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MEDICAL NUTRITION THERAPY GUIDELINES FOR THE USE OF PRO-STAT® & PRO-STAT® AWC FOR THE DIETARY MANAGEMENT OF PRESSURE INJURIES IN ADULTS

Pro-Stat contains 0% fruit juice

Pro-Stat® is a medical food designed for the dietary management of wounds and other conditions requiring increased protein in low volume. **Use under medical supervision.**

Note: The following is based on the 2019 European Pressure Ulcer Advisory Panel (EPUAP), National Pressure Injury Advisory Panel (NPIAP), Pan Pacific Pressure Injury Alliance (PPPIA) Prevention and Treatment of Pressure Ulcer/Injuries: Clinical Practice Guidelines[1] and the Nutrition Care Manual (NCM) from the Academy of Nutrition and Dietetics.[2] This guidance is intended to be a guide for healthcare organizations to develop their own facility-specific nutrition pressure injury guideline.

*Per the 2019 EPUAP/NPIAP/PPPIA Guidelines, "the recommendations in this clinical practice guideline are a general guide to appropriate clinical practice, to be implemented by qualified health professionals subject to their clinical judgment of each individual case and in consideration of the patient consumer's personal preferences and available resources. The guideline should be implemented in a culturally aware and respectful manner in accordance with the principles of protection, participation and partnership".**

The products named herein are used as examples; use of these products is subject to clinical judgment.

We thank Mary Ellen Posthauer RDN, LD, FAND, for her guidance in putting this document together.

**Haesler E, Ed. Prevention and Treatment of Pressure Ulcers/Injuries: Clinical Practice Guideline. The International Guideline. EPUAP/NPIAP/PPPIA, 2019.*

Printed copies of both the Quick Reference Guide and full 2019 International EPUAP/NPIAP/PPPIA Pressure Injury Prevention and Treatment Clinical Practice Guidelines can be obtained at https://guidelinesales.com/

Medical Nutrition Therapy Guidelines for the Use of Pro-Stat & Pro-Stat AWC for the Dietary Management of Pressure Injures in Adults

Contents

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1. BACKGROUND

Pressure Injuries (PIs) remain a major healthcare problem despite the advances in medical management modalities and support surfaces, especially for older adults or individuals whose nutritional status is compromised. The management of pressure injuries requires a collaborative, interdisciplinary team approach that includes the individual, family, and/or caregiver.[1]

Medical nutrition therapy (MNT) is an integral part of the wound management plan. Without adequate nutrition and hydration, healing is prolonged and quality of life diminishes. Pressure Injury (PI) healing is a complex process involving the replacement of injured tissue with new tissue. Nutrition including adequate calories, protein, vitamins and minerals plays a vital role in the prevention and management of PI and is essential for collagen and protein synthesis needed for the repair of body tissues. Protein needs increase with a PI.[1,2]

Some older adults may not consume enough protein to meet their estimated needs.[3,4] When it is not possible to achieve adequate levels of these essential nutrients through normal consumption of food, nutritional supplementation is necessary and has been clinically shown to promote wound healing.[5,6]

Table 1. Nutrients to Support & Repair Skin Integrity

Nutrients	Role in Skin Integrity	Recommendation
Calories	Energy source to preserve lean body mass and spare protein[1]	Optimize energy intake for adults at risk of PI and/or malnutrition[1,2] 30–35 kcal/kg body weight for adults with a PI who are malnourished or at risk of malnutrition (adjust per clinical condition)[1,2]
Protein	Tissue maintenance & repair, building lean body mass[1]	Adjust protein intake for adults at risk of PI who are malnourished or at risk of malnutrition[1,2] 1.25–2.0 g/kg body weight for adults with a PI who are malnourished or at risk of malnutrition (adjust per clinical condition)[1,2]
Fluid	Normal cell function & tissue integrity, adequate blood volume & circulation, nutrient & oxygen supply to tissues to support wound repair[1]	Provide and encourage adequate hydration. Example: 1 mL/kcal consumed, monitor hydration status[1]
Vitamin C	Connective tissue & collagen synthesis, supports formation of new blood vessels & wound strength, and enhances activation of leukocytes & macrophages to the wound site[1]	RDA = 90 mg for males; 75 mg for females UL = 2000 mg/day
Zinc	Essential trace mineral for DNA synthesis, cell division, collagen formation, protein synthesis, and immunity, all necessary processes for tissue regeneration & repair[1]	RDA = 11 mg for males; 8 mg/day for females UL = 40 mg/day.
Arginine	A biological precursor to nitric oxide, which increases blood flow, which can support collagen in wounds[7-10]	Supplemental arginine has shown benefits in wound healing[7,11-13]
Citrulline	Metabolizes into arginine which can help increase nitric oxide production	Consumption can raise plasma arginine levels more efficiently than supplemental arginine because it bypasses intestinal and liver breakdown.[9,14]

2. POLICY

MNT will be provided to all individuals identified with or at risk for malnutrition, and all individuals at risk for or have PIs. The nursing staff and registered dietitian nutritionist (RDN) in collaboration with the interdisciplinary team are responsible for implementing the MNT protocol, monitoring interventions, and documenting outcomes. The RDN will provide individualized nutrition goals that maintain or improve nutritional status, prevent infection, and optimize nutrient intakes in order to either reduce the risk of developing a PI or prevent impaired or delayed wound healing of existing PIs.[1,2]

The goals of MNT include:[2]

1. Consume food and fluid to meet estimated nutritional needs.
2. Maintain or increase body weight and prevent unintentional weight loss.
3. Meet estimated nutrient needs through meals, enteral or parenteral intake when appropriate, oral nutrition supplementation and/or medical foods when appropriate.

