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### LACK OF DEFINITIONS FOR COMMON TERMINOLOGIES IN THE SUPPORTIVE AND PALLIATIVE ONCOLOGY (SPO) LITERATURE

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**Background:** Both NIH and ASCO raised concerns regarding the lack of clear definitions for many terminologies in the SPO literature. We determined:

- (1) the frequency of 10 commonly used terms in the SPO literature;
- (2) the proportion of articles that provided definitions for each term; and
- (3) how each term was defined.

**Methods:** We systematically searched MEDLINE, PsychInfo, EMBASE, ISI Web of Science, and CINAHL for original

studies, review articles and systematic reviews related to palliative care (PC) and cancer in the first 6 months of 2004 and 2009. Twenty oncologists and PC specialists ranked 18 common terms based on the frequency of use and relative importance. We counted the number of occurrences for the top 10 terms in each article, reviewed them for the presence of definitions, and classified the journal type.

**Results:** Among the 1213 articles, 848 (70%) were original studies. “Palliative care” and “end of life” were the most frequently used terms (Table). “Palliative care”, “end of life” and “terminally ill” appeared more frequently in PC journals as compared to oncology journals ( $P < 0.001$ ), while “best supportive care” appeared more often in oncology journals ( $P < 0.001$ ). Only “palliative care” had a “consensus” definition (WHO in 20/35). “Supportive care” and many other terms were rarely defined (<5%).

**Conclusions:** Our findings highlighted the lack of definitional clarity for many key terms in the SPO literature. Standard definitions are needed to improve clinical communication and research standardization.

Term	Number of articles including the term N (%)	Median number of occurrences per article N (interquartile range)	Definition present N (%)
Palliative care	601 (50)	6 (2–14.5)	35 (6%)
End of life	386 (32)	4 (1–9)	0 (0%)
Terminally ill	245 (20)	2 (1–5)	5 (2%)
Hospice care	151 (12)	2 (1–4)	13 (9%)
Supportive care	106 (9)	1 (1–3)	2 (2%)
Terminal care	67 (6)	1 (1–2)	2 (3%)
Goals of care	55 (5)	2 (1–4)	1 (2%)
Best Supportive care	26 (2)	1 (1–2)	1 (4%)
Actively dying	15 (1)	1 (1–2)	1 (7%)
Transition of care	1 (0.1)	1 –	0 (0%)

[Table. Frequency and Definitions for 10 SPO Terms]

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### CHEMOTHERAPY INDUCED NAUSEA AND VOMITING FOLLOWING PROPHYLACTIC 5-HT<sub>3</sub>-RA ANTIEMETIC TREATMENT IN MODERATELY EMETOGENIC CHEMOTHERAPY

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**Objective:** To compare the risk of chemotherapy induced nausea and vomiting (CINV) following prophylactic use of

palonosetron vs. another 5-hydroxytryptamine-3 serotonin receptor antagonists (5-HT<sub>3</sub>-RA) in patients treated with a moderately emetogenic chemotherapy (MEC) regimen.

**Method:** This was a retrospective cohort analysis using HIPAA-compliant claims in a commercially-insured U.S. patient population. The study included MEC-treated breast, lung, or colon cancer patients receiving a prophylactic 5-HT<sub>3</sub>-RA between 4/1/2008 and 3/31/2009. Patients were followed during the first cycle of chemotherapy. Baseline variables included demographic data, cancer type, and comorbidity. The primary outcome was occurrence of CINV, defined as an antiemetic infusion or a medical claim

with a primary diagnosis of nausea and vomiting (ICD-9-CM 787.0x) or volume depletion (276.5x) on any day following chemotherapy. Multivariate analyses adjusted for baseline differences between groups.

