fasting as a Behavioral Intervention for Obesity Reduction and the Prevention of Progression in Precursor Multiple Myeloma
 - Every Day Counts: A Lifestyle Program for Women with Metastatic Breast Cancer
 - Impact of Web-Based Lifestyle Interventions on Prostate Cancer Prognosis
 - Physical Activity and Weight Control Interventions Among Cancer Survivors: Effects on Biomarkers of Prognosis and Survival (PAR-18-893 and PAR-18-016)
- **DOD/CDMRP's TRPA** (W81XWH-22-1-1021 and W81XWH-22-1-1022) will identify biological profile(s) for obese versus healthy weight African American and non-Hispanic White patients with pancreatic cancer.
- **The VA is supporting two grants** related to Panel Recommendations 11 and 14:
 - Preserving Physical Function in Older Adults with Cancer: Impact of an Optimizing Nutrition Intervention Applied Before and After Surgery
 - Enhanced Protein Intake During Obesity Reduction in Older Male Veterans: Differences in Physical Function and Muscle Quality Responses by Race—while not focused on cancer, this study may provide a framework for the impact of weight loss on muscle mass and function in older adults with obesity
- **The VA is supporting two grants** related to Panel Recommendation 8 and views recommendations 8 and 12 as high priority.
 - The Relationship Between Sarcopenia and Chemotherapy Toxicity in Patients with Cancer
 - The Feasibility of a Sarcopenia Screening and Treatment Protocol for Veterans in a VHA Cancer Center

1e. Panel Recommendations Related to Symptom Management

Symptom Management
<i>Independent Panel Recommendations</i>
Longitudinal studies to examine optimal timing of nutritional interventions that may enhance earlier diagnosis of adverse outcomes of cancer such as cachexia, sarcopenia, adverse events, and quality of life, or avoid or improve nutrition impact symptoms (Panel Recommendation 4; KQ 1, 2, 4)

Federal Partners described the following current and future efforts underway related to symptom management:

- **NCI's ENICTO in Cancer Survivors:** This consortium, described above, may offer insights for cancer-related symptom management.
- **The VA is supporting three grants** related to Panel Recommendation 4:
 - Preserving Physical Function in Older Adults with Cancer: Impact of an Optimizing Nutrition Intervention Applied Before and After Surgery
 - Prophylactic vs Reactive Feeding Tube Placement in Veterans with Head and Neck Cancer Receiving Chemoradiotherapy: The PRETUBE Trial
 - Diet Modulation of the Gut Microbiome During Treatment with Immune Checkpoint Inhibitors

1f. Panel Recommendations Related to Cost-Effectiveness Analysis

Cost-Effectiveness Analysis
<i>Independent Panel Recommendations</i>
Randomized controlled trials (RCTs) of nutritional interventions that incorporate cost-effectiveness analyses (CEAs) (Panel Recommendation 15; Contextual Question)
Use of methodologic approaches other than RCTs, such as robust modeling techniques (e.g., Cancer Intervention and Surveillance Modeling Network (CISNET), mini-models based on electronic health records and Learning Health Systems), analyses of large population-based data (e.g., National Health and Nutrition Examination Survey (NHANES), National Death Index (NDI), Surveillance, Epidemiology, and End Results (SEER), health insurance claims, Center for Medicare and Medicaid Innovation (CMMI) payment model data, “real-world” data from comparative effectiveness studies), including CEAs to answer “what if?” questions assessing the cost-savings or cost-effectiveness of effective nutritional interventions (Panel Recommendation 16; Contextual Question)
Increased adherence to national guidelines and guidance for systematic methods and approaches to CEA to enhance generalizability and replication of interventions in diverse settings and promote consistency and clarity with justification for every cost included in analyses. Robust methods include addressing the multiple perspectives (e.g., patient, payer, provider, or societal), capturing implementation- and intervention-specific costs, patient out-of-pocket costs, and changes in health care utilization that may be attributable or downstream to the intervention (Panel Recommendation 17; Contextual Question)

Federal Partners shared current and future work related to recommendations on cost-effectiveness including:

- **CMS' Enhancing Oncology Model:** This five-year payment and delivery model scheduled to begin in July 2023 focuses on innovative payment strategies to promote high-quality, person-centered care. While the payment flexibility is based on provider discretion, CMS is currently creating guidance for participants and welcomes input.
- **CMS' Medicare Advantage Value Based Insurance Design Model:** While this model is not targeted to cancer, it facilitates the provision of grocery supports and other related services through supplemental benefits.
- **AHRQ supports several grants** that offer methods or techniques to study cost-effectiveness in cancer such as:
 - Comparing Targeted and Non-Targeted Approaches to Improving the Value of Cancer Care Services
 - Effects of Insurance Expansions on Cancer Treatment: Recent Policy Changes and Implications for Future Reform
- **USDA/NIFA supports several areas of programming** related to Panel Recommendation 16 including:
 - Food Specific Molecular Profiles and Biomarkers of Food and Nutrient Intake, and Dietary Exposure (A1342)
 - Food and Human Health (A1344)
 - Diet, Nutrition and the Prevention of Chronic Disease (A1343)
 - Novel Foods and Innovative Manufacturing Technologies (A1364)
 - Produce Prescription
 - SBIR's programming area Food Science and Nutrition (8.5)
- **NCI is supporting two grants and projects related to Panel Recommendation 17:**
 - A randomized trial of lifestyle guidelines on breast cancer biomarkers and treatment adherence
 - Definition of nutrition terms project, which may be helpful for the heterogeneity in nutrition cancer outcome reporting and need consensus on malnutrition screening and assessing (validation), sarcopenia and cachexia, education vs medical nutrition therapy, etc.

2. Federal Partner General Comments, Observations, and Collaboration Opportunities

The second part of the meeting included a facilitated discussion of recommendations related to (a) screening in nutritional risks; (b) nutritional interventions and mechanistic studies; (c) body composition/weight management; (d) symptom management; and (e) cost-effectiveness analysis. The highlights below include Federal Partners' general comments and observations including opportunities for collaboration.

One overarching collaboration opportunity is future involvement with the White House Office of Science and Technology Policy's Cancer Moonshot workgroups, which are currently developing strategies for implementing the Cancer Moonshot with future work potentially aligning to address the panel's recommendations.

2a. Discussion Highlights for Screening in Nutritional Risks

The Federal Partners discussed barriers for screening for nutritional status including:

- Lack of consistent screening using validated tools
- Lack of screening tools that capture body composition changes, such as sarcopenia
- Lack of widespread use of screening for food insecurity such as the incorporation of the [Hunger Vital Sign™](#) into electronic health records
- Opportunities for standardizing and validating screening tools for all ages
- Evidence to guide screening procedures
- Practitioner training on the availability of screening tools

The Federal Partners raised the following needs related to screening tools including:

- Need for a short list of validated screening tools specific for children, adults and older adults, especially for use in outpatient settings
- Need for consistent screening at the time of diagnosis and at specific checkpoints throughout the treatment process
- Need to enhance body composition screening tools to capture sarcopenia
 - Need for an agreed upon definition for sarcopenia and other nutrition terms
 - Need for a better understanding of the connection between body composition and cancer outcomes and the relationships between obesity, cancer risk and cancer outcomes

Despite these needs, there was general agreement of the importance of the continued use of available validated screening tools while the terminology is standardized.

Potential Opportunities for Collaboration

- The VA has a number of programs that provide opportunities for collaboration to test tools, collect baseline data, track the trajectory of care, and promote alignment between national initiatives including:
 - [Clinical Nutrition Programs](#) (Veterans Health Administration (VHA) Directive 1438)
 - [National Oncology Program](#)
 - National TeleOncology Program
 - VA Cancer Committees
- The VA's [Corporate Data Warehouse](#) and [VA Informatics and Computing Infrastructure](#) may provide opportunities for collaboration related to screening for nutritional risk.
- AHRQ's [Outcome Measures Harmonization](#) projects have a process to develop standardized definitions, outcomes, and measures that has been used for five conditions and may be applied for this work.
- American Society for Parenteral and Enteral Nutrition (ASPEN) is in the process of completing a systematic review of malnutrition screening in outpatient cancer centers and updating [clinical guidelines](#) for adults, which may be available in six to nine months.
- The [Malnutrition Quality Improvement Initiative](#) may also be a potential partner for future work in this area.