POSITION RESPONSIBILITIES

Nurse:

- Screen individual for malnutrition and PI risk and refer to RDN for nutrition assessment.
- Offer supplements and/or medical foods as prescribed by the physician and document acceptance or refusal.
- Monitor acceptance and tolerance of oral and/or enteral nutrition.
- Alert physician and RDN of individual's changes in nutritional status such as meal/supplement decline or refusal, hydration status, infections, weight fluctuations and failure of PI healing.

Registered Dietitian Nutritionist (RDN):

- Complete comprehensive nutrition assessment including identifying malnutrition characteristics and estimating calories, protein and fluid requirements.
- Develop a nutrition diagnosis statement.
- Recommend nutrition interventions that reflect the individual's choices and preferences.
- Include referral to other disciplines such as speech or occupational therapy, if applicable.
- Monitor and evaluate acceptance of nutrition interventions.
- Re-assess status when condition changes or wounds fail to heal.
- Document all assessment, interventions, and nutrition status in the medical record.

3. PROCEDURE

1. The nursing staff will screen and assess the individual's skin condition and PI risk at admission, readmission, and when there is a significant change of condition using the facility's validated screening tools. Examples of validated screening tools include the Braden Risk Assessment Scale,[15] which has a nutrition sub-scale (total score < 16 indicates high risk for PI development) and The Mini Nutrition Assessment (MNA)[16] (score of 8-11 = risk of malnutrition; 0-7 = malnourished). Results from screening will be communicated to the interdisciplinary team and documented in the medical record. Note: there are other validated nutrition screening tools available.

   When the nursing staff identifies a PI, the physician, individual, family, and RDN will be notified immediately. The Interdisciplinary team will implement protocols for support surfaces, treatments, and PI nutrition management according to the facility's policy and the physician's orders.

2. All individuals at risk for malnutrition and/or skin breakdown and/or those with a PI will be promptly referred to the RDN. The RDN will review the results of the screening tools, the medical record, and complete a comprehensive nutrition assessment.

3. After interviewing the individual and reviewing the nutrition assessment, the RDN will write a nutrition diagnosis and calculate the individual's estimated requirement for calories, protein, and fluids. In addition to protein and calories, individuals not consuming a balanced diet may consider a multivitamin plus minerals with 100% of the Reference Daily Intake (RDI's).[1] In cases of impaired healing and/or suspected vitamin or mineral deficiency, check results to determine whether individual has a nutrient deficiency and replace when needed.[2] The RDN will collaborate with the interdisciplinary team and implement MNT for PI management *(See Table 2 and Figure 1)*.

   The MNT treatment plan will focus on providing sufficient calories as the energy source and protein for tissue maintenance and repair. All stages of PI healing require adequate protein, and research indicates increasing the amount of protein provided is an effective intervention to promote healing.[1,2,14] Certain amino acids, such as arginine and citrulline, become conditionally essential during periods of stress and trauma.[7-10,12,13] Key vitamins and minerals also play a role in healing wounds.[1,2]

4. The PI nutrition management plan will be implemented based on the individual's condition, preferences and desired outcomes. The plan will be monitored weekly or per facility policy for individuals at malnutrition risk and/or PI risk or those with a PI. Interventions and outcomes will be documented in the care plan in the medical record.

4. KEY MNT GUIDELINES FOR RDN CONSIDERATION

Consider the following Academy NCM and EPUAP/NPIAP/PPPIA guidelines for implementation considerations.[1,2]

Energy Intake:

1. Optimize energy intake for individuals at risk of pressure injuries who are at risk of malnutrition or malnourished.
2. Provide 30-35 kcal/kg body weight for adults with a pressure injury who are malnourished or at risk of malnutrition.

Protein Intake:

1. Adjust protein intake for individuals at risk of pressure injuries who are malnourished or at risk of malnutrition.
2. Offer 1.25-2.0 grams of protein/kg body weight daily for adults with a pressure injury who are malnourished or at risk of malnutrition.

