

Integrating Routine Nutritional Screenings for Cancer Patients at the Point of Care: Pilot Testing a Novel Care Planning System Plus Certified Professional Training

Target Audience

The target audience for these activities includes community-based medical oncologists, physician assistants, nurse practitioners, clinical nurse specialists, oncology nurses, nurse navigators, palliative/symptom management physicians and/or nurses, and other multidisciplinary members of the cancer care team.

Educational Objectives

After completing this activity, the participant should be better able to:

- Recognize which cancer patient populations are at greatest risk for malnutrition
- Implement a standardized clinical screening of nutrition among cancer patients
- Generate a personalized care plan on malnutrition prevention that is consistent with evidence-based practice guidelines management
- Provide appropriate care and counsel for patients and their families

Chair

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Physician Continuing Medical Education

Accreditation Statement

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Credit Designation

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Credit Designation

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Cancer and Nutrition - An Overview

Faith Ottery, MD, PhD, FACN

There are approximately 14.5 million cancer survivors living in the United States today^{1,2}, representing one of the fastest growing patient groups with chronic disease. However, as the late Maryl Winningham, RN, PhD, the acclaimed clinician and educator who had her own bout with cancer, noted,

“While diagnosis, treatment, and even cure-oriented research continues, it is imperative that there be a parallel commitment to the improvement of the status of everyday living for cancer survivors. Development of research-based clinical interventions in these areas holds promise for significant improvement in functioning and quality of life for cancer survivors and may constitute valuable rehabilitation techniques that can be adjunctive to standard therapies.”³

This commitment to the quality of care across the cancer continuum is the bedrock of successful treatment.

As early as 1980, Dewys and colleagues demonstrated the adverse impact of weight loss on performance status and outcomes.²³ The subsequent work by Winningham³, Courneya^{4,5}, Demark-Wahnefried⁶, Fearon⁷, Baracos,⁸ and others confirms that failing to address the nutritional and metabolic needs of patients adversely impacts oncologic outcomes and quality of survivorship. This monograph briefly reviews the definition, measurement, grading, and prognostic value of cancer-related weight loss, cachexia, and other relevant concepts.

Grading weight loss

For most therapy toxicities, the National Cancer Institute’s Common Terminology Criteria for Adverse Events (CTCAE) Grades 0 to 2 are considered acceptable or tolerable negative side effects. It is only when a patient experiences a Grade 3 toxicity that oncology protocols generally mandate changes such as treatment delays and dose modifications. Interestingly, while the CTCAE grades weight loss (Table 1),²⁴ significant degrees of such loss are accepted (Grades 0-2) without concern for the impact of this weight loss on outcomes.

Table 1. National Cancer Institute’s Common Toxicity Criteria for weight loss on treatment²⁴

NCI Grade	Severity	Degree of Weight Loss
0	None	<5%
1	Mild	5% to <10%
2	Moderate	10% to <20%
3	Severe	≥20%
4	Life-threatening	Not defined
5	Death	Death

The criteria also do not consider pretreatment weight loss, which is common in patients on presentation. Dewys and colleagues documented the prognostic implications of the loss of weight prior to chemotherapy in 3,047 patients with cancer who were enrolled in 12 chemotherapy protocols in the Eastern Cooperative Oncology Group (ECOG).²³ This early work demonstrated that the frequency of weight loss varied by tumor type, ranging from 31% for non-Hodgkin lymphoma to 87% in gastric cancer. Adverse oncology outcomes associated with weight loss included the following:

- Median survival was significantly shorter in nine protocols for the patients *with* weight loss compared to the patients *with no* weight loss.
- Chemotherapy response rates were lower in the patients with weight loss, but this difference was only significant in those with breast cancer.
- Decreasing weight was correlated with decreasing ECOG performance status, except for patients with pancreatic and gastric cancer.
- Within performance status categories, weight loss was associated with decreased median survival.
- The frequency of weight loss increased with an elevated number of anatomical sites involved with metastases, within categories of anatomical involvement, however, weight loss was associated with decreased median survival.
- These observations emphasize the prognostic effect of weight loss, especially in patients with a favorable performance status or a limited anatomical involvement with tumor.

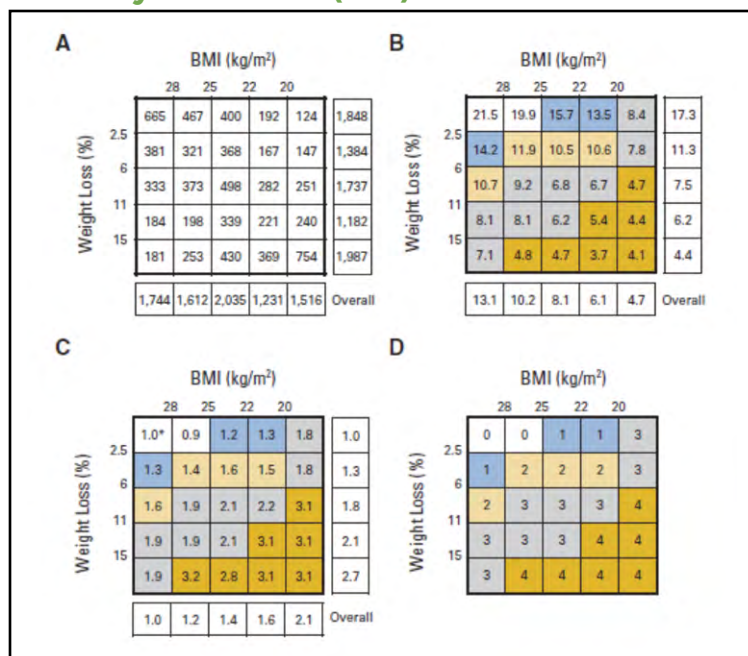
This and other studies indicate that weight loss as little as 2% to 5% (i.e., CTCAE Grade 0) is associated with:

- Decreased performance status^{25,26}
- Increased fatigue²⁶⁻³⁰
- Decreased quality of life^{25,26,31}
- Increased therapy toxicity^{25,31-33}
- Increased risk of dose modification and treatment delays^{25, 34-37}
- Decreased overall and progression free survival³⁴⁻⁴³
- Decreased patient compliance and completion of planned therapy³⁴⁻³⁷

Combining two simple parameters of weight loss and body mass index (BMI) has recently been shown by Martin and colleagues to be highly predictive of death in patients with cancer (Figure 1) and may be more accurate and useful than the CTCAE grading system.⁴⁴

A cohort of 8,160 Canadian and European patients with cancer was used to correlate BMI, percentage of weight loss (%WL), and overall survival. The data indicated that both %WL

Figure 1. Survival grading system based on weight and body mass index (BMI)⁴³



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and BMI independently predicted survival. A 5 x 5 matrix representing the five %WL categories within each of the five BMI categories was graded based on median survival and prognostic significance. Weight-stable patients with a BMI ≥ 25.0 kg/m² (grade 0) had the longest survival (20.9 months; 95% CI, 17.9 to 23.9 months), and %WL values associated with lowered categories of BMI were related to shorter survival ($P < 0.001$), as follows:

- Grade 1: 14.6 months
- Grade 2: 10.8 months
- Grade 3: 7.6 months
- Grade 4: 4.3 months

Cachexia: Definition and prognostic significance

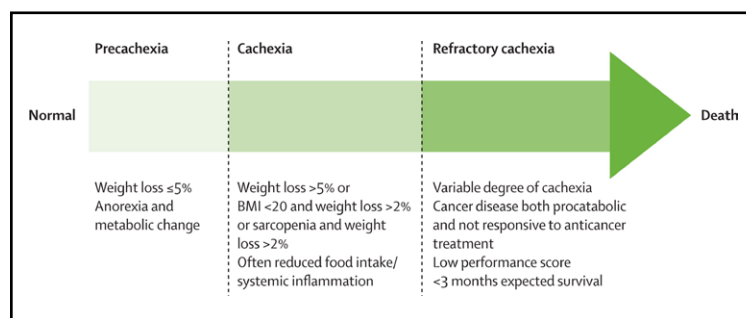
Historically, cancer cachexia—progressive weight loss, muscle atrophy, and anorexia in response to a malignancy—has been the focus of much research and literature in the area of cancer and nutrition. And the reasons why interest in advanced stages of malnutrition or cachexia has been so prevalent are manifold, including:

- Cancer diagnosis made at an advanced or metastatic stage
- Therapeutic anticancer interventions that either were inadequately effective in treating the cancer or were so aggressive, and with such severe side effects, that nutritional intake or absorption was nearly impossible for significant periods of time while the patient was on therapy
- Lack of adequately effective pharmacological management of nutrition impact symptoms or failure to proactively assess such symptoms as well as failure of patients to voice their symptoms for a variety of reasons, including not wanting to be perceived as being complainers

- Lack of adequate education or training regarding the importance of proactive nutritional screening, assessment, and intervention
- Lack of awareness of sarcopenic obesity, in which the patient is significantly overweight but may have significant, even life-threatening loss of lean tissue or muscle mass.
- Acceptance, often misplaced, that involuntary, unintentional, or inadvertent weight loss (IWL) is inherently part of the cancer continuum
- Some clinicians believe that the only way to effectively treat cancer-related weight loss is to cure, place in remission, or significantly ameliorate the cancer, with failure to appreciate that progressive catabolism and weight loss are themselves associated with adverse outcomes.