- NCI's [CISNET](#) uses simulation modeling to improve the understanding of cancer control interventions in prevention, screening, and treatment. The models may aid in work in this area.
- USDA [NIFA's Nutrition Security Webinar Series](#) may be a forum to examine issues related to food insecurity for people with cancer.

The Federal Partners also discussed the potential for aligning with national initiatives (e.g., American Cancer Society) and engaging industry in development of innovative tools.

2b. Discussion Highlights for Nutritional Interventions and Mechanistic Studies

The Federal Partners discussed general support for the recommendations related to Nutritional Interventions (see above) and interest in collaborative opportunities. While interagency agreements (IAAs) can be difficult to put in place, some Federal Partners expressed an interest in exploring other ways in which agencies fund cross-agency work. For example, work on human milk composition, which has not required IAAs, includes learning how to define and harmonize terms, bringing together collaborators, and publishing thought pieces. More specifically, the Federal Partners discussed the need to understand different mechanistic approaches and an interest in learning more from studies on fasting mimicking diets.

Potential Opportunities for Collaboration

- The VA has programs that provide opportunities for collaboration on recommendations related to mechanistic studies including:
 - [Precision Oncology Program's Applied Proteogenomics Organizational Learning and Outcomes network](#), which is a collaborative program with the VA, DOD, and NCI to incorporate proteogenomics into patient care
 - [PHASER](#) described above
- CDMRP funds TRPAs that support partnerships between clinicians and research scientists to move promising ideas towards clinical applications including pilot clinical trials and Focused Pilot Awards that support the exploration and development of innovative concepts in areas of pancreatic cancer research such as supportive care interventions.
 - Interest in collaborating to stay informed on what other federal agencies are learning related to what is successful
 - Interest in informing CDMRP investigators of larger awards that other agencies may fund
- CMS' waiver program may also be used to support real world clinical care such as:
 - The Medicare Advantage Value-Based Insurance Design Model, which allows Medicare Advantage plans to cover a wide range of supplemental benefits (i.e., meals and grocery support and non-medical transportation)
 - Social Security Act Section 1115 demonstrations that allow states to propose coverage of medically appropriate, time-limited interventions for health-related social needs

- Home and Community Based Services, which can cover meals and other services for a population that would otherwise not be able to remain at home
- CMS is currently seeking input as they develop guidance for the Enhancing Oncology Model that would support oncology physician group practices and other payers in providing innovative payment strategies that promote high-quality, person-centered equitable care to Medicare fee-for-service beneficiaries who are undergoing chemotherapy treatment.
- The Health Resources and Services Administration (HRSA) stated that health centers may be considered key recruitment sites since individuals receiving services are diverse, health centers screen for cancer and BMI, 74% also screen for social risk factors, and the [Uniform Data System](#) is moving from aggregated data to patient-level data providing greater opportunities for research collaborations.
- USDA's NIFA has five key programs that may provide opportunities for collaboration including:
 - [Expanded Food and Nutrition Education Program](#): Provides nutrition education for populations living below the federal poverty line
 - [Gus Schumacher Nutrition Incentive Program](#): Brings together stakeholders from various parts of the food and health care systems to conduct and evaluate projects providing incentives to increase the purchase or procure more fruits and vegetables by income-eligible consumers
 - [Community Food Projects](#): Supports community-led food projects including urban agriculture
 - [Food and Agriculture Service Learning Program](#): Supports programs that aim to increase knowledge of agriculture and improve the nutritional health of children
 - [Agricultural and Food Research Initiative competitive grant - Diet, Nutrition, and the Prevention of Chronic Diseases](#): Aimed to improve food security and nutritional health outcomes for individuals and families living below the federal poverty line
- Collaborations with non-federal partners such as the National Association of Community Health Centers may also further work in this area.

2c. Discussion Highlights for Body Composition/Weight Management

The Federal Partners discussed the need to understand which body composition measures are being used widely between agencies to bring some consistency and standardization. During the discussion, the Federal Partners also explored data sources on body composition including retrospective data from the VA on BMI, physical activity data on cancer survivors from NCI's [Cancer Epidemiology Cohorts](#) and NCI's [Connect for Cancer Prevention Cohort Study](#) that is collecting biospecimens over five years and exploring the causes of cancer for approximately 200,000 participants. HRSA's Uniform Data System is also moving from aggregated data to patient-level data, providing greater opportunities for research collaborations, and electronic health record data (24-hour recalls for food frequency questionnaires) has the potential to provide insights into life-style habits.

