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October 28, 2022

National Institute of Health: Pathway to Prevention Program Attn: Robert A Hiatt, M.D., Ph.D. University of California, San Francisco 550 16th Street, 2nd Floor Mission Hall San Francisco, California 94158

Re: Open for Comment - Panel's Draft Report: Nutrition as Prevention for Improved Cancer Health Outcomes

Dear Dr. Hiatt and the Pathway to Prevention Committee,

The Academy of Nutrition and Dietetics (the "Academy") is pleased to provide input on the first draft of the *Nutrition as Prevention for Improved Cancer Health Outcomes*. Representing more than 112,000 credentialed nutrition and dietetics practitioners, including registered dietitian nutritionists (RDNs),<sup>1</sup> RDNs possessing Board Certification as Specialists in Oncology Nutrition,<sup>2</sup> nutrition and dietetic technicians, registered (NDTRs), and advanced-degree nutritionists, the Academy is the world's largest organization of food and nutrition professionals. The Academy is committed to improving the nation's health and advancing the profession of dietetics through research, education and advocacy. RDNs independently provide professional services such as medical nutrition therapy (MNT)<sup>3</sup>, along with other nutrition care services to individuals throughout the lifecycle – prenatal care thought end of life care. MNT is an evidence-based, low-cost intervention shown to improve patient outcomes. The provision of MNT often includes nutrition assessment and reassessment; nutrition diagnosis; nutrition counseling and interventions; nutritional status monitoring and evaluation that typically results in prevention, delay, or management of diseases and/or conditions; education; and counseling.<sup>4</sup>

#### **Overarching Comments**

The Academy supports the first draft NIH-P2P Framework and recommendations addressing nutrition as prevention for improving outcomes for patients affected by cancer. We echo the authors' sentiments that addressing the unique nutritional needs for individuals with cancer is complex and often requires ongoing interdisciplinary team management to achieve optimal outcomes. Furthermore, the Academy acknowledges the

<sup>&</sup>lt;sup>1</sup> The Academy has approved the optional use of the credential "registered dietitian nutritionist (RDN)" by "registered dietitians (RDs)" to more accurately convey who they are and what they do as the nation's food and nutrition experts. The RD and RDN credentials have identical meanings and legal trademark definitions.

<sup>&</sup>lt;sup>2</sup> Commission on Dietetic Registration: <u>https://www.cdrnet.org/certifications/board-certification-as-a-specialist-in-oncology-nutrition</u>, October 25, 2022

<sup>&</sup>lt;sup>3</sup> Medical nutrition therapy (MNT) is an evidence-based application of the Nutrition Care Process. The provision of MNT (to a patient/client) may include one or more of the following: nutrition assessment/reassessment, nutrition diagnosis, nutrition intervention and nutrition monitoring, and evaluation that typically results in the prevention, delay, or management of diseases and/or conditions. <u>Academy of Nutrition and Dietetics' Definition of Terms List</u> Updated February 2020. Accessed October 19, 2022.

<sup>&</sup>lt;sup>4</sup> Academy of Nutrition and Dietetics' Definition of Terms list updated September 10, 2019. Accessed October 25, 2022.

significant challenges inherent in the medical management of cancer given the heterogeneity of cancer types, stage, progression, environmental and genetic implications. Hence, the challenges faced when identifying the specific role of nutrition in oncology care are vast. Access to nutrition care services provided by RDNs remains a barrier, despite the extensive training that oncology RDNs receive regarding the pathophysiology of carcinogenesis, malnutrition screening, medical nutrition therapy, management of nutrition impact symptoms, and behavioral in both the inpatient and ambulatory settings. The Academy offers the following recommendations for consideration.

# Conceptual Framework

The Academy supports the NIH-P2P's conceptual framework and recognize that key factors impact the timing of nutrition screening which, in turn, dictates the initiation and timeliness of nutrition interventions. We support RDNs as critical team members in the definition of key terms (Nutritional Assessment, Malnutrition Screening Tool and the Patient Generated Subjective Global Assessment) and consensus that RDN referrals be made when there is a risk of malnutrition. RDNs are well-positioned to contribute to quality care by performing nutrition screening, assessment, and providing care throughout treatment. In addition, "RDNs are qualified to discuss diet, nutrition, lifestyle recommendations for survivorship, health promotion and disease prevention." <sup>5</sup> We encourage NIH to consider specifying RDNs as key partners in Oncology Nutrition Care and as well as recognizing the critical role of RDNs in the framework.