**Results:** The final sample included 3,061 (69.7%) palonosetron users and 1,333 (30.3%) controls treated with another 5-HT3-RA. The palonosetron group was younger (mean 57.1 vs. 58.2 years,  $p=0.001$ ), had more women (72.6% vs. 65.4%,  $p<0.001$ ) and more breast cancer (49.7% vs. 38.7%) than the control group. In unadjusted comparisons, 19.4% of palonosetron users had CINV compared to 31.8% of controls ( $p<0.001$ ). After controlling for between-group differences with logistic regression, the odds ratio of CINV among palonosetron users vs. controls was 0.58 (95% CI 0.50–0.68,  $p<0.001$ ).

**Conclusion:** Among cancer patients treated with a MEC regimen, those treated with prophylactic palonosetron had significantly less post-chemotherapy CINV-related health care utilization or antiemetic use than users of another 5-HT3-RA.

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#### FATIGUE DOES NOT EXPLAIN THE IMPACT OF PHYSICAL ACTIVITY (PA) ON HEALTH-RELATED QUALITY OF LIFE (HRQL)

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**Objectives:** To assess whether the relationship between HRQL and PA is explained by the relationship between HRQL and fatigue in pediatric patients receiving chemotherapy for cancer.

**Methods:** Between 11/12/09 and 11/11/10, 24 pediatric oncology patients between 8 and 18 years of age completed the study. HRQL was assessed using PedsQL 4.0 and PedsQL 3.0 Cancer Module. PA was assessed by actigraphy as average daily activity counts. Fatigue was assessed by the Childhood Cancer Fatigue Scale. Pearson's correlations were computed between HRQL and PA as well as between HRQL and fatigue. The statistical significance of the difference between correlations was calculated.

**Results:** The correlation was significant between PA (mean=263,000 counts, range 47,000 to 433,000) and the PedsQL 3.0 scores from patients for nausea ( $r=0.43$ ;  $p=0.04$ ) and the PedsQL 4.0 scores from parents for overall HRQL ( $r=0.52$ ;  $p=0.01$ ) and physical ( $r=0.59$ ;  $p<0.01$ ). Both patients and parents demonstrated significant correlations between fatigue and the PedsQL 3.0 scores for pain ( $r=0.58$ ;  $p<0.01$  and  $r=0.50$ ;  $p=0.02$ ,

respectively). The correlation also was significant between fatigue scores and PedsQL 4.0 total HRQL score and school function in patients as well as PedsQL 3.0 cognitive domain in patients and worry domain in patients and parents. The correlation between PedsQL 3.0 treatment anxiety domain and PA was significantly different from the correlation with fatigue ( $p=0.04$ ).

**Conclusions:** Although PA and fatigue both significantly correlate with HRQL in pediatric oncology patients, different domains of HRQL are affected. Future research is needed to understand how PA affects HRQL.

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#### OCTYL GALLATE ENCAPSULATION IN LIPID NANOPARTICLES IMPROVES ITS ANTI-TUMOR ACTIVITY AND AMELIORATES ITS RENAL AND HEPATIC TOXIC EFFECTS

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Therapies used in advanced cases of melanoma such as chemotherapy, radiotherapy, biochemical therapy and vaccines, seem to be incapable to cure or improve survival rates of patients, making melanoma one of the most treatment-refractory malignancies. Furthermore, patient responses to chemotherapy are variable and often associated with significant degrees of toxicity and adverse side effects. This study evaluated the toxic effects and anti-melanoma activity of octyl gallate (G8, a molecule for which our group described an anti-melanoma activity), in a free form or incorporated into lipid nanoparticles, using a melanoma murine model. The nanoparticles G8-free or G8-full were produced and characterized physicochemically. G8 nano-encapsulation did not potentiate the antitumor activity of the compound, however, the side effects were ameliorated. Changes in body weight, hematological parameters, hepatic and renal function as well as the oxidative status of the liver were evaluated. A significant decrease of weight gain was observed in mice treated with free G8. Animals also showed other signs of toxicity such as endophthalmitis, piloerection, cachexia, ptosis, and dyspnea, which were not observed in animals treated with nano-encapsulated G8. Likewise, the biochemical and histological studies of hepatic and renal function showed that free G8 produced liver and kidney damages, which