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# Development of Guidelines for the Use of Orexigenic Drugs in Long- Term Care

John E. Morley, MB, BCh  
David R. Thomas, MD

Division of Geriatric Medicine  
Saint Louis University Health Sciences  
Center

GRECC, St. Louis VA Medical Center  
St. Louis, Missouri

*Council for Nutrition*



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**Chair:****John E. Morley, MB, BCH**

Dammert Professor of Gerontology  
 Director, Division of Geriatric Medicine  
 Saint Louis University Health Sciences Center  
 Director, GRECC  
 St. Louis Medical Center  
 St. Louis, Missouri

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 Little Rock, Arkansas

**David R. Thomas, MD, CMD, FACP, AGSF**

Professor of Medicine  
 Division of Geriatric Medicine  
 Saint Louis University Health Sciences Center  
 St. Louis, Missouri

**Margaret-Mary G. Wilson, MBBS, MRCP**

Assistant Professor of Geriatric/Internal Medicine  
 Division of Geriatric Medicine  
 Saint Louis University Health Sciences Center  
 St. Louis, Missouri

**Shing-shing Yeh, PhD, MD**

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**Council Facilitator:****Wendy C. Ashmen**

Programs in Medicine  
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The Geriatric Anorexia Nutrition (GAIN) Registry clearly demonstrated that persons living in long-term care who are losing weight have a higher mortality compared to those who stop losing weight.<sup>1</sup> Those who gained weight had a lower mortality than those in whom weight stabilized.

Numerous other studies have shown that weight loss and protein energy malnutrition in older persons is associated with an increase in mortality.<sup>2-4</sup> Weight loss is also associated with a variety of other adverse effects (Table I).<sup>5</sup> In addition, protein energy malnutrition aggravates the deterioration in the immune system that is normally associated with aging and causes a decline in CD<sub>4</sub><sup>+</sup> T lymphocytes (Table II).<sup>6</sup> For these reasons, weight loss has been considered a sentinel event in the life of the nursing home resident.

Estimates of the prevalence of protein energy malnutrition in cross-sectional studies of nursing home residents range from 23-85%.<sup>7</sup> In a prospective study of admissions to a long-term care facility, 54% of the residents were malnourished at the time of admission.<sup>8</sup> Serum albumin levels below 3.5 g/dL occur in 6-43% of nursing home residents. While low serum albumin levels are often associated with protein deficiency, they are also caused by cytokine excess, which inhibits albumin production in the liver and causes albumin leakage into the extravascular space. The effects of cytokines on albumin make it a poor marker of nutritional status. Pyridoxine deficiency occurs in 65% of residents, thiamine deficiency in 19%, and ascorbic acid deficiency in 2% of residents.<sup>9</sup>

Because of the importance of weight loss for residents in nursing homes, the Council for Nutritional Clinical Strategies in Long-Term Care has developed a series of

guidelines for nutritional assessment and management in long-term care (Tables III and IV).<sup>10</sup> At a recent meeting of the Council, it was felt that it would be useful to develop guidelines for the use of orexigenic agents in long-term care. In this article, we present a review of the efficacy and safety of orexigenic agents and the recommendations of the Council for Nutritional Clinical Strategies in Long-Term Care on the use of orexigenic agents in long-term care residents.

### Protein and Energy Supplementation in Malnourished Older Persons

While there is a paucity of high-quality studies on liquid protein and energy supplementation in malnourished older persons, the *Cochrane Database of Systematic Reviews* found 31 trials with 2464 randomized participants that could be analyzed.<sup>11</sup> Based on their analysis, they found that

supplements were associated with weight gain, decreased mortality (RR 0.67, 0.52-0.87), and decreased length of hospitalization by 3.4 days. No decrease in the risk of non-nutritional morbidity was

**Table I**  
Adverse Effects of Weight Loss in Older Persons

Anemia  
Immune dysfunction  
Infection  
Hip fracture  
Pressure ulcers  
Fatigue  
Decreased cognition  
Edema  
Muscle loss  
Osteoporosis  
Falls