The Federal Partners also discussed a number of programs that may be leveraged for work in this area including:

- [NIH All of Us Research Program](#) and [Nutrition for Precision Health](#) may be leveraged as a platform for future work.
- NCI's [SBIR Notice of Funding Opportunities \(NOFO\)](#) may also provide opportunities for future research on body composition.
- The VA's [Corporate Data Warehouse](#) and [VA Informatics and Computing Infrastructure](#) may provide opportunities for comparative studies and research collaborations.
- The CDC's [NHANES](#) and [National Health Interview Survey](#) may be leveraged for future research.

Potential Opportunities for Collaboration

- Partnerships between NCI, HRSA, CDMRP, and others may be helpful to understand the body composition measures that are used widely between agencies.
- DOD/CDMRP may be able to collaborate with intramural NIH labs to further work in this area.
- The CDC's Division of Nutrition, Physical Activity, and Obesity has three programs that provide opportunities for collaboration including:
 - [State Physical Activity and Nutrition \(SPAN\)](#) funds 16 state recipients to implement evidence-based strategies to improve nutrition and physical activity.
 - [Racial and Ethnic Approaches to Community Health \(REACH\)](#) is a national program to reduce disparities that funds communities to plan and implement local, culturally appropriate programs to address a wide range of health issues.
 - [High Obesity Program \(HOP\)](#) funds land grant universities to work with community extension services to increase access to healthier foods in counties with high obesity rates.
- The CDC's Division of Population Health has two programs that provide opportunities for collaboration including:
 - [Prevention Research Centers](#) is a network of 26 academic research centers that study how people and their communities reduce the risk for chronic diseases—some focused on physical activity and nutrition.
 - [Healthy Tribes program](#) partners with American Indian/Alaska Native communities to promote health, prevent disease, and strengthen cultural connections to improve health including healthy eating.
- [NIH Common Fund's Molecular Transducers of Physical Activity Consortium](#) (MoTrPAC) is a six-year program to study the molecular changes that occur during and after exercise and ultimately aims to advance the understanding of how physical activity improves and preserves health that may be leveraged for work in this area.
- FDA's [Oncology Center of Excellence](#) and [Office of Clinical Pharmacology](#) are looking at the impact of BMI and systematic therapy dosing on cancer outcomes using real-world data; however body composition is not available.

2d. Discussion Highlights for Symptom Management

The Federal Partners discussed how data collection on symptom management seems to be scarce and that there is a need to develop metrics and use standardized measures to better understand the impact of symptom management. One challenge is that symptom management is often considered as a secondary outcome in research studies, and there is a reluctance by funding agencies to specify too many outcomes for potential grantees. The Federal Partners considered the possibility of adding measures to non-nutrition studies as qualitative research to capture this type of data.

Potential Opportunities for Collaboration

- Patient reported outcomes research may provide some insights. The [FDA Oncology Center of Excellence](#) has a patient-focused drug development program; while not specific to nutrition interventions, lessons may be useful and transferable.
- The VA has programs that provide opportunities for collaboration on recommendations related to symptom management including:
 - [Clinical Nutrition Programs](#) (VHA Directive 1438)
 - [National Oncology Program](#)
 - National TeleOncology Program
- Non-profits and other non-federal organizations working in this area include:
 - National Comprehensive Cancer Network (NCCN)
 - [Cancer Support Community](#), which launched the Cancer Experience Registry collecting data on symptoms management and recently added about 10 questions on nutrition (data not released to date)
- Symptom management helps patients complete treatment; pharmaceuticals companies may be interested in supporting research studies.

2e. Discussion Highlights for Cost-Effectiveness Analysis

The Federal Partners discussed approaches to promote cost-effectiveness research. One consideration is to incorporate cost-effectiveness into NOFOs, especially using modeling. Reimbursement systems and capturing cost-effectiveness is complicated. The Federal Partners discussed that studying the length of hospitalization and pre- and post-intervention costs may be helpful. Possible examples to consider include [Kaiser Permanente projects](#) using modeling.