Originally, cachexia was defined in an end-stage, terminal setting, but it is now considered more of an ongoing catabolic process. Figure 2 below summarizes recent developments in this understanding.⁷

Figure 2. Stages of cancer cachexia⁷



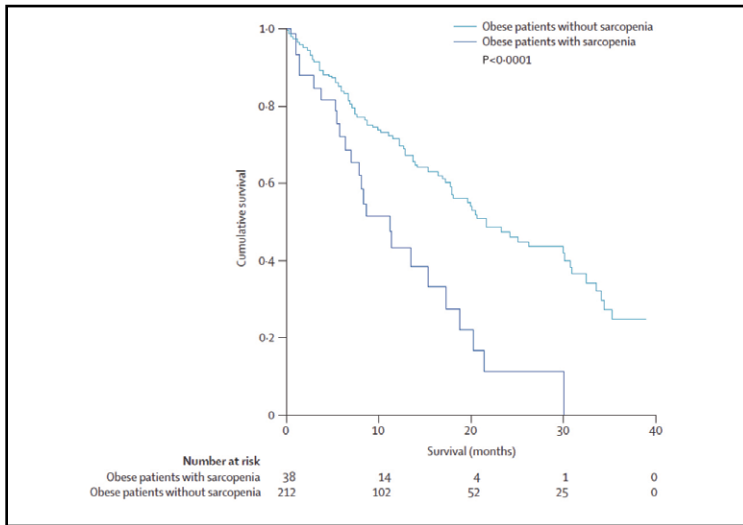
Reprinted from The Lancet, Vol. 12(5), Fearon K, et al, *Definition and classification of cancer cachexia: an international consensus*, 489-95, Copyright (2015), with permission from Elsevier.

Cachexia, however, represents a spectrum through which not all patients will progress. There are currently no robust, validated biomarkers to identify those precachectic patients who are likely to progress further along the continuum or the rate at which they will do so. Refractory cachexia is defined essentially based on the patients' clinical characteristics and circumstances.

While weight loss is the metric most often assessed in patients with cachexia, the body component that is lost is of even greater import. Use of a methodology developed by Prado and Baracos and their colleagues now allows clinicians to better understand the impact of body composition on outcomes such as therapy toxicity, performance status, and survival.^{11,15,17,20-22,45} In one study, 2,115 patients with solid tumors of the respiratory or gastrointestinal tracts were identified over a three-year period in a cancer center serving northern Alberta, Canada.²⁰ Lumbar computerized tomography (CT) images of the obese patients (15% of the total) were analyzed for total skeletal muscle cross-sectional area, with values also used to estimate fat-free mass (FFM). Associations between low muscle mass and mortality were ascertained by optimum stratification analysis. The data indicated that 15% of 250 patients were classified as having sarcopenia. Sarcopenic obesity was associated with poorer functional status

compared with obese patients who did not have sarcopenia and was also an independent predictor of survival (Figure 3). Estimated FFM showed a poor association with body-surface area. Assuming that FFM represents the volume of distribution of many cytotoxic chemotherapy drugs, the studies' authors estimated that individual variation in FFM could account for up to a three times' variation in effective volume of distribution for chemotherapy administered per unit body-surface area.

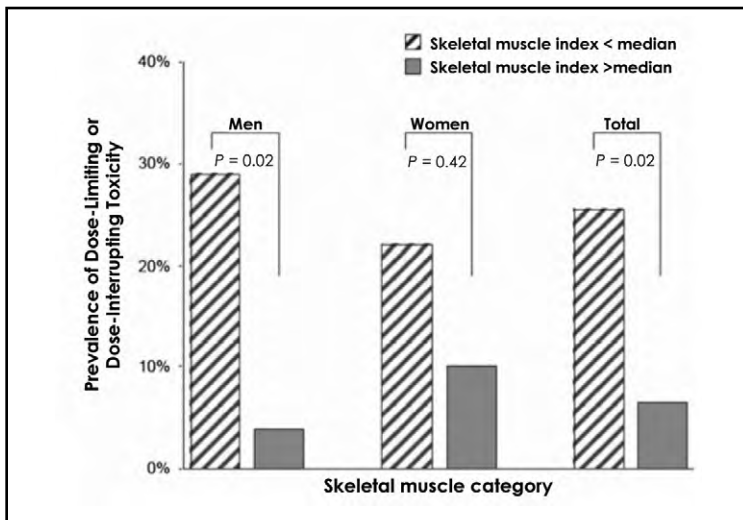
Figure 3. Survival of obese patients with and without sarcopenia.²⁰



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In more recent work by Cousin and colleagues, the effect of low muscle mass in patients undergoing treatment in phase I trials was associated with increased therapy toxicity.¹⁰ Patients with a low skeletal muscle index (SMIndex, cm²/m²) experienced more severe toxic events: 25.5% compared to 6.5% of patients with a high SMIndex, although this difference was only statistically significant in men (Figure 4).

Figure 4. Prevalence of severe toxicity events according to skeletal muscle category.¹⁰



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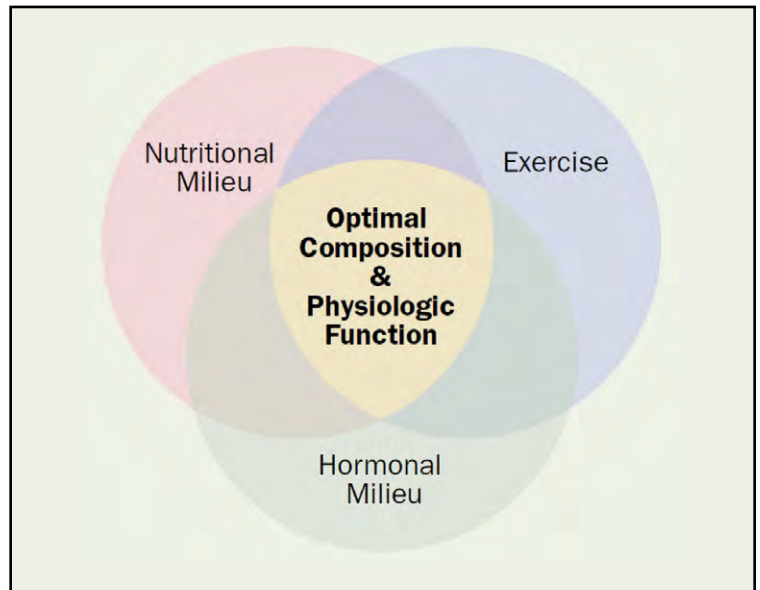
Researchers have also determined that sarcopenia, with or without obesity, is a probable risk factor for treatment toxicity and/or survival in patients with esophago-gastric, colon, renal, or metastatic breast cancer.^{9-11, 16-20, 45-52}

Anabolic Competence

In recent years, there is a growing appreciation of the importance of a multimodality supportive interventional approach in patients with cancer, which has expanded well beyond that of intervention in those with cancer cachexia simply by addressing macro- and micronutrients and considering weight loss as the only parameter of interest.⁵³⁻⁵⁶

Anabolic competence is "that state which optimally supports protein synthesis and lean body mass" (Figure 5).⁵⁵ It includes muscle and organ function, immune competence, functionality, and quality of life and depicts the primary components of optimal interventions: nutrition, hormonal milieu (including both classic hormones and cytokines), and exercise. While defined in the 1990s, this integrative and multimodality approach is increasingly being appreciated as critical in shaping how we think of intervention during cancer treatment, particularly in the context of optimizing oncologic outcomes and quality of survivorship.

Figure 5. Anabolic competence

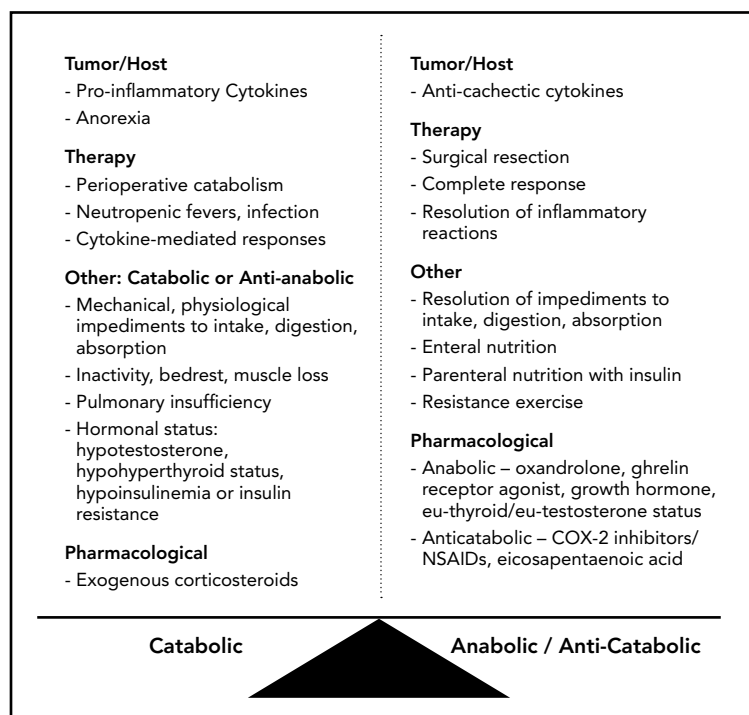


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The milieu of the patient with cancer can vary based position along the cachexia continuum (Figure 2) as well as by a variety of internal and external catabolic and anabolic forces. In the shifting of the balance from catabolic to anabolic, the opportunity arises to treat and reverse the adverse impact of cancer-related weight loss and body compositional change (Figure 6).