**Table II**  
Alterations in Immune Function With Aging and Protein Energy Undernutrition

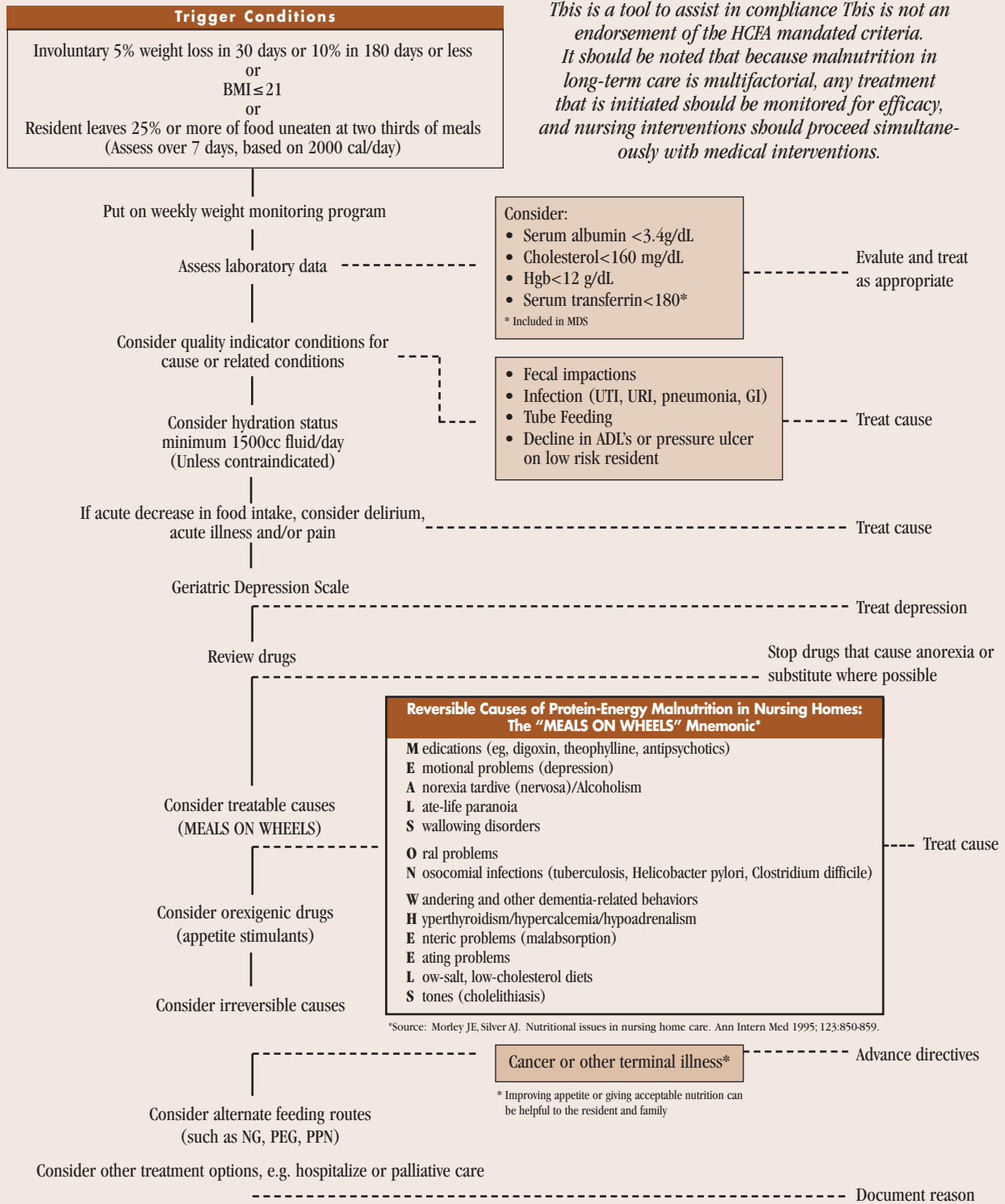
	<b>Aging</b>	<b>Protein Energy Undernutrition</b>
Thymus	Involution	Atrophy
Delayed hypersensitivity	Decreased	Decreased
Response to immunization	Decreased	Decreased
Neutrophil function	Decreased	Decreased
Circulating immune complexes	Increased	Increased
Helper/inducer T cells (CD <sub>4</sub> <sup>+</sup> )	Unchanged	Decreased
CD <sub>4</sub> <sup>+</sup> /CD <sub>8</sub> <sup>+</sup> T cell ratio	Increased	Decreased

found, and there were inadequate numbers to judge the effects on function (eg, grip strength, walking distance, and Barthel index). Most studies were considered too short to have a realistic probability of detecting changes in function, quality of life, or morbidity.