The potential benefits of cost-effectiveness research for addressing workforce issues were also discussed. The Federal Partners considered challenges related to the reimbursement of registered dietitian nutritionists (RDNs). While RDNs are commonly employed in inpatient settings, few are hired in outpatient settings, where the majority of cancer patients are treated. The Federal Partners discussed how more information on cost-effectiveness may promote hiring RDNs in outpatient settings to facilitate nutrition screening, the identification of malnutrition, nutritional interventions, and medical nutrition therapy.

Potential Opportunities for Collaboration

- CMS has state-specific waivers (described above), which need to demonstrate that they are budget neutral; partnerships with states can help further work in this area.
- The VA has resources that provide opportunities for collaboration on the panel's recommendations related to cost effectiveness analyses including:
 - [Health Economics Resource Center \(HERC\)](#) is the economic coordinating center conducting cost-effectiveness research for the Cooperative Studies Program
 - [VA Informatics and Computing Infrastructure](#)
 - [Corporate Data Warehouse](#)
- AHRQ has several initiatives that may be leveraged to support real-world data from comparative effectiveness studies including:
 - [Special Emphasis Notice \(SEN\): AHRQ Announces Interest in Health Services Research to Advance Health Equity \(NOT-HS-21-014\)](#)
 - [AHRQ's Dissemination and Implementation Initiative for patient-centered outcomes research \(PCOR\)](#)
 - [Cancer Patient Safety Learning Laboratory](#) (CaPSLL): Preventing Clinical Deterioration in Outpatients
- NCI, CMS, HRSA, and VA expressed interest in continuing the dialogue and determining next steps for work in this area.

3. Federal Partner Prioritized Activities

Short-Term (1-2 years)	
Screening for Nutritional Risks	Develop a working group to identify a short list of validated screening tools specific for children, adults, and older adults and specifically for capturing sarcopenia, especially for use in outpatient settings.
	Promote awareness of existing validated screening tools, i.e., Malnutrition Screening Tool, through NOFOs and other means.
	Raise awareness and build evidence on screening challenges and interventions to overcome them.
	Explore opportunities to work with non-federal partners like National Association of Community Health Centers and others to understand landscape, opportunities, and challenges related screening for nutritional risks.

Short-Term (1-2 years)	
Nutritional Interventions & Mechanistic Studies	Convene federal and non-federal partners including the Academy of Nutrition and Dietetics' Malnutrition Quality Improvement Initiative and the American Cancer Society to standardize cancer terminology for nutritional interventions; use the human milk composition work and AHRQ's Outcome Measures Harmonization projects as a model.
	Leverage the ASPEN's revised clinical guidelines for adults (available in 6- 9 months).
	Develop/revise NOFOs to examine nutritional interventions and support mechanistic studies; raise awareness and build evidence.
	Explore opportunities for mechanistic studies with the VA Precision Oncology Program's biobank.
	Engage oncology physician group practices participating in the CMS Enhancing Oncology Model or waiver programs in effectiveness studies.
	Create a forum to bring together federal partners, non-federal partners, and other stakeholders to share updates, new programs, and research findings related to cancer nutrition research and practice needs.
	Explore opportunities for trans-agency partnerships for research collaboration and agreements (e.g., HRSA Health Centers patient-level data may provide insights for secondary research, FDA Oncology Center of Excellence real-world data research collaborations, etc.)
Body Composition/ Weight Management	Convene Federal Partners to share information on which body composition measures are widely used to promote consistency and standardization and explore data sources.
Symptom Management	Leverage the Cancer Support Community's survey data, other patient reported outcomes data, and experience and expertise such as the FDA's patient-focused drug development team data to provide insights for symptom management.
Cost-Effectiveness Analysis	Convene a working group (e.g., NCI, CMS, HRSA, and VA) to determine next steps for promoting cost-effectiveness analysis.
	Work with the Academy of Nutrition and Dietetics Oncology Nutrition Practice Group to develop a cost-effectiveness model and support modeling studies; consider resources such as the VA's HERC.
	Engage in demonstration projects on cost effectiveness of screening and nutrition interventions such as with oncology physician group practices participating in the CMS Enhancing Oncology Model or waiver programs.
	Support micro-costing and/or budget impact analysis.