Maintenance of weight in patients with cancer has historically addressed only nutritional intake, digestion, and absorption. The field of nutritional oncology is currently at a very exciting turning point. We now have standardized assessment tools that allow nutritional risk and deficit to be addressed in a

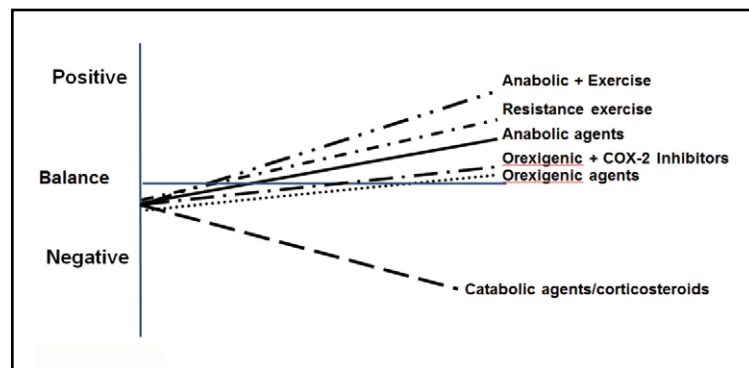
Figure 6. Balancing catabolic and anabolic forces



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standardized manner in clinical trial settings. In addition, we have an increasing understanding of the importance of supporting anabolism through several different approaches: adequate nutrient intake, digestion, absorption, and utilization. The latter part of that formula can be addressed with both anabolic (pharmacological, hormonal, and exercise) and anti-catabolic (e.g., omega-3 fatty acids or COX-2 inhibitors). Orexigenic agents (agents that work only through appetite stimulation), as noted in Figure 7 below, tend to have compromised outcomes in terms of nitrogen balance.

Figure 7. Multi-modality options impacting nitrogen balance and anabolic competence



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Important considerations in the treatment of disease-related involuntary weight loss include:

1. Does the intervention slow or reverse weight loss? Is the intervention associated with weight gain?
2. What component of body composition is altered with weight gain: fluid, fat, lean tissue?
3. Is the intervention associated with improvement in nitrogen retention, nitrogen balance, muscle or non-muscle protein synthesis, or decrease in protein catabolism? In other words, is there an improvement in the balance of anabolic and catabolic forces?
4. Does weight gain or slowing of weight loss translate into any type of psychological, functional, or survival advantage?

A core tenet of successful supportive intervention in patients along the cancer continuum is awareness. One of the most effective ways of maintaining awareness of malnutrition and/or risk for malnutrition is through proactive and consistent nutritional screening and assessment. The Patient-Generated Subjective Global Assessment (PG-SGA) is the most widely used and recognized instrument to facilitate this approach and is addressed in detail in this extensive material on nutrition and cancer.

Conclusion

The topic of cancer and nutrition can encompass aspects of both cancer prevention and complementary aspects of care of the patient with the disease. Additionally, the role of specific nutrients is also of interest to patients, their families and many clinicians. Nutrients are deserving of the attention of oncology clinicians, but this monograph has focused on the important nutritional and body compositional variables that impact oncologic outcomes – those aspects such as response rates, toxicity, and survival that are often the gold standards in terms of oncologic outcomes.

While the concept of multidisciplinary care of the patient with cancer is often addressed, true interdisciplinary approaches are critical in optimizing the care of patients with cancer, regardless of what treatment modality for the underlying cancer is being considered or whether treatment intent is curative or palliative. The accompanying monographs address specific aspects of identifying nutritional risk and deficit in patients with cancer as well as addressing the importance of nutrition impact symptoms and the use of oral nutritional supplements as an adjunctive aspect of oncologic care.

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Scored Patient-Generated Subjective Global Assessment (PG-SGA)

Faith Ottery, MD, PhD, FACN

Inconsistent malnutrition screening practices have contributed to a poor understanding of its prevalence in the outpatient cancer population. A recent estimate of oncology patients in the outpatient setting found that 32% of the 1,453 patients screened were at risk for malnutrition.¹

In 2002, the American Society of Parenteral and Enteral Nutrition (ASPEN) endorsed screening for malnutrition in their evidence-based clinical practice guidelines for nutrition support of the adult oncology population that was undergoing cancer treatment.² The ASPEN guidelines endorse screening of all patients with cancer who are receiving treatment and provide recommendations for comprehensive nutritional assessment and care planning for those at risk. The goal of a screening program is to identify patients with cancer with the potential for malnutrition early to plan the best possible intervention and follow-up during treatment and progression.

There are numerous screening tools with demonstrated specificity for identifying malnutrition in a variety of populations, including oncology. The three most commonly used are the Malnutrition Screening Tool (MST), the Malnutrition Universal Screening Tool (MUST), and the Patient-Generated Subjective Global Assessment (PG-SGA).

The Malnutrition Screening Tool and the Malnutrition Universal Screening Tool

The MUST was developed for the detection of protein-calorie malnutrition and the identification of malnutrition risk using evidence-based standards.³ The MUST uses three independent criteria for determination of the overall risk of undernutrition: body mass index (BMI), percentage of weight loss over the previous 3 to 6 months, and whether there has been or is likely to be no nutritional intake for >5 days. This instrument has been validated as a nutritional screening tool in patients with cancer in multiple outpatient settings, although the results have been mixed. In patients undergoing radiotherapy, the MUST showed high sensitivity (80%) and specificity (89%) in relation to the PG-SGA.⁴ Other studies of the MUST, however, have demonstrated high sensitivity (72%) in the detection of nutritional risk in patients with cancer, but low specificity (49%) when compared with the PG-SGA.⁵ The percentage of weight loss, an important factor in the MUST questionnaire, may be responsible for the differences between studies.⁶

The MST is a simpler tool based on weight loss and appetite changes and consists of three questions related to unintentional weight loss and low food intake because of decreased appetite. This tool provides a score between 0 and 5, with a score of ≥ 2 indicating the risk of undernutrition. The MST has been validated in the general hospital population as well as in outpatients with cancer⁷⁻⁹, although the sensitivity and specificity data have been variable. In a comparison of screening tools in patients with gastric and colorectal cancer, the MST showed the lowest sensitivity (52%) and highest

specificity (84%) in relation to the PG-SGA.⁵ Similarly, a study of 126 oncology inpatients demonstrated that the MST had a relatively low sensitivity of 66%, but with good specificity (83%).¹⁰ In another study of cancer outpatients, the MST was found to have a sensitivity of 81% and a specificity of 72% compared with SGA global ratings.¹¹ Higher sensitivity (100%) and specificity (92%), though, have been reported by Isenring and colleagues (2006), who compared the MST and the PG-SGA in oncology outpatients. These discrepancies may be due to the fact that the MST does not include questions on recent weight gain after weight loss and does not differentiate between changes in fluid status and true gains in body mass and adipose stores.¹²

With any tool, there is a trade-off between sensitivity and specificity. Nutritional screening aims to support a proactive approach to malnutrition; therefore, optimizing sensitivity is more useful in a screening tool. Despite varying data, it is quite notable that subjective nutritional screening tools such as the MUST and the MST are more sensitive than objective methods such as BMI, phase angle, and serum albumin⁵ in identifying patients at risk of malnutrition, but may be less sensitive than the PG-SGA.

The Patient-Generated Subjective Global Assessment

The PG-SGA is broadly recognized in both clinical practice and in academic research as the “gold standard” in addressing the nutritional status of patients with cancer. Research studies and clinical experience have been published by authors globally. The PG-SGA was developed as a modification of the original clinician-generated SGA, developed at the University of Toronto by Drs. Jeejeebhoy, Baker, and Detsky and published in a usable format in 1987.¹³

The tool was originally developed as a one-page instrument that globally assessed a patient in terms of both nutritional risk and nutritional deficit and was not scored. After the initial development, it became abundantly clear that clinical utilization would be more likely if the form were scored, which also would lead to additional use in the clinical trial setting. A scoring system was developed based on combined input from both medical/oncologic and nutritional perspectives.

The PG-SGA scoring system

The scoring system of the PG-SGA Short Form (particularly Boxes 1 to 4) is based on the following considerations:

- Patient perception and patient-reported concerns;
- Variables of risk for malnutrition or prediction of degree of nutritional deficit;
- Options for intervention in terms of both nutritional intake and nutrition impact symptoms (NIS) to prevent or reverse malnutrition;
- Known prognostic variables such as degree and acuteness of weight loss and performance status;

- A scoring schema of 0 to 4 is used throughout oncologic disciplines and toxicity criteria (normal or minimal impact on nutritional status or risk; mild impact; moderate impact, potentially severe impact, and potentially life-threatening impact, respectively); and
- Disproportionate weight of scoring for patient input rather than clinician evaluation for the total PG-SGA score.

The weight given to patient input was based on the following considerations:

- The clinician component would likely not be performed for all patients when due to either time concerns or clinician inexperience.
- Training and experience might be required to ensure accuracy and completeness of the PG-SGA's professional components.

- Data collected from the patient in Boxes 1 to 4 provides a "snapshot" of the patient at a given time, in turn allowing for a continuous variable assessment rather than a categorical one. This enables the assessment to be a more sensitive indicator for improvement or deterioration in patient status.
- Scores were dependent on patient input and could undergo rapid change with corrective intervention, thereby empowering the patient on multiple levels.

After the original scored version was used clinically, input from practicing clinicians (i.e., dietitians, nurses, physicians) led to a modification of the one-page format such that the patient-generated components were increased in font size and limited to the front page of a two-sided paper version of the fully scored PG-SGA. Based on this modification, patient input (Figure 1) was physically separated from the professional assessment (Figure 2).

Figure 1.