**Table III**  
**Clinical Guide to Prevent and Manage Malnutrition in Long-Term Care**

**FOR PHYSICIANS, PHARMACISTS, AND DIETITIANS (EVALUATE, DOCUMENT AND TREAT)**

*The American Dietetic Association supports the Clinical Guide to Prevent and Manage Malnutrition in Long-Term Care. Representatives from the American Dietetic Association were instrumental in its development. These Guidelines were developed by the Council for Nutrition. A special committee of The Gerontological Society of America (GSA) served as critical reviewers and provided input and modification of the final Guidelines. While GSA does not endorse specific clinical measures, we support the principles underlying these Guidelines and their potential to improve nutrition in the nursing home.*

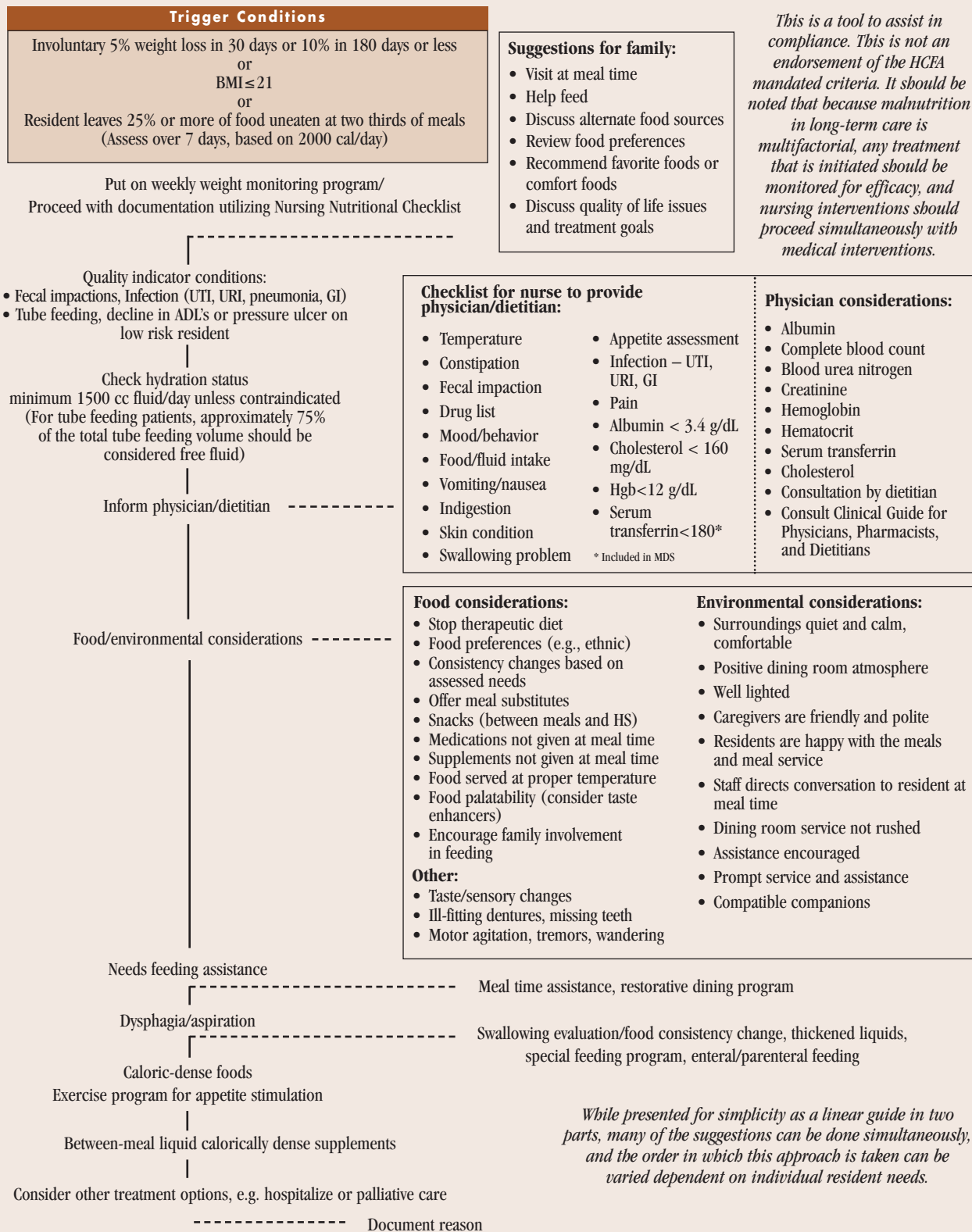


*While presented for simplicity as a linear guide in two parts, many of the suggestions can be done simultaneously, and the order in which this approach is taken can be varied dependent on individual resident needs.*

**Table IV**  
**Clinical Guide to Prevent and Manage Malnutrition in Long-Term Care**

**FOR NURSING STAFF AND DIETARY STAFF AND DIETITIANS (EVALUATE, DOCUMENT AND TREAT)**

*The American Dietetic Association supports the Clinical Guide to Prevent and Manage Malnutrition in Long-Term Care. Representatives from the American Dietetic Association were instrumental in its development. These Guidelines were developed by the Council for Nutrition. A special committee of The Gerontological Society of America (GSA) served as critical reviewers and provided input and modification of the final Guidelines. While GSA does not endorse specific clinical measures, we support the principles underlying these Guidelines and their potential to improve nutrition in the nursing home.*



*While presented for simplicity as a linear guide in two parts, many of the suggestions can be done simultaneously, and the order in which this approach is taken can be varied dependent on individual resident needs.*

Based on the finding that glucose when infused into the duodenum increased hunger in older persons compared to younger persons,<sup>12</sup> Wilson et al<sup>13</sup> studied the effect of a liquid caloric supplement administered concomitantly with the meal, or 60 minutes before the meal. They found that when a caloric liquid supplement was administered 60 minutes before a meal, it increased total caloric intake (supplement plus meal), but had no effect when given with the meal. It is, therefore, recommended that caloric supplements be given *between* meals and not with meals.