Medium Term (3-5 years)	
Screening for Nutritional Risks	Engage HRSA Health Centers in research related to screening for nutritional risks; analyze publicly available Uniform Data System data related to screening, BMI, and cancer outcomes.
	Consider findings from NCI's SBIR program that supports the development of automated nutrition screeners and potential for expanding innovative approaches.
	Consider findings from the VA's related grants such as The Feasibility of a Sarcopenia Screening and Treatment Protocol for Veterans in a VHA Cancer Center and potential for further learning related to defining and capturing sarcopenia.
	Connect dots between CDC's SPAN, HOP, REACH and other community-focused programs and HRSA Health Centers as appropriate to promote screening awareness, education, and resource utilization.
Nutritional Interventions & Mechanistic Studies	Consider findings from NCI, CDMRP, and the VA's related grants and projects and potential for further learning.
	Plan a pre-conference workshop at the annual ASPEN conference.
Body Composition/ Weight Management	Consider findings from NCI's ENICTO, MoTrPAC, and other related grants and projects from NCI, CDMRP, and the VA for further learning.
	Explore collaborations with the FDA's Oncology Center of Excellence and Office of Clinical Pharmacology , which are currently examining the impact of BMI and systematic therapy dosing on cancer outcomes.
Symptom Management	Consider findings from related grants and projects from NCI and the VA for further learning.
	Collaborate with the Cancer Support Community , which launched the Cancer Experience Registry collecting data on symptoms management and recently added about 10 questions on nutrition (data not released to date).
Cost-Effectiveness analysis	Consider findings from demonstration projects on the cost-effectiveness of screening and nutritional interventions for further learning.
	Leverage real-world data from comparative effectiveness studies such as data from AHRQ's PCOR and CaPSLL initiatives, the VA's Corporate Data Warehouse, and HRSA's Uniform Data System.

Long-Term (>5 years)	
Screening for Nutritional Risks	Support the development of organizational and practitioner training on the use of validated screening tools and innovative screening approaches.
	Engage non-federal partners in promoting the addition of body composition data to electronic health records.
Nutritional Interventions & Mechanistic Studies	Work with USDA's NIFA ASCEND for Better Health , a virtual science center for coordinating precision nutrition research to understand alignment and opportunities
	Consider collaborations with the CDC's Prevention Research Centers and CDC's National Comprehensive Cancer Control Programs, HRSA Health Centers, or non-federal partners such as the National Association of Community Health Centers for nutritional intervention and mechanistic studies.
Body Composition/ Weight Management	Explore use of HRSA's patient-level data on body composition for further analysis and insights; data may be available for secondary analysis.
	Develop a central repository for data collected from across agencies (similar to the VA's Corporate Data Warehouse).
Symptom Management	Explore collaborations with the VA's Clinical Nutrition Programs and National Oncology Program as well as non-federal organizations such as NCCN to explore work in this area.
	Consider engaging pharmaceuticals companies to support research studies in this area.
Cost-Effectiveness analysis	Apply learnings from cost-effectiveness research to address workforce issues related to the shortage of RDNs.

4. Next Steps and Concluding Remarks

Federal Partners are asked to disseminate the systematic evidence review and P2P workshop panel report publications to their networks and audiences. Federal Partners are encouraged to look for opportunities to share the findings with their networks of investigators and other stakeholders. Federal Partners are also encouraged to initiate activities to implement short-, medium-, and long-term goals outlined in this report.

ODP conducts assessments of the impact of the P2P program. Impact assessments focus on capturing whether the P2P process promotes investments, impacts the science, promotes new partnerships and collaborations, and encourages collaborations with professional and community groups.