# Access to and Coverage for Nutrition Services by Qualified Practitioners

Nutrition therapy aims to maintain or improve energy and protein intake, mitigate metabolic abnormalities, preserve physical function, reduce the risk of treatment intolerance, and improve quality of life before, during and after curative or palliative treatment.<sup>6</sup> Aligning with the standards and guidelines of reputable oncology care organizations, the Academy recommends the routine provision of MNT by RDNs throughout the continuum of cancer care. The American College of Surgeons' Commission on Cancer (CoC), the Association of Community Cancer Centers, American Society of Clinical Oncology (ASCO), The National Comprehensive Cancer Network's 2019 Guidelines for Older Adult Oncology, the American and European Societies of Parenteral and Enteral Nutrition (ASPEN/ESPEN), all "...advocate for formalized nutrition screening and assessment, nutrition care plans, and early medical nutrition therapy (MNT) when deficits are detected among patients with cancer."<sup>7 8 9 10</sup> <sup>11,12</sup> The CoC's 2020 Standards for Oncology Nutrition Services also specify that oncology nutrition services be provided by an RDN, identifying the RDN as "uniquely trained to address treatment-related symptom management, nutrition support, and quality of life concerns through MNT and education."<sup>5</sup>

<sup>&</sup>lt;sup>5</sup> <u>American College of Surgeons Optimal Resources for Cancer Care 2020 Standards</u> Commission on Cancer. Updated November 2021. Accessed October 19, 2022.

<sup>&</sup>lt;sup>6</sup> Muscaritoli M, Arends J, Bachmann P et al (2021) ESPEN practical guideline: clinical nutrition in cancer. Clin Nutr. <u>https://doi.org/10.1016/j.clnu.2021.02.005</u>

<sup>&</sup>lt;sup>7</sup> <u>American College of Surgeons Optimal Resources for Cancer Care 2020 Standards</u> Commission on Cancer. Updated 2021. Accessed October 19, 2022.

<sup>&</sup>lt;sup>8</sup> National Comprehensive Cancer Network Clinical Guidelines Older Adult Oncology. 2019. Version 1. <u>https://www.nccn.org/professionals/physician\_gls/default.aspx#senior</u>

<sup>&</sup>lt;sup>9</sup> Cancer Center Services: A Practical Guide for Cancer Programs Rockville MD: The Association of Community Cancer Centers; 2012.

<sup>&</sup>lt;sup>10</sup> Arends J, Baracos V, Bertz H, et al. ESPEN expert group recommendations for action against cancer-related nutrition. Clin Nutr. 2017; 36(5): 1187-1196.

<sup>&</sup>lt;sup>11</sup> August DA, Huhmann MB. A.S.P.E.N clinical guidelines: nutrition support therapy during adult anticancer treatment and in hematopoietic cell transplantation. JPEN. 2009; 33(5): 472-500.

<sup>&</sup>lt;sup>12</sup> National Institute for Health and Care Excellence. <u>http://www.nice.org.uk/Guidance/Topic</u>. Accessed October 19, 2022

Despite these recommendations, many oncology patients lack access to comprehensive nutrition care, and most cancer patients never receive nutritional counseling during their treatment.<sup>13, 14</sup> **The vast majority of cancer patients do not have access to oncology nutrition services in the outpatient setting, where 90% of treatment occurs.** MNT is not consistently included in multidisciplinary outpatient cancer care<sup>15</sup> and 30-66% of patients report that their nutrition information needs were unmet.<sup>16</sup> In fact, the average dietitian-to-patient ratio in ambulatory cancer settings across the United States is one RDN to every 2,308 cancer patients, far below the estimated ratio of one RDN to every 120 cancer patients for proactive nutrition care.<sup>17</sup> The 2016 National Academy of Sciences, Engineering and Medicine (NASEM) workshop, *Examining Access to Nutrition Care in Outpatient Cancer Centers*, examined challenges to accessing nutrition care in ambulatory oncology settings. This workshop identified the lack of integration of nutrition services into the cancer health care system and suboptimal RDN staffing in cancer centers secondary to inadequate reimbursement for services as major limitations to adequately accessing and implementing oncology nutrition care.<sup>18</sup> The absence of payment for MNT and the need to expand nutrition resources is a significant barrier to nutrition cancer care.<sup>19</sup>