A number of recent caloric supplementation trials further support the positive conclusions of the *Cochrane Database*. Beattie et al<sup>14</sup> examined 101 malnourished surgical patients and found that caloric supplements postoperatively retarded weight loss and improved grip strength, quality of life, and morbidity compared to the control group. Lauque et al<sup>15</sup> examined the effect of a 400-kcal oral supplement daily in persons at nutritional risk living in nursing homes. They found an increase in daily protein and energy intake, body weight ( $1.4 \pm 0.5$  kg), and nutritional status in the supplemented group. In a 60-month randomized, placebo-controlled trial of 82 patients who had experienced a hip fracture (mean age, 80.7 years), protein repletion resulted in increased serum levels of insulin-like growth factor-1 (IGF-1), attenuation of proximal femur bone loss, and decreased length of stay in the rehabilitation setting.<sup>16</sup>

These studies confirm the utility of protein-calorie supplementation to improve outcomes, but to a limited extent, suggesting the need for a more aggressive therapeutic effect. Caloric supplements should be given between meals. The utility of “med-pass” supplements (the giving of medications with a nutritional supplement) requires a controlled trial.

## Depression

Depression is a common cause of severe weight loss in older persons, particularly those living in long-term care.<sup>17-19</sup> All persons losing weight should be screened for depression, using validated tools such as the Geriatric Depression Scale (if not demented) or with the Cornell Scale for Depression in Demented Persons. At present, the drug of choice for treating depression in persons with weight loss is mirtazapine, since it has

most often been associated with weight gain. However, weight gain may accompany improvement in depression despite the particular drug used.<sup>20-24</sup> There is some evidence that mirtazapine has specific orexigenic as well as antidepressant properties. However, any antidepressant that reverses depression will cause weight gain. If antidepressants are ineffective and the weight loss continues to be of significant concern, electroconvulsive therapy should be considered.