<div style="border: 1px solid black; padding: 5px;">  <h3 style="text-align: center;">Scored Patient-Generated Subjective Global Assessment (PG-SGA)</h3> <p>History: Boxes 1 - 4 are designed to be completed by the patient. [Boxes 1-4 are referred to as the PG-SGA Short Form (SF)]</p> <p>1. Weight (<i>See Worksheet 1</i>)</p> <p>In summary of my current and recent weight:</p> <p>I currently weigh about _____ pounds I am about _____ feet _____ inches tall</p> <p>One month ago I weighed about _____ pounds Six months ago I weighed about _____ pounds</p> <p>During the past two weeks my weight has:</p> <p><input type="checkbox"/> decreased (1) <input type="checkbox"/> not changed (0) <input type="checkbox"/> increased (0)</p> <p style="text-align: right;">Box 1 <input type="checkbox"/></p> </div>	<div style="border: 1px solid black; padding: 5px;"> <p style="text-align: center;">Patient Identification Information</p> <hr/> <p>2. Food intake: As compared to my normal intake, I would rate my food intake during the past month as</p> <p><input type="checkbox"/> unchanged (0) <input type="checkbox"/> more than usual (0) <input type="checkbox"/> less than usual (1)</p> <p>I am now taking</p> <p><input type="checkbox"/> <i>normal food</i> but less than normal amount (1) <input type="checkbox"/> little solid food (2) <input type="checkbox"/> only liquids (3) <input type="checkbox"/> only nutritional supplements (3) <input type="checkbox"/> very little of anything (4) <input type="checkbox"/> only tube feedings or only nutrition by vein (0) Box 2 <input type="checkbox"/></p> </div>																		
<div style="border: 1px solid black; padding: 5px;"> <p>3. Symptoms: I have had the following problems that have kept me from eating enough during the past two weeks (check all that apply)</p> <table style="width: 100%; border: none;"> <tr> <td><input type="checkbox"/> no problems eating (0)</td> <td><input type="checkbox"/> vomiting (3)</td> </tr> <tr> <td><input type="checkbox"/> no appetite, just did not feel like eating (3)</td> <td><input type="checkbox"/> diarrhea (3)</td> </tr> <tr> <td><input type="checkbox"/> nausea (1)</td> <td><input type="checkbox"/> dry mouth (1)</td> </tr> <tr> <td><input type="checkbox"/> constipation (1)</td> <td><input type="checkbox"/> smells bother me (1)</td> </tr> <tr> <td><input type="checkbox"/> mouth sores (2)</td> <td><input type="checkbox"/> feel full quickly (1)</td> </tr> <tr> <td><input type="checkbox"/> things taste funny or have no taste (1)</td> <td><input type="checkbox"/> fatigue (1)</td> </tr> <tr> <td><input type="checkbox"/> problems swallowing (2)</td> <td></td> </tr> <tr> <td><input type="checkbox"/> pain; where? (3) _____</td> <td></td> </tr> <tr> <td><input type="checkbox"/> other (1)** _____</td> <td></td> </tr> </table> <p>**Examples: depression, money, or dental problems Box 3 <input type="checkbox"/></p> </div>	<input type="checkbox"/> no problems eating (0)	<input type="checkbox"/> vomiting (3)	<input type="checkbox"/> no appetite, just did not feel like eating (3)	<input type="checkbox"/> diarrhea (3)	<input type="checkbox"/> nausea (1)	<input type="checkbox"/> dry mouth (1)	<input type="checkbox"/> constipation (1)	<input type="checkbox"/> smells bother me (1)	<input type="checkbox"/> mouth sores (2)	<input type="checkbox"/> feel full quickly (1)	<input type="checkbox"/> things taste funny or have no taste (1)	<input type="checkbox"/> fatigue (1)	<input type="checkbox"/> problems swallowing (2)		<input type="checkbox"/> pain; where? (3) _____		<input type="checkbox"/> other (1)** _____		<div style="border: 1px solid black; padding: 5px;"> <p>4. Activities and Function:</p> <p>Over the past month, I would generally rate my activity as:</p> <p><input type="checkbox"/> normal with no limitations (0) <input type="checkbox"/> not my normal self, but able to be up and about with fairly normal activities (1) <input type="checkbox"/> not feeling up to most things, but in bed or chair less than half the day (2) <input type="checkbox"/> able to do little activity and spend most of the day in bed or chair (3) <input type="checkbox"/> pretty much bed ridden, rarely out of bed (3)</p> <p style="text-align: right;">Box 4 <input type="checkbox"/></p> </div>
<input type="checkbox"/> no problems eating (0)	<input type="checkbox"/> vomiting (3)																		
<input type="checkbox"/> no appetite, just did not feel like eating (3)	<input type="checkbox"/> diarrhea (3)																		
<input type="checkbox"/> nausea (1)	<input type="checkbox"/> dry mouth (1)																		
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<input type="checkbox"/> problems swallowing (2)																			
<input type="checkbox"/> pain; where? (3) _____																			
<input type="checkbox"/> other (1)** _____																			
<p><i>The remainder of this form is to be completed by your doctor, nurse, dietitian, or therapist. Thank you.</i></p>																			
<p>Additive Score of Boxes 1-4 <input type="checkbox"/> A</p>																			

Figure 2.

Scored Patient-Generated Subjective Global Assessment (PG-SGA)

Worksheet 1 – Scoring Weight Loss

To determine score, use 1-month weight data if available. Use 6-month data only if there is no 1-month weight data. Use points below to score weight change and add one extra point if patient has lost weight during the past 2 weeks. Enter total point score in Box 1 of PG-SGA.

Weight loss in 1 month	Points	Weight loss in 6 months
10% or greater	4	20% or greater
5-9.9%	3	10- 19.9%
3-4.9%	2	6- 9.9%
2-2.9%	1	2- 5.9%
0-1.9%	0	0- 1.9%

Numerical score from Worksheet 1

Additive Score of Boxes 1-4 (See Side 1) **A**

5. Worksheet 2 – Disease and its relation to nutritional requirements:
Score is derived by adding 1 point for each of the following conditions:

<input type="checkbox"/> Cancer	<input type="checkbox"/> Presence of decubitus, open wound or fistula
<input type="checkbox"/> AIDS	<input type="checkbox"/> Presence of trauma
<input type="checkbox"/> Pulmonary or cardiac cachexia	<input type="checkbox"/> Age greater than 65
<input type="checkbox"/> Chronic renal insufficiency	

Other relevant diagnoses (specify) _____
 Primary disease staging (circle if known or appropriate) I II III IV Other _____

Numerical score from Worksheet 2 **B**

6. Worksheet 3 – Metabolic Demand

Score for metabolic stress is determined by a number of variables known to increase protein & caloric needs. **Note:** Score fever intensity or duration, whichever is greater. The score is additive so that a patient who has a fever of 38.8 °C (3 points) for < 72 hrs (1 point) and who is on 10 mg of prednisone chronically (2 points) would have an additive score for this section of 5 points.

Stress	none (0)	low (1)	moderate (2)	high (3)
Fever	no fever	> 99 and < 101	≥ 101 and < 102	≥ 102 °F
Fever duration	no fever	< 72 hours	72 hours	> 72 hours
Corticosteroids	no corticosteroids	low dose (< 10 mg prednisone equivalents/day)	moderate dose (≥ 10 and < 30 mg prednisone equivalents/day)	high dose (≥ 30 mg prednisone equivalents/day)

Numerical score from Worksheet 3 **C**

7. Worksheet 4 – Physical Exam

Exam includes a subjective evaluation of 3 aspects of body composition: fat, muscle, & fluid. Since this is subjective, each aspect of the exam is rated for degree. Muscle deficit/loss impacts point score more than fat deficit/loss. Definition of categories: 0 = no abnormality, 1+ = mild, 2+ = moderate, 3+ = severe. Rating in these categories is *not* additive but are used to clinically assess the degree of deficit (or presence of excess fluid).

Muscle Status		Fat Status	
temples (temporalis muscle)	0 1+ 2+ 3+	orbital fat pads	0 1+ 2+ 3+
clavicles (pectoralis & deltoids)	0 1+ 2+ 3+	triceps skin fold	0 1+ 2+ 3+
shoulders (deltoids)	0 1+ 2+ 3+	fat overlying lower ribs	0 1+ 2+ 3+
interosseous muscles	0 1+ 2+ 3+	Global fat deficit rating	0 1+ 2+ 3+
scapula (latissimus dorsi, trapezius, deltoids)	0 1+ 2+ 3+	Fluid status	
thigh (quadriceps)	0 1+ 2+ 3+	ankle edema	0 1+ 2+ 3+
calf (gastrocnemius)	0 1+ 2+ 3+	sacral edema	0 1+ 2+ 3+
Global muscle status rating	0 1+ 2+ 3+	ascites	0 1+ 2+ 3+
		Global fluid status rating	0 1+ 2+ 3+

Numerical Score for Worksheet 4 **D**

Point score for the physical exam is determined by the overall subjective rating of the total body deficit.

No deficit	score = 0 points	Again, muscle deficit/loss takes precedence over fat loss or fluid excess.
Mild deficit	score = 1 point	
Moderate deficit	score = 2 points	
Severe deficit	score = 3 points	

Total PG-SGA Score (Total numerical score of A+B+C+D)

Global PG-SGA Category Rating (Stage A, Stage B or Stage C)

Worksheet 5 – PG-SGA Global Assessment Categories

Category	Stage A	Stage B	Stage C
Well-nourished	No weight loss	Moderate/suspected malnutrition	Severely malnourished
Weight	OR recent non-fluid wt gain	≤ 5% loss in 1 month (≤ 10% in 6 months)	> 5% loss in 1 month (> 10% in 6 months)
Nutrient intake	No deficit OR Significant recent improvement	OR Progressive weight loss	OR Progressive weight loss
Nutrition Impact	None	Definite decrease in intake	Severe deficit in intake
Symptoms (NIS)	OR significant recent improvement allowing adequate intake	Presence of NIS (Box 3 of PG-SGA)	Presence of NIS (Box 3 of PG-SGA)
Functioning	No deficit OR Significant recent improvement	Moderate functional deficit	Severe functional deficit
Physical Exam	No deficit OR chronic deficit but with recent clinical improvement	OR Recent deterioration	OR Recent significant deterioration
	Evidence of mild to moderate loss of muscle mass &/or muscle tone or palpation &/or loss of SQ fat	Evidence of mild to moderate loss of muscle mass &/or muscle tone or palpation &/or loss of SQ fat	Obvious signs of malnutrition (e.g., severe loss muscle, fat, possible edema)

Nutritional Triage Recommendations: Additive score is used to define specific nutritional interventions including patient & family education, symptom management including pharmacologic intervention, and appropriate nutrient intervention (food, nutritional supplements, enteral, or parenteral triage).