Centers for Medicare & Medicaid Services' Oncology Care Model (OCM) ended on June 30, 2022. This model offered incentives to treat patients more effectively, holistically and make proactive steps to keep patients out of the hospital. To receive incentive payments, known as Monthly Enhanced Oncology Services (MEOS), practices needed to ensure that patients had access to staff and cost-effective therapies, including nutrition care. Without the supportive payments, practices are faced with the choice of forgoing therapies such as nutrition care or offering the therapies and then passing the cost to the patient. It is crucial that there are sustainable delivery models of care to support access to MNT provided by RDNs. Medicare Part B benefits for MNT do not include coverage for any oncology diagnoses, nor related complications that include nutrition impact symptoms or malnutrition.<sup>20</sup> Leveraging the OCM allowed for the allocation of payment for MNT as a component of integrated cancer care, overcoming an immense barrier that would otherwise require congressional action to address. Currently, MNT is statutorily limited to Medicare beneficiaries with diabetes, non-dialysis chronic kidney disease, or are 36 months post-transplant. In May 2021, the Academy championed the introduction of the Medical Nutrition Therapy Act during the 117<sup>th</sup> U.S. Congress, a bill that seeks to expand access to care for Medicare beneficiaries by providing Medicare Part B coverage for MNT, beyond just diabetes and kidney disease, including malnutrition and cancer.

### Malnutrition Screening

Health care teams cannot treat what has not been identified. Early identification and diagnosis of malnutrition leads to interventions that positively impact not only body composition and functional status, but also improve

<sup>&</sup>lt;sup>13</sup> Trujillo EB, Dixon SW, Claghorn K, Levin RM, Mills JB, Spees CK. Closing the gap in nutrition care at outpatient cancer centers: ongoing initiatives of the oncology nutrition dietetic practice group. J Acad Nutr Diet. 2018;118:(4):749-760.

<sup>&</sup>lt;sup>14</sup> Arends J, Bachmann P, Baracos V, et al. ESPEN guidelines on nutrition in cancer patients. Clin Nutr. 2017; 36(1):11-48.

<sup>&</sup>lt;sup>15</sup> Platek ME, Johnson J, Woolf K, Makarem N, and Ompad DC. Availability of outpatient clinical nutrition services for patients with cancer undergoing treatment at comprehensive cancer centers. J Oncol Pract. 2015;11(1):1-5.

<sup>&</sup>lt;sup>16</sup> Van Veen MR, Beijer S, Adriaans AMA, Vogel-Boezeman J, and Kampman E. Development of a website providing evidence-based information about nutrition and cancer: fighting fiction and supporting facts online. JMIR Res Protoc. 2015. 4:33; e110.

<sup>&</sup>lt;sup>17</sup> Trujillo E.B., Claghorn K, Dixon SW, Hill EB, Braun A, Lipinski E, Platek ME, Vergo MT, and Spees CK. Inadequate nutrition coverage in outpatient cancer centers: results of a rational survey. J Oncol. 2019; Article ID 7462940 <u>https://doi.org/10.1155/2019/7462940</u> Accessed December 6, 2019.

<sup>&</sup>lt;sup>18</sup> Examining Factors in Access to Nutrition Care in Outpatient Cancer Centers Proceedings of a Workshop. National Academies of Sciences Engineering Medicine. August 15 2016. Accessed November 18, 2019.

<sup>&</sup>lt;sup>19</sup> Prado, C.M., Livian, A., Gillis, C. *et al.* Examining guidelines and new evidence in oncology nutrition: a position paper on gaps and opportunities in multimodal approaches to improve patient care. *Support Care Cancer* 30, 3073–3083 (2022). https://doi.org/10.1007/s00520-021-06661-4

<sup>&</sup>lt;sup>20</sup> Decision Memo for Medical Nutrition Therapy Benefit for Diabetes & ESRD February 28, 2002. Accessed November 17, 2019

quality of life and treatment tolerance.<sup>21</sup> There is consensus among oncology care providers and organizations that patients should be screened for malnutrition risk using a validated screening tool.<sup>21</sup> In the United States, just over 50% of cancer centers screen for malnutrition risk, with only 65% of those using a validated screening tool. It is further documented that the rate of screening increases when a validated, standardized malnutrition screening tool is embedded in an electronic health record/electronic medical record.<sup>21</sup>