## Anabolic Agents

Two types of anabolic agents have been utilized to increase weight in malnourished older persons (ie, the anabolic steroids and growth hormone). Insulin growth factor-1 levels, which are regulated by growth hormone, decline to low levels in older persons, and fall even further with the onset of malnourishment.<sup>25</sup> Thus, growth hormone was a reasonable agent to test in reversing protein energy undernutrition in older persons. Early studies demonstrated that in these individuals growth hormone caused nitrogen retention and produced weight gain.<sup>26</sup> Chu et al<sup>27</sup> found that growth hormone could improve nutritional status in malnourished older persons. However, a large study on malnourished patients in intensive care units found that growth hormone increased length of hospitalization, ventilator dependence, and death.<sup>28</sup> Thus, at present, growth hormone cannot be recommended for use in older malnourished persons.

Ghrelin is a peptide hormone produced by the fundus of the stomach. Ghrelin increases food intake and releases growth hormone.<sup>29</sup> It produces these effects by activating nitric oxide synthase in the hypothalamus. Ghrelin appears to be an excellent potential mediator for the development of drugs to treat anorexia and weight loss.

Testosterone levels decline in men and women with aging.<sup>30,31</sup> Testosterone is an anabolic steroid. It increases strength, decreases fat mass, increases bone mineral density, and improves visuospatial cognition.<sup>31,32</sup> Low testosterone levels have been shown to be highly related to the development of sarcopenia<sup>33-35</sup> and to poor function (frailty).<sup>36</sup> Bakhshi et al<sup>37</sup> showed that testosterone administration improved function in men during rehabilitation following hospitalization. While there are no studies conducted in long-term care on testosterone replacement, it would appear that this

may be a reasonable option for malnourished men with low testosterone levels.

Other anabolic steroids have been used in malnourished ill patients. Nandrolone has been shown to enhance nutritional status in persons with renal failure.<sup>38</sup> Oxandrolone has been shown to decrease weight loss, nitrogen loss, time to healing, and length of hospitalization in elderly burn patients.<sup>39</sup> In an open-label trial, oxandrolone 10 mg twice daily produced weight gain in patients with chronic obstructive pulmonary disease.<sup>40</sup> No trials on the effects of oxandrolone on residents in longer-term care are available.

### Megestrol Acetate

Megestrol acetate is a progestational agent that increases food intake. A number of studies on cancer patients have shown that megestrol acetate increases appetite and weight, and improves quality of life.<sup>41-43</sup> Similar findings have been reported in patients with AIDS.<sup>44,45</sup>

There is limited experience of the use of megestrol in geriatric patients. Castle et al<sup>46</sup> reported that two out of four patients receiving megestrol acetate had weight gain. In a retrospective study of 27 long-term care patients, 74% had an increase in body weight, with weight gain being greater in women than in men.<sup>47</sup> Karcic et al<sup>48</sup> reported increased food intake, body mass index, albumin prealbumin, hemoglobin, and lymphocyte count in a small number of nursing home residents who received megestrol.

Yeh et al,<sup>49</sup> in a placebo-controlled randomized 3-month trial of megestrol, found that there was a significant increase in weight in the 3 months following megestrol administration. It is now well recognized that cytokines decrease food intake, inhibit albumin synthesis, cause muscle wasting, decrease nitrogen retention, and cause extravasation of albumin from intravascular spaces (Figure 1).<sup>50,51</sup> Yeh et al<sup>52</sup> reported that megestrol produced a decrease in interleukin-6,

tumor necrosis factor receptor-p75, and soluble interleukin-2 receptor levels. Lambert et al<sup>53</sup> also found that megestrol reduced interleukin-6 levels. These findings suggest that megestrol may be a useful drug in persons with cytokine excess. Cytokine excess may be gauged by measuring a C-reactive protein.