First line nutrition intervention includes optimal symptom management.

Triage based on PG-SGA point score

0-1 No intervention required at this time. Re-assessment on routine and regular basis during treatment.

2-3 Patient & family education by dietitian, nurse, or other clinician with pharmacologic intervention as indicated by symptom survey (Box 3) and lab values as appropriate.

4-8 Requires intervention by dietitian, in conjunction with nurse or physician as indicated by symptoms (Box 3).

≥ 9 Indicates a critical need for improved symptom management and/or nutrient intervention options.

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Advantages of the PG-SGA

The PG-SGA was early in adopting the concept that the patient—not the clinician or caregiver—is better at reporting what he or she is experiencing.¹⁴ Other advantages of the PG-SGA include the following:

- The PG-SGA identifies, in a standardized and consistent manner, potentially treatable impediments that can be proactively rather than reactively addressed.
- The PG-SGA empowers patients (and indirectly their caregivers) by asking them about matters that can often be overlooked or that can be seen as of lesser importance. It identifies numerous variables that patients may not want to address because they do not want to be seen as complainers, they have no idea that intervention is possible, or they believe that the symptoms may mean the cancer is worsening or returning and, therefore, they may find it better not to bring them up.

- Given that clinicians may not have time to complete the professional aspect of the fully scored PG-SGA, the scoring is designed so that 80-90% for any given patient is based on the patient-generated aspects in Boxes 1 to 4 of the Short Form (see Figure 1). The validity of this design has been confirmed by a number of studies.¹⁵⁻¹⁸

- While the PG-SGA is seen as a nutritional screening or assessment tool, it has multiple additional uses: standardized symptom assessment, streamlining clinic flow, and optimizing time for patient interaction. Since patients fill out the form prior to interacting with their clinician, clinic flow can be shortened with accompanying improvement in quality and productivity. Because the patient self-identifies those issues that impact him/her, the time with the patient is not spent asking a plethora of questions but rather spending the time with quality interaction and intervention.

- The PG-SGA is an excellent screening tool not only for nutritional risk but also for identifying specific components that place a patient at risk for nutritional deficit or malnutrition. For example, a patient may not have lost any significant weight on the initial assessment (or may have lost weight in the past 2 weeks) and may have a normal (0) ECOG performance status. If they check off several nutrition impact symptoms for which they do not receive timely intervention, however, they clearly will have deterioration/progression of their nutritional status and likely negative effects on their quality of life.

While the fully scored PG-SGA (for clinicians) and the PG-SGA Short Form (for patients) are known predominantly for use in patients with cancer, there have been a number of different applications (Table 1).¹⁹

Table 1. Patient populations screened or assessed utilizing the PG-SGA or the PG-SGA Short Form¹⁹

General Population	Specific Data Cohorts
Oncology	<ul style="list-style-type: none"> • General or specific cohorts such as the elderly • Variable therapy: pretreatment screening or baseline assessment; undergoing surgery, chemotherapy (general or specific), and/or radiation therapy • Specific solid tumor sites: head and neck; gastrointestinal (gastric, esophageal, colorectal); gynecologic; lung; breast; urologic, including bladder; • Hematological malignancies: leukemia, lymphoma • Early or advanced/metastatic
General vs. specific cohorts	<ul style="list-style-type: none"> • All consecutive admissions or clinic visits • Specific cohorts: e.g., elderly
Variable settings	<ul style="list-style-type: none"> • Inpatient • Outpatient • Rehabilitation • Palliative care • Hospice
Neurological conditions	<ul style="list-style-type: none"> • Parkinson’s disease • Stroke/cerebral infarction
Miscellaneous	<ul style="list-style-type: none"> • Inpatients at nutritional risk, regardless of underlying medical condition • General surgery patients, including specific noncancer categories such as appendectomy • Stem cell transplant (autologous and allogeneic) • Chronic graft-vs.-host disease • Chronic kidney disease, hemodialysis • HIV • Systemic immunoglobulin light chain amyloidosis • Lower extremity edema

The first PG-SGA was developed with input from patients at the Fox Chase Cancer Center in Philadelphia, Pennsylvania, and for them to complete while waiting for their clinic appointment.^{20,21} The instrument was originally unscored. Two Philadelphia-based dietitians, Suzanne Kasenic, RD, CSO, and Susan DeBolt, PhD, RD, were integral to the development of the scored version and oversight of the original Protocol 9601, a volunteer research network of 55 centers around the globe that developed and validated the original scoring through the now defunct Society for Nutritional Oncology Adjuvant Therapy (NOAT).²¹ Entry criteria for the 9601 study was not limited to patients with cancer and allowed those with chronic kidney disease (many on dialysis) and individuals in a New York City-based hospice that included patients with a variety of underlying conditions, including malignancy, HIV/AIDS, and other terminal diseases. In total, 2,150 patients at 55 institutions were evaluated: 81% outpatient and 19% inpatient. About three-quarters were 50 to 79 years of age, and the majority of them were overweight or obese.

It was clear from the 9601 study that clinicians were not asking the correct questions. For example, for the question *As compared to my normal intake, I would rate my food intake during the past month as unchanged/changed*, some 16% of patients who checked *unchanged* also checked *very little of anything*. For those who checked *less than usual*, 25% also checked *very little of anything* (Table 2).²¹

Table 2. Categorization of food intake during the past month in the NOAT 9601 trial (n = 2,040)²¹

Status	Frequency	Percentage of total	Percentage reporting eating “very little of anything”
Less than usual	676	33.1	25%
Unchanged	1,117	54.8	16%
More than usual	247	12.1	NA

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In answering the question, *I have had the following problems that have kept me from eating enough during the past 2 weeks (check all that apply)*, 58% reported that they had no problems but 55% of them checked one or more NISs, often with >5. Patients often did not specifically think of these symptoms as falling under the general category of *problems eating*. For patients in that category, the percentage reporting specific NISs ranged from 10% with mouth sores to 56% with no appetite. For those patients reporting *no problems eating*, NISs ranged from 1% with no appetite to 10% with mouth sores. Again, for each of these groups, individual symptoms generally did not occur in isolation but included a complex of symptoms (Table 3).²¹

Table 3. Nutrition impact symptoms: “No Problems Eating” vs. “Problems Eating” ²¹

Symptom	If “No Problems Eating”	If “Problems Eating”
No appetite	1.3%	56.3%
Nausea	2.8%	30.1%
Vomiting	1.9%	17.1%
Constipation	4.8%	22.6%
Diarrhea	4.8%	14.3%
Mouth sores	9.8%	9.8%
Dry mouth	6.5%	26.9%
Pain	5.9%	30.7%
Taste changes	3.0%	30.5%
Smell changes	2.3%	13.0%
Other* (please specify)	3.0%	21.3%

*Original test version did not include fatigue, but it was subsequently added based on answers.

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Clinician Rater Modifications of the Tested PG-SGA

In addition to the addition of variables such as fatigue and the subsequent modification of the PG-SGA layout, the scoring triage system was also modified based on input from the clinicians as shown in Table 4.

Table 4. Results when clinicians were asked to agree or disagree with the originally defined triage categories ²¹

Additive Score	Original Triage	Percent Agreement	Basis for Disagreement
0-1	<ul style="list-style-type: none"> No intervention required at this time 	90.2%	
2	<ul style="list-style-type: none"> Indication for education by nurse or dietitian with pharmacological triage as indicated by symptom survey 	100%	No disagreement
3-8	<ul style="list-style-type: none"> Requires intervention of dietitian with interaction of nurse/physician as indicated for pharmacological symptom management 	64.6%	Primarily for those patients with a score of 3 points
≥9	<ul style="list-style-type: none"> Indicates a critical need for symptom management and/or nutritional intervention Requires interdisciplinary discussion/meeting to address all symptoms as well as nonoral options 	68.3%	Primarily due to a lack of clarification of definitions specifically in terms of interventions

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As a result, triage categories were changed to reflect these disagreements:

- 0-1 = No intervention required at this time. Re-assessment on routine and regular basis during treatment.
- 2-3 = Patient and family education by dietitian, nurse, or other clinician with pharmacological intervention as indicated by symptom survey (Box 3) and lab values as appropriate.
- 4-8 = Requires intervention by dietitian in conjunction with nurse or physician as indicated by symptoms (Box 3).
- ≥9 = Indicates a critical need for improved symptom management and/or nutrient intervention options.

Summary

The scored PG-SGA is widely recognized as the gold standard for nutritional screening and assessment in patients with cancer. It is considered a 4-in-1 instrument that facilitates proactive risk assessment (screening), nutritional assessment, interventional triage, and outcomes monitoring.

Studies have consistently confirmed its high sensitivity and specificity and its ability to predict both adverse and improved clinical outcomes. Importantly, the time-consuming aspects of nutritional screening and assessment are completed by the patient, streamlining clinic work flow and improving the quality of interaction between the clinician and the patient.

The validated tools (scored PG-SGA and PG-SGA Short Form) are broadly utilized internationally in both the original English version and a variety of subsequent translations. The PG-SGA is a living and evolving instrument, with international research collaborations ongoing to expand its use in electronic medical records, telephonic nutritional consulting, and algorithm-driven self-scoring apps. Certified versions in multiple languages are available at www.pt-global.org.