It is the Academy's position that the Malnutrition Screening Tool (MST) should be used to screen adults for malnutrition regardless of their age, medical history or setting. The MST is validated, easy to use and can be performed by a variety of clinical staff; therefore, the Academy advocates for use of a single tool to screen all adults for malnutrition, regardless of setting. <sup>22</sup> However, we also recognize there are other validated, reliable nutrition risk screening tools, other than the MST, and that there may be a need to utilize one based on setting or population needs. For example, Academy member feedback supported the use of the PG-SGA, particularly in the inpatient setting. The Academy does support the use a validated diagnostic tool when appropriate and when it is implemented correctly.

Patients identified as at-risk for malnutrition should be referred to an RDN for a comprehensive nutrition assessment, including a nutrition-focused physical exam, to identify physical signs of nutrient deficiencies and the presence of malnutrition, as well as to identify interventions to maximize adequate intake.<sup>23</sup> Literature has well established that malnutrition, muscle loss and cachexia are key challenges for many patients with cancer, and are also factors associated with poor health outcomes. Malnutrition is more prevalent in older patients, rural residents and those with racial and ethnic disparities.<sup>24,25</sup> Evaluation of nutritional status helps to inform expected responses to treatment and enables the identification of sub-populations at risk who might not otherwise be identified, such as those with the co-existence of overweight or obesity and malnutrition.<sup>26</sup> Additionally, evaluation of nutritional status facilitates the possibility of timely nutrition counseling and interventions to reduce the risk of complications. There is strong evidence that poor nutritional status in adults with cancer is associated with greater hospital admissions and readmissions, increased hospital length of stay, interruptions in treatment, treatment-related toxicities, lower quality of life and mortality.<sup>21</sup> The role of MNT in mitigating nutrition impact symptoms during active treatment is demonstrated across cancer types and treatment modalities.<sup>27</sup>

### Nutrition Research

The Academy supports research efforts to implement and test nutrition interventions throughout the cancer continuum to inform the standard of care and develop best practices for cancer care. We support the research

<sup>&</sup>lt;sup>21</sup> Thompson, KL, Elliott, L, Fuchs-Tarlovsky, V., Levin, RM, Coble Voss, A, and Piemonte, T. Oncology evidence-based nutrition practice guidelines for adults." J Acad Nutr Diet. 2017; 117(2): 297-310.

<sup>&</sup>lt;sup>22</sup> Position of the Academy of Nutrition and Dietetics: Malnutrition (Undernutrition) Screening Tools for All Adults. J Acad Nutr Diet. 2020; 120 (4): 709-713

<sup>&</sup>lt;sup>23</sup> Philips W, Janowski W, Brennan H, and Leger-LeBlanc G. Nutrition Focused Physical Exam improves accuracy of malnutrition diagnosis. J Acad Nutr Diet. 2019; 119(9); S68.

<sup>&</sup>lt;sup>24</sup> Extermann M, Boler I, Reich RR, Lyman GH, Brown RH, DeFelice J, et al. Predicting the risk of chemotherapy toxicity in older patients: the Chemotherapy Risk Assessment Scale for High-Age Patients (CRASH) score." Cancer. 2012;118(13):3377–86. https://doi.org/10.1002/cncr.26646

<sup>&</sup>lt;sup>25</sup> Ferrat E, Paillaud E, Laurent M, Le Thuaut A, Caillet P, Tournigand C, et al. Predictors of 1-year mortality in a prospective cohort of elderly patients with cancer. J Gerontol A Biol Sci Med Sci. 2015;70(9):1148–55. <u>https://doi.org/10.1093/gerona/glv025</u>

<sup>&</sup>lt;sup>26</sup> Xiaotoa Z, Sun M, McKoy JM, Bhulani NNA, Valero V, Barcenas CH., Ropat UR., Karuturi Sri M., Shah JB., Dinney CP, Hedberg AM, Champlin R, Tripathy D, Holmes HM, Stroehlein JR, Edwards BJ. Malnutrition in older patients with cancer: appraisal of the Mini Nutritional Assessment, weight loss, and body mass index. Letter to the editor. J of Geriatr Oncol. 2018; 9:81-83