A major potential problem with megestrol is that it produces an increase mainly in fat mass rather than fat-free mass.<sup>54</sup> While an exercise program increased thigh muscle,

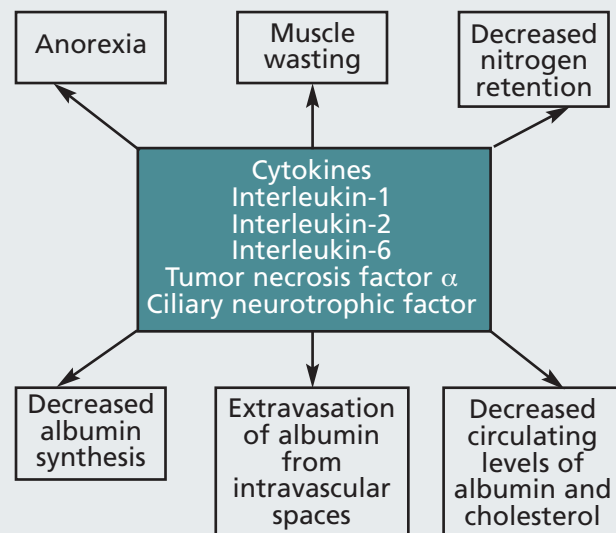
cross-sectional area megestrol failed to do this. Megestrol acetate markedly decreased testosterone levels over a short time period. In addition to hypogonadism, megestrol acetate has been reported to produce hyperglycemia, adrenal suppression,<sup>55</sup> and possibly deep vein thrombosis (Table V).<sup>56</sup> For the latter reason, megestrol acetate should not be used in immobile persons. The effective dose of megestrol acetate was 800 mg daily.

### Dronabinol

Cannabis was first recognized as an appetite stimulant in Aryurvedic medicine, and then in Arabic medicine by Al Badri in 1251. In 1838, O'Shaughnessy pointed

**Table V**  
Side Effects of Megestrol Acetate

Hypogonadism  
Impotence (erectile dysfunction)  
Hyperglycemia  
Adrenal suppression  
Deep vein thrombosis



**Figure 1.** Effect of cytokines on nutrition.

out that cannabis made patients voraciously hungry, and in *The Lancet* in 1890, Reynolds wrote that cannabis "...when pure and administered carefully is one of the most valuable medicines we possess." In the 1970s, during studies on the psychological effects of cannabis, it was noted to increase the intake of marshmallows and chocolate milk. In 1973, Morley et al<sup>57</sup> reported that cannabis increased the desire for food, made substances taste better and smell richer, decreased pain, and increased happiness. These are the ideal properties of a drug for palliative care.

Based on these findings, the active ingredient of cannabis, tetrahydrocannabinol, was isolated and a therapeutic agent, dronabinol, became available. Dronabinol has been shown to increase appetite in persons with cancer<sup>58-60</sup> or AIDS.<sup>61-63</sup>

Volicer et al<sup>64</sup> studied 11 patients with Alzheimer's disease and disturbed behavior. They ranged in age from 65-82 years. Dronabinol, on average, produced a 3-pound weight gain compared to placebo. In addition, dronabinol improved scores on the Cohen-Mansfield Agitation Index.

Jatoi et al<sup>58</sup> found that dronabinol and megestrol improved appetite and produced weight gain. There was no advantage of utilizing the drugs in combination. Neither drug had any major side effects.

Another major effect of dronabinol is its antiemet-

ic effect.<sup>65</sup> It is a particularly potent agent in preventing anticipatory nausea and vomiting in chemotherapy patients. In addition to dronabinol's appetite stimulation effects and reduction of aggressive behavior in patients with Alzheimer's disease, it is also an antispasmodic and an analgesic.<sup>66</sup> As an analgesic, it is an

excellent adjuvant therapy with opioids for use in central post-stroke pain and neuropathic pain.

Because dronabinol produces appetite stimulation,

has anti-nausea properties, decreases pain, and enhances general well being, it is considered the ideal drug for the management of end-of-life palliative care (Figure 2).