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Nutrition Impact Symptoms in the Patient with Cancer: Awareness, Implications, and Management

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Cancer and its treatment can profoundly impact nutritional status, and the spectrum of nutrition impact symptoms is vast. Such symptoms impede oral intake and include but are not limited to anorexia, nausea, vomiting, diarrhea, constipation, stomatitis, mucositis, dysphagia, changes in taste and smell, pain, depression, dyspnea, fatigue, and anxiety.^{1,2} Importantly, there is no such thing as “typical” when addressing the nutrition impact symptoms associated with cancer care.

Background

With an estimated 1.66 million new cancer cases expected to be diagnosed in 2015³ and some 14.5 million cancer survivors currently living in the United States,⁴ this group of chronic disease patients is one of the fastest-growing. The nutritional challenges faced by this population must be countered to maximize positive outcomes in these individuals. The advent of medical options for effectively managing the majority of cancer symptoms and adverse effects has led to the ability to deliver most oncology care in outpatient settings. Approximately 90% of patients with cancer receive treatment in outpatient cancer centers and clinics⁵, and as a result, this patient population is no longer guaranteed malnutrition screening on a timely basis.

Standards set by the Joint Commission on Accreditation of Healthcare Organizations mandate that every patient be screened for nutritional status within 24 hours of admittance to the hospital.⁶ In contrast, ambulatory nutritional care standards are both ambiguous and inconsistently applied. Access to oncology nutritional care is left to the discretion of the outpatient oncology treatment facilities or individual healthcare providers. As a result, oncology nutritional care delivery is quite uneven.

To resolve these issues, the entire medical team must take an active role in nutritional screening and assessment, must intervene early in the process when malnutrition or risk of malnutrition is first detected, and must refer, as appropriate, to a Registered Dietitian Nutritionist for more intensive medical nutrition therapy.

Addressing individual nutritional needs

Oncology clinicians, specialists, and researchers understand that cancer is not a single disease. This is certainly true by tumor type and also applies to patients with the same cancer diagnosis. Similarly, the types of nutrition impact symptoms experienced may vary widely from person to person.

The costs of failing to detect and treat malnutrition are high for the patient as well as for the healthcare system. A comprehensive review published in the Academy of Nutrition and Dietetics’ Evidence Analysis Library notes that poor nutritional status is associated with increased morbidity and mortality, and that weight loss, malnutrition, sarcopenia, cachexia, and fatigue are associated with increased mortality.⁷

In addition, malnutrition decreases the likelihood of receiving the full and on-time course of oncologic treatment;⁸⁻¹⁰ reduces quality of life (QoL)^{11,12} and functional status;¹³ increases the risk of longer^{12,14,15} and unplanned hospital admissions;¹⁶ contributes to more severe treatment side effects and dose-limiting toxicities;¹⁷⁻¹⁹ decreases time to progression in metastatic disease;¹⁹ and boosts risk of cancer recurrence²⁰ and poorer long-term outcomes.²¹⁻²⁴ Furthermore, unaddressed malnutrition contributes to increased healthcare costs precisely because malnutrition is an independent risk factor for longer hospital stays and an increased risk of post-operative complications.^{12,14,15,25}

Obesity may appear to represent the opposite end of the nutritional spectrum. A person who falls into the obese body mass index (BMI) category, however, may be at a high risk for malnutrition. This can be related to undiagnosed protein malnutrition or the presence of sarcopenic obesity or oncology clinicians mistakenly thinking that the obese patient has plenty of reserve and actually needs to lose weight. Several studies have demonstrated obesity itself may be a risk factor for more severe malnutrition.²⁶⁻³⁰ Compared with a patient beginning cancer treatment at a normal body weight, an overweight or obese individual with sarcopenia who experiences unintentional weight loss during treatment appears to have a higher risk of malnutrition-related poor outcomes.³¹ Regardless of BMI, weight loss, low muscle mass index, and loss of lean body mass all predict poorer survival.²⁶ Obesity offers no protection against malnutrition, particularly when considered in the context of poor protein status and low lean body mass. For this reason, it is vitally important to thoroughly screen every patient for malnutrition, assess each person’s current nutritional status, and initiate appropriate nutritional interventions to address such deficits.

Given that the consequences of malnutrition are costly to the patient and to the healthcare system, referral to a Registered Dietitian Nutritionist for specialized nutritional care should be a priority for the most at-risk patients. Among the best evidence of the benefits of specialized nutritional care for oncology outpatients comes from a clinical trial by Ravasco and colleagues.³² Their study is unique in terms of randomization, statistical design to ensure adequate ability to detect differences in intervention groups, and follow-up. Similar to nearly all nutrition intervention research, it was not blinded, because subjects are aware of what they are eating and to whom they are referred (e.g., the dietitian).

One-hundred and eleven colorectal cancer patients who were being treated in an outpatient radiation therapy clinic were randomized to one of three groups. Group 1 (G1) received specialized nutritional care delivered by a registered dietitian (n = 37), Group 2 (G2) was asked to consume two oral liquid nutrition supplements per day (n = 37), and Group 3 (G3) received usual care (n = 37), which consisted of instruction to maintain ad libitum intake. Randomization utilized permutation blocks of three to ensure equal distribution of cancer stages among study groups. Use of other medications and dietary supplements, and compliance with dietary recommendations were monitored weekly. Follow-up with complete data included 100% of enrolled subjects.

At radiotherapy completion:

- energy intake had increased in G1 and G2 ($P \leq 0.04$), though the increase was significantly greater in G1 compared with G2 ($P = 0.001$);
- energy intake decreased in G3 ($P < 0.01$);
- protein intake increased in G1 and G2 ($P = 0.007$), with no significant differences between these groups;
- protein intake decreased in G3 ($P < 0.01$);
- QoL function scores improved proportionally to adequate intake or nutritional status in G1 ($P < 0.05$);
- three of six QoL function scores improved proportionally to protein intake in G2 ($P = 0.04$); and
- all QoL function scores worsened in G3 ($P < 0.05$).

At three months' follow-up:

- in G3, QoL remained as poor as after radiotherapy, and G2 patients experienced improvement in two of six function scores only ($P < 0.05$).
- G1 patients maintained or improved function, symptoms, and single-item scores ($P < 0.02$); and
- rates of anorexia, nausea, vomiting, and diarrhea were higher in G3 ($P < 0.05$) compared with G1 and G2;
- only G1 maintained adequate nutritional intake while G2 and G3 returned to baseline;

Overall, both interventions positively influenced outcomes during treatment, while at three months' post-treatment, only dietary counseling sustained a significant impact on patient outcomes.

In 2012, Ravasco and colleagues published a paper on this group's long-term follow-up (median = 6.5 years).³³ Complete data were available on 89 of 111 original study subjects, with the results highlighting the long-term survival benefits of a brief nutritional intervention as part of the cancer care process. Adequate nutritional status was maintained in 91% of G1 patients and 0% of G3 patients ($P = 0.002$). Median survival in G3 was 4.9 years (30% died); in G2, 6.5 years (22% died); and in G1, 7.3 years (8% died) ($P = 0.01$). Late radiotherapy toxicity, comprised predominantly of permanent flatulence, abdominal distention, and/or diarrhea, presented in 65% of G3, 59% of G2, and 9% of G1 ($P = 0.001$). QoL was worse in G3 and G2 than in G1 ($P = 0.002$). Worse radiotherapy toxicity, QoL, and mortality were associated with deteriorated nutritional status and intake ($P = 0.001$), and depleted intake, nutritional status, and QoL predicted shorter survival and late toxicity (HR: 8.25; 95% confidence interval [CI]: 2.74-1.47; $P = 0.001$).

Research by other investigators confirms these findings: Nutritional intervention improves treatment tolerance, reduces symptoms and adverse events, ameliorates poor QoL outcomes for patients with a wide range of tumor types.^{16,34-38}

Enteral and parenteral nutrition, enzyme replacement therapy, and nutrition impact symptoms that require medical intervention

A number of patient populations, including individuals with head and neck, gastric, advanced ovarian, small bowel, or pancreatic cancers, are likely to benefit from more intensive nutritional intervention. This may include enteral nutritional support, pancreatic enzyme replacement therapy, or total or supplemental parenteral nutrition. In these cases, early intervention, and even prophylactic placement of feeding tubes, may be considered.

Prophylactic feeding tubes

Placement of prophylactic feeding tubes in those with head and neck cancer remains controversial. A lack of controlled trials hinders assessment of the true benefits and risks of prophylactic enteral feeding. A 2013 Cochrane review concluded that the evidence is insufficient to determine the optimal method of enteral feeding—percutaneous endoscopic gastrostomy (PEG), radiologically inserted gastrostomy (RIG), or nasogastric (NG) tube for patients with head and neck cancer.³⁹ One other issue is the concern for potentially implanting tumor cells in the abdominal wall or stomach when "traction" method of PEG tube placement is carried out. This is not necessarily an issue when treatment of the cancer is palliative but can be an issue if the treatment intent is curative. An additional concern related to prophylactic feeding tube placement is potential impact on long-term swallowing function. Increased dysphagia and risk of esophageal stenosis often are cited as reasons for avoiding enteral feeding in this population, though controlled trials indicate that implementation of pre-treatment swallowing exercises will ensure maximal preservation of swallow function and minimize long-term dysphagia risk.^{40,41}

A 2014 retrospective analysis of 109 veterans being treated with standard concurrent chemotherapy and radiotherapy (CRT) for stage III/IV head and neck cancer examined clinical outcomes in those who received a prophylactic feeding tube (PFT), a reactive feeding tube (RFT), or no feeding tube (no-FT).⁴² Individuals with a PFT experienced significantly less weight loss during CRT and fewer nutrition-related emergency department visits or hospitalizations, and completed higher proportions of chemotherapy cycles compared with patients with an RFT or no-FT. At one-year follow-up post-CRT, PFT placement was not associated with higher rates of dysphagia or 100% feeding tube dependency compared with an RFT or no-FT.