<sup>&</sup>lt;sup>27</sup> Lee JL, Leong LP, Lim SL. Nutrition intervention approaches to reduce malnutrition in oncology patients: a systematic review. Support Care Cancer 2016; 24:469-80.

recommendations for adults put forth in Table 3 of the draft recommendations but note these recommendations appear to be specific to the adult population with cancer, versus pediatrics. The Academy recommends highlighting the focus on adults in either the title, abstract or both. Also, if appropriate, we encourage acknowledging that these same research questions are relevant for pediatric patients with cancer, which is an even bigger research gap. Additionally, we support using the Nutrition Care Process<sup>28</sup> and standardized terminology, such as the electronic Nutrition Care Process Terminology (eNCPT),<sup>29</sup> when conducting nutrition research; this not only provides a structure for nutrition care but also offers a standardized framework for how nutrition care is documented and can be used to support the evaluation of outcomes and comparisons among future research.

Table 3: Expert Panel Recommendations for Moving the Field Forward

- **Recommendation #3** Screening for nutritional status, risk, and body composition using validated and standard measurement approaches with defined cut points to identify malnutrition.
  - As written, this appears to be more of a clinical recommendation versus a research recommendation.
  - Consider adjusting the beginning of the statement to read: *"Consistent screening for nutrition status, risk and body composition using validated..."*.
  - Recommend ending the statement with "should be routinely implemented throughout care and across all cancer care settings."
- **Recommendation #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.
  - Consider adjusting statement to read: "optimal timing of nutrition assessment that may enhance early diagnosis and intervention for..."
- **Recommendation #5** Examination of nutritional 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.
  - Request further clarification on what is meant by "nutritional mechanisms".
  - Consider adjusting statement to read: "Research to identify therapeutic nutrition interventions appropriate for specific cancer patients with respect to age, ethnicity, and sex, as well as for differing types of cancer diagnoses and treatments."
- **Recommendations #6** Studies 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 mortality) by cancer type, treatment type, malnutrition status, comorbidity status, and across the lifespan.
  - Recommend adding quality of life, unplanned hospitalizations, interruptions in treatment, and emergency department visits as examples of outcomes.
- **Recommendation #7** Large nutrition intervention studies to evaluate the efficacy of nutrition-related interventions on improving important outcomes such as cancer treatment tolerance, health care resources utilization, treatment-limiting side effects, survival, and mortality.
  - Recommend adding quality of life, unplanned hospitalizations and ER visits as example outcomes.

<sup>&</sup>lt;sup>28</sup> Nutrition Care Process: <u>https://www.eatrightpro.org/research/projects-tools-and-initiatives/nutrition-care-</u>

process#:~:text=The%20Nutrition%20Care%20Process%20is,and%20nutrition%20monitoring%20and%20evaluation. Accessed on October 25, 2022

<sup>&</sup>lt;sup>29</sup> Electronic Nutrition Care Process Terminology: <u>https://www.ncpro.org/</u>. Accessed on October 25, 2022

- We are unclear as to the distinction between #6 and #7, could these possibly be combined?
- **Recommendation #10** Rigorous studies in the assessment of symptoms as an integral part of exposure and important study outcomes.
  - Consider providing more clarity in this recommendation as to help differentiate from Recommendations #6 and #7. For example, is this a call to improve methods for assessing nutrition impact symptoms and the outcomes listed in #6/#7?

#### Additional recommendations to consider:

- The Academy encourages the committee to consider:
  - A recommendation that is focused on implementation science to understand the best ways to consistently implement nutrition risk screening and effective nutrition interventions across cancer treatment settings.
  - A specific identification of interventions that decrease inequities and nutrition insecurity in cancer outcomes by race/ethnicity, socioeconomic status and other social determinants of health.
  - $\circ$   $\;$  A recommendation that is focused on cancer prevention.

Thank you for your consideration of the Academy's comments on the Panel's Draft Report: Nutrition as Prevention for Improved Cancer Health Outcomes. The Academy urges NIH to specify RDNs as key partners in Oncology Nutrition Care and stress that there is a critical need for sustainable financial support for RDN services in order for there to be full integration of nutrition into oncology care. Please contact Jeanne Blankenship (by 312-899-1730 or <u>iblankenship@eatright.org</u>) or Carly Léon (312-899-1773 or <u>cleon@eatright.org</u>) with any questions or requests for additional information.

Sincerely,

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