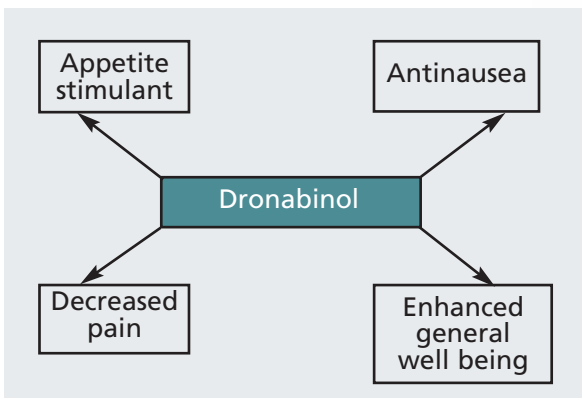
Because persons naïve to dronabinol may have mild delirium when first exposed to the drug, it should first be given at a dose of 2.5 mg prior to bedtime. After 1 week, the 2.5-mg dose should be given before supper. After 2 weeks, if there has been no response, the nursing home resident should be given 2.5 mg before lunch and supper (Table VI).

Table VI Dosing for Dronabinol in Long-Term Care
<p>Start dosing at 2.5 mg before bed at night                      After 1 week, administer 2.5-mg dose before supper                      If no response after 2 weeks, administer 2.5-mg dose before lunch and supper</p>

### Council for Nutritional Clinical Strategies in Long-Term Care Recommendations for Use of Orexigenics

As weight loss is a sentinel event, the Council recommends:

- Previous recommendations of the Council for non-pharmacologic interventions should be instituted in persons at nutritional risk.
- Persons who are depressed should receive treatment with an antidepressant that has orexigenic properties (eg, mirtazapine). In depressed persons with severe weight loss, electroconvulsive therapy should be considered.
- Orexigenics should be used when no obvious treatable cause of weight loss is present, or when the above recommendations fail to reverse weight loss.
- Use of anabolic steroids, preferably testosterone, should be used only to treat sarcopenia, not anorexia.



**Figure 2.** Use of dronabinol for palliative care.

- Megestrol acetate should be used in ambulatory persons with cytokine excess.
- Because megestrol acetate reduces testosterone levels, it should be used in men only together with testosterone.
- Megestrol acetate should be given for a maximum of 3 months.
- Persons receiving megestrol acetate should be monitored for adrenocortical insufficiency.
- Dronabinol should be used early when weight loss occurs without an apparent cause, or when no reversible cause is present.
- Dronabinol appears to be an ideal drug for end-of-life and palliative care.

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# FAX-BACK SURVEY

Please Fax to 1-888-528-1588 (Toll Free)

As the Council works to sponsor educational programming that meets the unique needs of elder care clinicians, we are asking that you please take a few moments to answer the following questions:



Receive this high-quality executive pen in appreciation for completing this survey



1. Approximately how many patients do you care for in each of the following settings:
- Skilled nursing facility \_\_\_\_\_
  - Assisted living \_\_\_\_\_
  - Home health care \_\_\_\_\_
  - Private practice \_\_\_\_\_

2. How many skilled nursing facilities do you serve?
- 1-2     3-5     > 5

3. What is the total skilled care bed size for these facilities?
- < 100                       100 – 150
  - 151 – 200                 > 200

4. On average, how frequently do you see each of your skilled care patients?
- Once a week
  - At least once a month
  - Once every 2-3 months

5. In a typical month, what percentage of your skilled care patients experiences some nutrition problems (eg, appetite loss and weight loss)? \_\_\_\_\_%

6. What are the three most common diseases or conditions associated with appetite loss and reduced food intake in your skilled care patients?

- Cancer
- HIV or AIDS
- Renal disease
- Pulmonary disease
- Heart disease
- Stroke (CVA)
- Alzheimer's disease
- GI disease
- Psychological illness (eg, depression, anxiety)
- Other; please specify: \_\_\_\_\_

7. Based upon your clinical judgment, what do you believe to be the underlying cause of the appetite loss for most skilled care patients?