A 2014 systematic review comparing outcomes for PEG and NG tubes in head and neck cancer patients concluded that there are advantages and disadvantages to each method, and the enteral nutrition delivery method in this population should be considered on a case-by-case basis in consultation with a dietitian.⁴³ Both methods appear efficacious in improving and maintaining nutritional status, though one study noted a nutritional advantage with PEG tubes over NG tubes in terms of body weight, hemoglobin, and lean body mass at six weeks and six months post-insertion. Similar infection rates were

noted for PEG and NG tubes, although one study noted a decreased complication rate and infection risk with antibiotic prophylaxis for the “pull” placement method only for PEG tubes. Poor cosmesis, less mobility, higher risk of tube dislodgement, decreased QoL, and more difficulty with use were associated with NG tubes, while PEG tubes may delay a return to oral diet, raise the risk of dysphagia and need for pharyngoesophageal dilatation, and increase pain in the first week post-insertion.

A 2015 comprehensive review on the effect of prophylactic PEG tube placement on swallowing in people being treated for head and neck cancer concluded that 100% of the 20 studies meeting their inclusion criteria were at risk for bias.⁴⁴ The results were varied and inconclusive regarding the impact of PEG tubes on swallowing. The authors highlighted a need for well-controlled, randomized trials to determine whether or not a prophylactic PEG tube places patients at a greater risk of developing long-term dysphagia. This type of research is being planned,⁴⁵ and more definitive answers should emerge in the near future.

Though firm conclusions cannot be drawn regarding the absolute benefit of prophylactic enteral feeding by any route, all patients should be referred to a speech language pathology program for implementation of swallowing preservation exercises. This may be especially important for individuals with a PEG tube placement.

Pancreatic enzyme replacement therapy

For those with pancreatic cancer, surgical intervention is a mainstay of treatment, with the pancreatoduodenectomy (Whipple procedure) being the most commonly used surgery. Many patients will require post-operative pancreatic enzyme replacement therapy (PERT); and even in the absence of surgical intervention, pancreatic insufficiency can develop. Available evidence suggests many individuals who could benefit from PERT may not receive it. In a follow-up of 129 patients diagnosed with pancreatic cancer between 2010 and 2012, Landers and colleagues documented that greater than 70% of the study population exhibited symptoms consistent with malabsorption, including abdominal pain, bloating, flatulence, and steatorrhea, yet only 21% were prescribed PERT.⁴⁶ Every individual being treated for pancreatic cancer

Table 1: Symptom Management⁵¹

Nausea	Poor appetite/early satiety	Diarrhea/loose stools	Constipation	Mouth sores
Acupuncture ¹	Eat by the clock, not by hunger cues	Take anti-diarrheal meds as prescribed	Take laxatives/stool softeners as prescribed	Use oral rinses exactly as prescribed
5-6 small meals and snacks and low-odor, bland foods ²	Eat more when appetite is stronger ⁹	Sip fluids frequently to avoid dehydration	Use meds prior to constipation worsening	Eat soft, bland foods ²²
Avoid food prep area and odors	Keep convenience foods handy ¹⁰	Avoid sugary beverages ¹⁵	Drink adequate fluid; urine should be pale straw color	Try smoothies with non-seeded fruits
Eat in cool, well-ventilated room	Reduce stress at mealtimes	Eat soluble (“sticky”) fiber foods ¹⁶	Try hot and warm beverages throughout day	Use oral nutritional supplements
Use covered to-go mug for liquids to limit odor	Find non-food options to socialize	Try a psyllium fiber supplement ¹⁷	Gradually increase fiber intake up to 25-35 grams ²⁰	Try smooth puddings and yogurt
Sit up or raise head of bed for ≥ 1 hour after eating ³	Keep food in purse, briefcase, or backpack ¹¹	Avoid or limit caffeine	Use fiber supplement as needed ²⁰	Avoid irritating spices such as chili
Separate liquids and solid food by 15-30 minutes ⁴	Try light physical activity before meals	Avoid or limit alcohol	Inulin, wheat dextrin, and psyllium are fiber options	Avoid tobacco and alcohol
Sip small amounts of fluids frequently ⁵	Try breakfast for dinner or dinner for breakfast	Try small meals/snacks	Only take fiber with plenty of fluid ²¹	Avoid acidic/vinegar-preserved foods ²³
Sip ginger tea, suck on ginger candies ⁶	Consider medical factors in anorexia ¹²	Avoid sugar alcohols ¹⁸	Gradually add high-fiber cereals into diet	Try lukewarm foods (cooked, then cooled)
Avoid sweet, fatty, fried, spicy foods ⁷	Address psychosocial issues ¹³	Try eliminating dairy foods ¹⁹	Increase intake of vegetables and fruits	Try frozen grapes, melon balls ²⁴
Address medical issues contributing to nausea ⁸	Engage family and caregivers ¹⁴	Lie down post-meals (unless nauseous)	Contact medical team if no bowel movement for 3 days	Consider other pain-management options

1 Chemotherapy-related nausea (Data compiled from a single source.⁵²); 2 Oatmeal, rice/rice porridge, cream of wheat, yogurt, cereal, toast, plain pasta, potatoes, baked chicken; 3 Explain benefits of using gravity to keep food moving through digestive tract; 4 Drink only as needed to comfortably swallow food and have additional fluids between meals/snacks; 5 Explain that dehydration may worsen nausea; 6 Data compiled from a single source.⁵³; 7 Cakes, cookies, pies, French fries, pizza, fast food, chips; 8 Delayed gastric emptying, gastric hyper-acidity, malabsorption; 9 If appetite is better in the morning, eat food, and use oral nutritional supplements later in the day when appetite is poor; 10 Soups, stews, and casseroles that can be reheated quickly, crackers, oatmeal, yogurt, cold chicken, pre-cooked hard-boiled eggs; 11 Bananas, apples, dried fruits, nuts. If mouth sores are present, take oral nutritional supplement; 12 If pain or nausea prevents eating, consider additional/different medication options and delivery routes (Data compiled from various sources.^{54,55}); 13 Refer as appropriate to social work/therapy, psycho-oncology care provider, support groups, art therapy, music therapy; 14 Educate family on barriers to eating, fluctuating nature of appetite, how to provide support without adding stress; 15 Soda, juice, and punch can worsen diarrhea, but diluted juice may be better tolerated; 16 Oats/oatmeal, bananas, mashed potatoes, natural applesauce (no added sugar), well-cooked and mashed lentils, peeled or canned pears, barley, white rice; 17 This type of fiber can normalize bowel function, minimizing both constipation and diarrhea; 18 Sorbitol, xylitol, and other “ols,” found in sugarless gum/candy; 19 Treatment may cause temporary lactose intolerance; 20 Do not increase fiber if low-residue diet is prescribed or if abdominal surgery mandates low-fiber diet; 21 Fiber without adequate fluids will worsen constipation; 22 Warm soup, cooked cereals, oatmeal and cream of wheat, pasta with olive oil or butter (no tomato), egg noodles, and gravy; 23 Citrus, pickled foods, tomato products; 24 Do not use cold foods if on platinum-based chemotherapy medications (cisplatin, carboplatin, oxaliplatin).

should be assessed for exocrine pancreatic insufficiency (EPI) at initial consultation, post-surgery, or if symptoms suggest EPI may have developed due to disease progression. While symptoms alone often are enough to justify a PERT trial, fecal elastase is another option for the objective confirmation of EPI.

While most oncology patients presenting with EPI will have pancreatic involvement, other diagnoses may contribute to EPI as well. Huddy and colleagues describe the presence of EPI in a population of post-esophagectomy patients;⁶³ patients were screened, with 10 identified as experiencing EPI (fecal elastase < 200 µg/g). Of the 10 patients with objectively identified EPI, nine (90%) had symptomatic improvement and seven (70%) increased their weight after initiation of PERT.⁴⁷ Friess and colleagues further identify partial and total gastrectomy as potential contributors to EPI.⁴⁸ A review of potential causes of EPI includes gastrectomy and notes that clinically available pancreatic function tests lack the diagnostic accuracy to identify mild EPI, which may benefit from implementation of PERT.⁴⁹ Also of note is that individuals with EPI may fail PERT due to a misunderstanding of how to use these medications, under-dosing of enzymes, or failure to use them consistently. The required dose of PERT is proportional to the fat content of the meal or snack, with a dose of 40,000 to 50,000 units of lipase per meal, and 20,000 to 25,000 units per snack recommended for initial treatment. Adding a proton pump inhibitor and increasing the lipase dose up to a doubling of the trial dose can be attempted for individuals who do not obtain symptom resolution with initial treatment.⁵⁰

While more controlled trials are required to further characterize which patients are most likely to experience EPI that requires PERT, this diagnosis should be considered

in individuals who have undergone pancreatic or upper gastrointestinal tract surgical procedures or in whom symptoms of malabsorption are present.

Dietary manipulation for optimal management of nutrition impact symptoms

For many patients in the cancer care process, dietary-focused nutritional interventions will provide adequate support to prevent or limit malnutrition. If symptoms are extremely severe, such as uncontrolled vomiting or diarrhea, the medical care team must be consulted. An interdisciplinary approach is vital to ensuring optimal outcomes. The best nutritional advice, support, and therapy are useless if the patient experiences severe symptoms and adverse effects. Failure to properly manage symptoms medically can lead to dehydration requiring intravenous fluids, bowel obstructions, fluid and electrolyte imbalances, and other serious events that necessitate hospitalization. This reinforces the importance of interdisciplinary interaction and communication, as well as timely intervention for nutrition services. Once severe symptoms are managed medically, any lingering nutrition impact symptoms are more likely to respond to appropriate dietary manipulation and nutritional intervention.