APPENDIX A

NATIONAL INSTITUTES OF HEALTH PATHWAYS TO PREVENTION (P2P) PROGRAM: NUTRITION AS PREVENTION FOR IMPROVED CANCER HEALTH OUTCOMES FEDERAL PARTNERS MEETING ROSTER

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Appendix B
NATIONAL INSTITUTES OF HEALTH PATHWAYS TO PREVENTION (P2P) PROGRAM:
INDEPENDENT PANEL RECOMMENDATIONS

	Recommendations	KQ1 & KQ2	KQ3	KQ4	Contextual
1	Rigorous, well-designed nutritional intervention studies conducted in the U.S. in adults diagnosed with cancer who are at risk for or have definite cancer-associated malnutrition to allow for comparisons across studies.	x	x	x	
2	Studies examining malnutrition across a larger variety of cancer diagnoses, and in outpatient settings. Pragmatic studies embedded in clinical practice or mirroring real world clinical care will help to address issues inherent to both vulnerable populations and varied settings.	x	x	x	
3	Screening for nutritional status, risk, and body composition using validated and standard measurement approaches with defined cut points to identify malnutrition should be routinely integrated throughout the care process and across all cancer care settings.	x	x	x	
4	Longitudinal studies to examine optimal timing of nutritional interventions that may enhance earlier diagnosis of adverse outcomes of cancer such as cachexia, sarcopenia, adverse events, and quality of life, or avoid or improve nutrition impact symptoms.	x	x		
5	Examination of biological mechanisms that would assist in designing approaches such as dietary restriction versus supplementation for specific cancer patients with respect to age, ethnicity, and sex as well as for differing types of cancer diagnoses and treatments.	x			
6	Studies that integrate dietitians and their expertise into the health care team and that are powered to examine the impact of nutrition interventions on cancer outcomes (e.g., cancer treatment tolerance, health care resources utilization, treatment-limiting side effects, survival, and quality of life) by cancer type, treatment type, wasting status, comorbidity status, and across the lifespan.	x	x		
7	Large nutrition intervention studies to evaluate the efficacy of common interventions on improving important outcomes such as cancer treatment tolerance, health care resources utilization, treatment-limiting side effects, survival, and quality of life.	x			
8	Studies that disentangle age from cancer-related sarcopenia and cachexia.				

	Recommendations	KQ1 & KQ2	KQ3	KQ4	Contextual
9	Greater diversity among cancer diagnoses and inclusion of those with differing body composition prior to and during treatment to better understand the relationships among physiologic muscle wasting and deterioration and cancer treatment and suggest optimal timing for nutritional intervention, screening, and support. This might be accomplished by creating large biobanks of both host and tumor specimens and body composition data to understand mechanisms leading to muscle abnormalities.	x		x	
10	Improved screening methods to identify loss of muscle volume or function that can occur even in the presence of obesity. Reliance on edema-dependent markers and BMI alone is ineffective.	x		x	
11	More direct measures of adiposity and muscle mass to add rigor to the investigation of the relationships between body composition and outcomes of different types of cancer treatment. Prospective studies exploring the role of body composition in predicting dose-limiting toxicities and the relationship between dose modification and clinical outcome to lay a foundation for more customized treatment dosing and timing.			x	
12	Research on weight and cancer outcomes to consider a patient's disease trajectory and body composition changes across time.	x		x	
13	Randomized controlled dietary interventions that incorporate intentional weight loss before and during cancer treatment designed to address variables such as timing, rate, and mode of weight loss that may influence outcomes.			x	
14	Since evidence supports physical activity during cancer treatment as beneficial in managing quality of life, its potential to minimize loss of lean body mass during weight loss warrants its inclusion in weight loss intervention trials. Interventions that test physical activity with and without weight loss to provide insight for optimal treatment of people who have overweight or obesity.			x	
15	RCTs of nutritional interventions that incorporate CEAs.				x

Recommendations		KQ1 & KQ2	KQ3	KQ4	Contextual
16	Use of methodologic approaches other than RCTs, such as robust modeling techniques (e.g., CISNET, mini-models based on electronic health records, and Learning Health Systems), analyses of large population-based data (e.g., NHANES, NDI, SEER, health insurance claims, CMMI payment model data, “real-world” data from comparative effectiveness studies), including CEAs to answer “what if?” questions assessing the cost-savings or cost-effectiveness of effective nutritional interventions.				x
17	Increased adherence to national guidelines and guidance for systematic methods and approaches to CEA to enhance generalizability and replication of interventions in diverse settings and promote consistency and clarity with justification for every cost included in analyses. Robust methods include addressing the multiple perspectives (e.g., patient, payer, provider, or societal), capturing implementation- and intervention-specific costs, patient out-of-pocket costs, and changes in health care utilization that may be attributable or downstream to the intervention.				x



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