- Medication
- Depression
- Acute infection/illness
- Disease-related
- Surgical procedure
- Other; please specify: \_\_\_\_\_

8. How frequently are nutritional assessments typically performed on your skilled care patients?

- At least once a week
- Once every 2 weeks
- Once a month
- Once every 3 to 6 months
- If less frequent, please specify: \_\_\_\_\_

9. Who conducts the nutritional assessment?

- Physician
- Physician Assistant

- Nurse Practitioner
- Skilled care nurse
- Dietitian
- Other; please specify: \_\_\_\_\_

10. How do you typically first become aware that your skilled care patients have a nutritional problem?

- You diagnose the problem
- You are notified by a skilled care nurse
- You are notified by someone else in the skilled nursing facility
- You are notified by a dietitian
- Other; please specify: \_\_\_\_\_

11. At what point are your skilled care patients first treated for appetite and/or weight loss?

- At first signs of appetite loss, but before weight loss has occurred
- Weight loss of less than 5% of normal body weight
- Weight loss of 5% or more of normal body weight
- Other; please specify: \_\_\_\_\_

12. What is the typical first-line treatment that you prescribe for your skilled care patients who experience appetite and weight loss?

- Nutritional supplements
- Tube feeding
- Drug therapy
- Total parenteral nutrition (TPN)
- Other; please specify: \_\_\_\_\_

13. Of all your skilled care patients who experience appetite and/or weight loss, what percent are treated at any point with drug therapy? \_\_\_\_\_%

14. Of the following drugs, please check those with which you are familiar:

- Cyproheptadine (Periactin) \_\_\_\_\_%
- Oxandrolone (Oxandrin) \_\_\_\_\_%
- Dronabinol (Marinol) \_\_\_\_\_%
- Oxymetholone (Anadrol) \_\_\_\_\_%
- Growth hormone \_\_\_\_\_%
- Testosterone \_\_\_\_\_%
- Megestrol acetate (Megace) \_\_\_\_\_%
- Mirtazapine (Remeron) \_\_\_\_\_%
- Other; please specify: \_\_\_\_\_

15. Which of the following drugs do you currently use with your patients who have experienced appetite and/or weight loss, and please indicate percentage of total with the total equaling 100%.

- Cyproheptadine (Periactin) \_\_\_\_\_%
- Oxandrolone (Oxandrin) \_\_\_\_\_%
- Dronabinol (Marinol) \_\_\_\_\_%
- Oxymetholone (Anadrol) \_\_\_\_\_%

- Growth hormone \_\_\_\_\_%
- Testosterone \_\_\_\_\_%
- Megestrol acetate (Megace) \_\_\_\_\_%
- Mirtazapine (Remeron) \_\_\_\_\_%
- Other; please specify: \_\_\_\_\_%

16. Which of the following drugs do you plan to use with your patients who experience appetite and/or weight loss:

- Cyproheptadine (Periactin)
- Oxandrolone (Oxandrin)
- Dronabinol (Marinol)
- Oxymetholone (Anadrol)
- Growth hormone
- Testosterone
- Megestrol acetate (Megace)
- Mirtazapine (Remeron)
- Other; please specify: \_\_\_\_\_

17. Please rank in order of importance the impact of the following factors in your drug selection using a scale of 1 to 7, where "1" means most important and "7" means least important:

- \_\_\_\_\_ Product efficacy
- \_\_\_\_\_ Product cost
- \_\_\_\_\_ Ease of use and patient compliance
- \_\_\_\_\_ Prior experience with product
- \_\_\_\_\_ Patient/family request
- \_\_\_\_\_ Product is on formulary or part of formal protocol
- \_\_\_\_\_ Other; please specify: \_\_\_\_\_

18. Please rate the degree of influence that each of the following parties has on your supportive care prescribing decisions using a scale of 1 to 5, where "1" means not at all influential and "5" means extremely influential (circle rating).

	Not at all Influential				Extremely Influential
Skilled nursing home formulary	1	2	3	4	5
Skilled care director of nursing	1	2	3	4	5
Skilled care nurses	1	2	3	4	5
Dietitians	1	2	3	4	5
Consultant pharmacist	1	2	3	4	

19. Would you be interested in participating in research involving the use of orexigenic agents in your long-term care facility(ies)?

- Yes     No

20. What type of educational programs focusing on nutrition would you like to see?

\_\_\_\_\_

If you would like to be added to the mailing list to receive future Council publications and materials and/or participate in research, please complete the following information:

Full Name \_\_\_\_\_ Degree(s) \_\_\_\_\_

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Thank you for your responses, they are very important to us.