Conclusion

Ideally, every individual affected by cancer should have access to a Registered Dietitian Nutritionist specializing in oncology nutrition. In the absence of this access, it is the responsibility of the entire medical team to ensure that nutrition impact symptoms are addressed and to allow cancer patients to remain on treatment, out of the hospital, and on the road to a healthier future.

Table 2: Symptom Management⁵¹

Dysphagia (pain/difficulty swallowing)	Taste and smell changes	Weight loss	Weight gain
For head and neck radiation, pay special attention ¹	If foods have no taste, try fruit marinades for meats	Add high-calorie foods to dishes ⁸	Consider overeating triggers: boredom, stress, anxiety, eating for comfort
Refer for evaluation by speech/swallowing therapist ²	If no mouth sores present, use lemon, herbs, and spices	Focus on high-calorie, high-protein drinks ⁹	If "emotionally eating," refer to support group or therapy for coping
If PEG tube placed, implement pre-tx swallowing exercises ²	For "off" taste, try fruity and salty flavors	Use oral nutritional supplements ⁷	Consider medications as a cause of weight gain ¹³
Sit up straight/use good posture when eating ³	If water tastes bad, flavor with lemon or cucumber	Avoid/limit no-calorie beverages ¹⁰	Try to get some regular, moderate physical activity every day
Limit talking and distractions while eating ⁴	For metallic taste, use plastic or bamboo utensils to eat	Eat by the clock, not by hunger cues	If cleared medically for activity, try walking and light resistance training
Eat moist foods of a similar texture ⁵	For bitter/metallic taste, try fresh basil, oregano, thyme	Take 1-2 bites/sips every 15-30 minutes	Avoid liquid calories, which may not be as satisfying as solid food ¹⁴
Try low-acid smoothies and shakes ⁶	Flavor meats with fruit marinades, sweet/sour	Consider appetite-stimulant options	Try plant-based diet; focus on vegetables, legumes, fruits, whole grains, nuts, seeds ¹⁵
Thicken oral nutritional supplements as needed ⁷	For salty/acidic taste, cook without salt, try sweet flavors	Consider medical and psychosocial factors ¹¹	Find non-food social options, such as inviting friends to walk with you
Consider additional pain-management options	Meat tastes "off," try other protein (eggs, nuts, tofu, beans)	Manage all symptoms appropriately ¹²	Ask for a referral to a dietitian ¹⁶

1 Difficulty swallowing can indicate a serious problem, such as increasing swallowing dysfunction, which may increase aspiration risk; 2 Data compiled from various sources^{40,41}; 3 Slouching may worsen aspiration risk; 4 Talking during mealtimes may worsen aspiration risk; 5 Keep food textures similar to encourage formation of one cohesive bolus, combining liquids and solids may worsen choking and aspiration risk; 6 Melons, bananas, mangos, peaches blenderized with yogurt, milk, or tofu; 7 Blenderize oral nutritional supplement with bananas, peaches, yogurt, tofu, or smooth nut butter to reach prescribed textures; 8 Add olive oil to potatoes, casseroles, and stews for extra calories; 9 Try smoothies with dairy or non-dairy milk, fruit, a scoop of plain or flavored protein powder, and nut butter; 10 Tea, coffee, diet soda, diet juice drinks, sparkling water; 11 If pain or nausea prevents eating, consider additional/different medication options and delivery routes (Data compiled from various sources^{54,55}), and refer as appropriate to social work/therapy, psycho-oncology care provider, support groups, art therapy, music therapy; 12 If symptoms and side effects are unmanaged medically, weight stabilization may not be possible; 13 Some medications increase appetite and may boost craving for sweet foods, being aware of this can help patient better manage food choices; 14 Data compiled from a single source.⁵⁶ (Note: study population includes lap-band and control [no lap-band] subjects); 15 Data compiled from various sources⁵⁷⁻⁵⁹; 16 Data compiled from various sources.⁶⁰⁻⁶²

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Managing Malnutrition in the Patient with Cancer: The Role of Oral Supplements

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Oral nutritional supplements (ONS) can play an important role in managing malnutrition in patients with cancer.^{1,2} ONS are typically drinks that are nutritionally balanced to contain calories from proteins, carbohydrates, and fats along with vitamins and minerals. Products such as powders, gels, puddings, ice creams, juices, and bars are also available for specific patient populations, such as those with swallowing impairments.

The term “oral nutritional supplement” is different from “nutrition support,” during which a patient instead relies on intravenous feeding. Further confusion can arise from the term “dietary supplement,” which refers to vitamins, minerals, herbs, botanicals, amino acids, concentrates, metabolites, or extracts.³ ONS are generally regarded as food whereas dietary supplements are not. This monograph focuses specifically on ONS use in the management of malnutrition in patients with cancer, including circumstances when ONS should be used, available products, and logistical concerns when recommending or prescribing ONS for individuals.

Review of the evidence

ONS can vary in their composition, but generally provide between 30 and 45 calories and 1 to 1.5 grams of protein per ounce. Patients may be advised to take supplements to meet their total nutritional needs or they may be given a specific calorie target to reach with supplements alone. ONS generally have been shown to increase the calories and protein that patients consume during the day despite the variation in supplement composition and recommendations.⁴ However, ONS do not always forestall weight loss or muscle loss nor do they improve quality of life or increase patients’ functional status.¹ ONS combined with targeted nutritional advice that is provided by a registered dietitian or other qualified healthcare educator can achieve better overall outcomes than the ONS alone. The advantages of using solely ONS are that the liquids are convenient, easy to use, and generally affordable.

Product considerations

Commercially available ONS products are typically gluten- and lactose-free, although many do contain milk protein, which can be a concern for patients with true dairy allergies rather than lactose intolerance. Products such as Boost® and Ensure® (and their generic counterparts) are balanced to provide calories from carbohydrates, fats, and proteins. For those having difficulty with blood sugar management, such products as Glucerna® and Boost Glucose Control® are designed especially for patients with diabetes or pre-diabetes. ONS formulations vary, but many vitamins and minerals are provided in the 25% daily required intake range. For patients with specific electrolyte needs, specialty products such as Nepro® or Renalcal® can be used to increase caloric intake without adding unwanted potassium or phosphorous. Alternative forms of supplements also exist for patients with difficulty swallowing. Highly specialized immune nutrition

products have been developed for patients who are critically ill. These formulas contain specific amino acids and fats that may be helpful to these patients, although little evidence exists for their use in the outpatient setting.

In addition, specialty manufacturers have begun offering a variety of products with specific consumer concerns in mind. These include those made from organic ingredients, with alternatives to dairy and soy protein, and with fats believed to have an “anti-inflammatory” profile are all offered on the market. Furthermore, a great number of powders can be included under the heading of ONS, including Carnation Breakfast Essentials® or Boost® High Protein powder. Products marketed as “whole foods powders,” however, are not well-regulated and may be contaminated with lead or arsenic, despite the veneer of health claims.⁵

Malnourished patients legitimately concerned with adding more fruits and vegetables to their diet should be strongly encouraged to work with a registered dietitian to ensure that they are able to meet their overall nutritional needs while still increasing fruit and vegetable consumption. Common strategies that dietitians often recommend are to include high-calorie fruits such as avocado, mango, and coconut and to include fruits and vegetables in smoothie drinks that may also contain an ONS. These strategies should be tailored to meet the needs of the person seeking guidance.

Logistical concerns

There are several reasons why malnourished patients may not follow their clinicians’ suggestions to drink an ONS. Often-cited reasons include the product’s taste, cost, and/or occasional gastrointestinal (GI) distress. Many common products are palatable, but given that patients may be advised to take 2 to 3 servings per day, even acceptably tasting supplements can become tiresome. Most commercially available supplements come in an assortment of flavors, and patients should be encouraged to rotate them to avoid taste fatigue. Supplements can also be mixed with ice cream, yogurt, or a frozen banana to improve taste and to add calories. GI distress such as nausea or diarrhea is usually mild and self-limiting. A strategy that may help tolerability is to take smaller amounts of the ONS more frequently throughout the day. However, in patients recovering from pancreatic cancer surgery, these symptoms may indicate exocrine pancreatic insufficiency, requiring pancreatic enzyme replacement therapy (PERT) (see the monograph “*Nutrition Impact Symptoms in the Patient with Cancer: Awareness, Implications, and Management*”).

The daily cost of 2 to 3 servings of a standard prepared liquid ONS can be as low as \$1 to \$2, particularly if a patient uses a generic brand or other means to ameliorate costs, such as coupons or store loyalty programs. Specialty brands, however, can result in out-of-pocket costs as high as \$10 or more per day for the same calories and proteins. Medicare and many private insurers do not typically cover ONS for malnutrition, even with an oncology diagnosis, but some manufacturers offer an assistance plan that is open to low-income patients. Additionally, there are a number of

patient support groups that may provide monetary help. On a national level, the Partnership of Prescription Assistance may be able to help connect patients with resources. Finally, sales representatives from ONS manufacturers may be able to provide clinicians' offices with samples and coupons for patient use.

Guideline summary

The American Society for Parenteral and Enteral Nutrition (ASPEN) and the Academy of Nutrition and Dietetics support ONS use to help manage malnutrition in patients with cancer.⁶⁻⁸ Although the guidelines vary, individuals who have been identified as malnourished should start drinking 1 to 3 ONS per day to increase calorie and protein intake. In the best-case scenario, the addition of energy and protein to the diet may also help address some of the other sequelae that result from malnutrition.

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