



Exceptional Opportunity

PG-SGA: Simple, Evidence-Based, Global Impact – Patients, Outcomes, and Quality

What is the research problem?

The idea of cachexia (from Greek κακός *kakos* "bad" and ἕξις *hexis* "condition") or severe malnutrition as a terminal outcome of cancer and/or its treatment is as old as the disease itself. It is dreaded by patient, carer, and clinician alike, and adversely impacts both oncologic outcomes (such as survival) and patient quality of life.

Progressive inanition can be prevented or ameliorated in many patients by utilizing proactive and standardized assessment and interventional protocols. But the questions remains: do patients die of their cancer, the complications of their treatment, or the associated malnutrition?

We need to address these questions in a new way – to proactively and prospectively use and integrate a validated and easy to use global nutritional assessment instrument with rapidly advancing technology in order to bring these approaches into global oncology clinical trials and standard of care clinical practice settings.

What is your proposed solution?

The Patient-Generated Subjective Global Assessment (PG-SGA – full, Short Form) is a validated clinical and research instrument that is short in format, completed quickly, and is primarily based on patient-generated (patient reported) information. With approximately 180 referenced articles in PubMed (most primary research-based; see bibliography at www.pt-global.org), the PG-SGA is accepted as the gold-standard of nutritional assessment and screening for nutritional deficit or risk in patients with cancer.

Since the inception of the PG-SGA, its validation and research data base have been the products of a remarkable interdisciplinary global volunteer research network of more than 200 clinicians and researchers. The availability, particularly starting within the past two years of multilingual, cross-culturally adapted translations as a simple downloadable paper version, a web-based tool, or a digital app (iOS, Android, WindowsPhone) truly makes this an approach that holds the potential to change the world and the lives of patients with cancer and those who care for them. In the past two years, the www.pt-global.org website has been visited by researchers and clinicians from approximately 140 cities and 3,350 cities globally, with several language versions available or currently in development, including all major European languages and a variety of South American, Asian and Middle Eastern languages and regional variations. In addition, as the co-creator of the PG-SGA is Native American, there is also interest in translations based on languages of endogenous peoples globally.

The score generated by the patient-generated component of the PG-SGA ranges from 0 to 36 points, with triage based on scores of 0-1, 2-3, 4-8 and ≥ 9 , with the latter indicating critical need for improved symptom management and/or nutritional intervention options. In recent data from Brazil, women with gynecologic cancer with a score >10 were 30.7 times more likely (95% confidence interval, 11.8–79.4) to die, with a 52.1% rate of mortality within 1 year. Patients classified as having any degree of malnutrition had a significantly lower median survival rate. Of note, while the PG-SGA was created for proactive use to prevent progressive malnutrition or inanition, it is also used to assess incidence and prevalence of malnutrition in various clinical settings as a baseline prior to standardized intervention or to gauge nutritional status and quality of nutritional care in specific clinical settings or patient populations.

Performed in a consistent standardized way, use of the PG-SGA

- Identifies pre-existing malnutrition or risk of malnutrition at the time of cancer diagnosis or treatment initiation



- Streamlines patient care and patient flow through clinical care settings;
- Improves quality of patient/carer/clinician interaction and conversations;
- For those who are hospitalized, consistently demonstrates the ability to identify, at time of admission, those who are at risk for prolonged length of stay;
- Identifies risk factors (e.g., nutrition impact symptoms or other modifiable impediments or issues) and facilitates specific interventions of identified contributors to the triage score that impact patient quality of life and ability to tolerate anticancer therapy.
- Importantly, proactive and routine use of the PG-SGA increases patient and carer awareness, resulting in increased patient and carer empowerment

How will your solution make a difference?

Integration of proactive PG-SGA (multilingual) with current and evolving technology will help answer the critical questions above and will improve quality of care, patient experience across the cancer continuum, oncologic outcomes and global interdisciplinary collaboration.

The vision of the researchers and clinicians developing and using the PG-SGA in clinical use and research settings has been, and continues to be, the integration of proactive and routine use of the PG-SGA with global cooperative oncology group clinical trials, with the electronic medical/health record, and with development of a secure, globally compliant central repository of PG-SGA generated data that interfaces with Big Data (e.g., CancerLinQ) – to understand the impact addressing (or failing to address) simple variables such degree and rapidity of weight loss, general nutritional intake, nutrition impact symptoms (GI, sensory, pain, psychological, as well as variables such as finances, etc.), and ECOG performance status on patients and their outcomes, ranging from quality of life to survival or cure.

The time is now to take this simple tool, the PG-SGA, already used globally, to these next steps. And this goal truly reaches the level of the visionary statement of President Kennedy “We choose to go to the moon in this decade” that is the basis of the Cancer Moonshot challenge.

The original moonshot took something (the moon) that is integral to everyday life -- as is nutrition -- and gave voice to an innately simple idea - a moon landing by decade end - that seemed nearly impossible according to convention wisdom or standard thinking at the time but gave us a vision that changed the world. Today's vision: PG-SGA + Technology = Cancer Success. For the patient, their carer, their clinical team, and for society. We welcome this opportunity to share our vision and for the opportunity to not only make a difference, but to change the world of oncology as it is known in 2016.

Bibliography:

Rodrigues CS, et al. Patient Generated Subjective Global Assessment as a prognosis tool in women with gynecologic cancer. *Nutrition*. 2015;31:1372-8.

Dewys WD, et al. Prognostic effect of weight loss prior to chemotherapy in cancer patients. Eastern Cooperative Oncology Group. *Am J Med*. 1980;69:491-7.

Torosian MH et al. Reduction of methotrexate toxicity with improved nutritional status in tumor-bearing animals. *Cancer*. 1988;61:1731-5. (Decreased death rate from toxicity in rats from 100% to 0%)

Ottery FD (ed). Integrating routine nutritional screenings for cancer patients at the Point of Care: Pilot testing a novel care planning system plus certified professional training.

<https://www.carevive.com/integrating-routine-nutritional-screenings-for-cancer-patients-at-the-point-of-care/>



Fearon K, et al (Ottery). Definition and classification of cancer cachexia: an international consensus. *Lancet Oncol.* 2011;12:489-95.

Bennani-Baiti N, Walsh D. What is cancer anorexia-cachexia syndrome? A historical perspective. *J R Coll Physicians Edinb.* 2009;39:257-62

Ottery FD (ed). *Oncology Issues* (Association of Community Cancer Centers, ACCC). *Issues in Nutrition and Cancer: Update 2004; Mar/Apr 2004; 2-14*

Ottery FD et al. *Oncology Issues.* The design and implementation of a model nutritional oncology clinic. 2002; Mar/Apr;2-6.

Langer et al. (Ottery). Clinical Significance of weight loss in cancer patients: rationale for the use of anabolic agents in the treatment of cancer related cachexia. *Nutr* 2001;17:S1-S20

Ottery FD. Definition of standardized nutritional assessment and interventional pathways in oncology. *Nutrition.* 1996 Jan;12(1 Suppl):S15-9.

Ottery FD. Rethinking nutritional support of the cancer patient: the new field of nutritional oncology. *Semin Oncol.* 1994 Dec;21(6):770-8.