Supplemental Nutrition Intake:

1. Offer high calorie, high protein fortified foods and/or nutritional supplements and/or medical foods in addition to the usual diet for adults who are at risk of developing a pressure injury and who are also malnourished or at risk of malnutrition, if nutritional requirement cannot be achieved by normal dietary intake.
2. Offer a high calorie, high protein supplements and/or medical foods in addition to the usual diet for adults with a pressure injury who are malnourished or at risk for malnutrition, if nutritional intake cannot be achieved by normal dietary intake.
3. Provide high calorie, high protein, arginine, zinc and antioxidant oral nutritional supplements and/or medical foods or enteral formula for adults with a category/stage 2 or greater pressure injury who are malnourished or at risk for malnutrition.

Hydration:

1. Provide and encourage adequate water intake for hydration for an individual with or at risk of a pressure injury, when compatible with goals of care and clinical condition.

Artificial Nutrition/Enteral Feeding

1. Discuss the benefits and harms of enteral or parenteral feeding to support overall health considering preferences and goals of care with individuals at risk of pressure injury who cannot meet their nutritional requirements through oral intake despite nutritional intervention.
2. Discuss the benefits and harms of enteral or parenteral feeding to support pressure injury treatment considering preferences and goals of care for individuals with pressure injury who cannot meet their nutritional requirements through oral intake despite nutritional interventions.

Table 2. Management Plan for Adults at Pressure Injury Risk or With A PI(s)	
Risk Factors	**PI Trigger Conditions:** • Validated screening tool triggers PI risk (e.g. Braden Scale[15] <16 and/or MNA[16]≤11) • Unintended wt. loss > 5% in 30 days, >10% in 180 days • BMI (< 18.5 or > 30) • Poor oral intake • Receiving enteral/parenteral nutrition • Immobility, decline in ADLs • Infections, including urinary tract infections, pneumonia, wound infections • Identified moderate to high risk for malnutrition • Diminished functional status: (e.g. measured by hand grip strength) • Decline in ability to eat independently • Chewing/swallowing problem/dysphagia • Co-morbid conditions: end-stage renal disease, diabetes, CHF • Cognitive impairments: dementia, end-stage Alzheimer's • Skin exposure to urinary or fecal incontinence • History of PIs • Medical record confirms PI stages 1-4, deep tissue injury, multiple PIs or chronic non-healing PIs
Nutrition Assessment	**RDN Assess:** • Diagnosis/medical condition • Review of skin assessment/validated nutrition screening tools • Diet and/or enteral/PN nutrition • Current weight, Determine deviation from current and/or usual body weight • Estimated nutritional needs • Interview for food preferences & intolerances • Medications/medical treatments (antibiotics, steroids) • Average food/fluid intake including oral nutrition supplements (% consumed) • Chewing/swallowing status/ability to eat independently (refer to speech therapist or occupation therapist when appropriate) • Nutrition focused physical exam • For stages 2,3,4 or multiple PIs: Renal & liver function to ensure tolerance of protein levels • Hydration status for individuals with elevated temperature, vomiting, profuse sweating or heavily draining wounds
Nutrition Intervention	**Estimate Nutrient Needs:** • Calories: 30-35 kcal/kg body weight for adults with a PI (adjust per clinical condition) • Optimize energy intake for adults at risk of PI, malnourished or at risk of malnutrition • Protein: 1.25-2.0 grams/kg body weight for adults with a PI (adjust per clinical condition)[1,2] • Adjust protein intake for individuals at risk of PI • Fluid: Provide and encourage adequate water for hydration. Example: 1 mL per day per kcal consumed, unless contraindicated & monitor hydration status[1] • Offer preferred food/beverage at appropriate texture • Liberalize restrictive diets • Offer vitamin/mineral supplement with 100% of RDI's if intake is poor or deficiencies are suspected or confirmed[1] • Weigh weekly or per facility policy • Request MD order for concentrated liquid protein such as **Pro-Stat®***: - Individuals at malnutrition and/or PI risk: **Pro-Stat®**; dose as per RDN assessment and recommendation to meet estimated protein needs - Pressure Injury (PI): **Pro-Stat®**; dose as per RDN assessment and recommendation - Stages 2-4 PI, multiple PIs, and hard-to-heal wounds: **Pro-Stat® AWC**; dose as per RDN assessment and recommendation • Provide concentrated liquid protein such as **Pro-Stat** or **Pro-Stat AWC** with medication pass or via enteral feeding tube. Consider mixing in favorite beverage for additional fluid.

Table 2. Management Plan for Adults at Pressure Injury Risk or With A PI(s)	
Monitor	**Monitor Weekly or Per Facility Policy:** • Skin condition and/or wound status • Acceptance and tolerance of oral intake, nutrition supplement/medical food • Calorie, protein & fluid adequacy compared to estimated requirements • Weight status • Laboratory values, if available • Ability to meet nutrient needs orally • Consider enteral feeding consistent with individual's wishes, if intake is inadequate
Evaluate	**Outcomes:** • Intact skin or progress toward healing • Improved and/or stable nutritional status • Intake meets estimated caloric, protein and fluid requirements • Effectiveness of intervention in collaboration with interdisciplinary team and adjust if condition changes, improves or declines • Document in medical record and re-assess per policy

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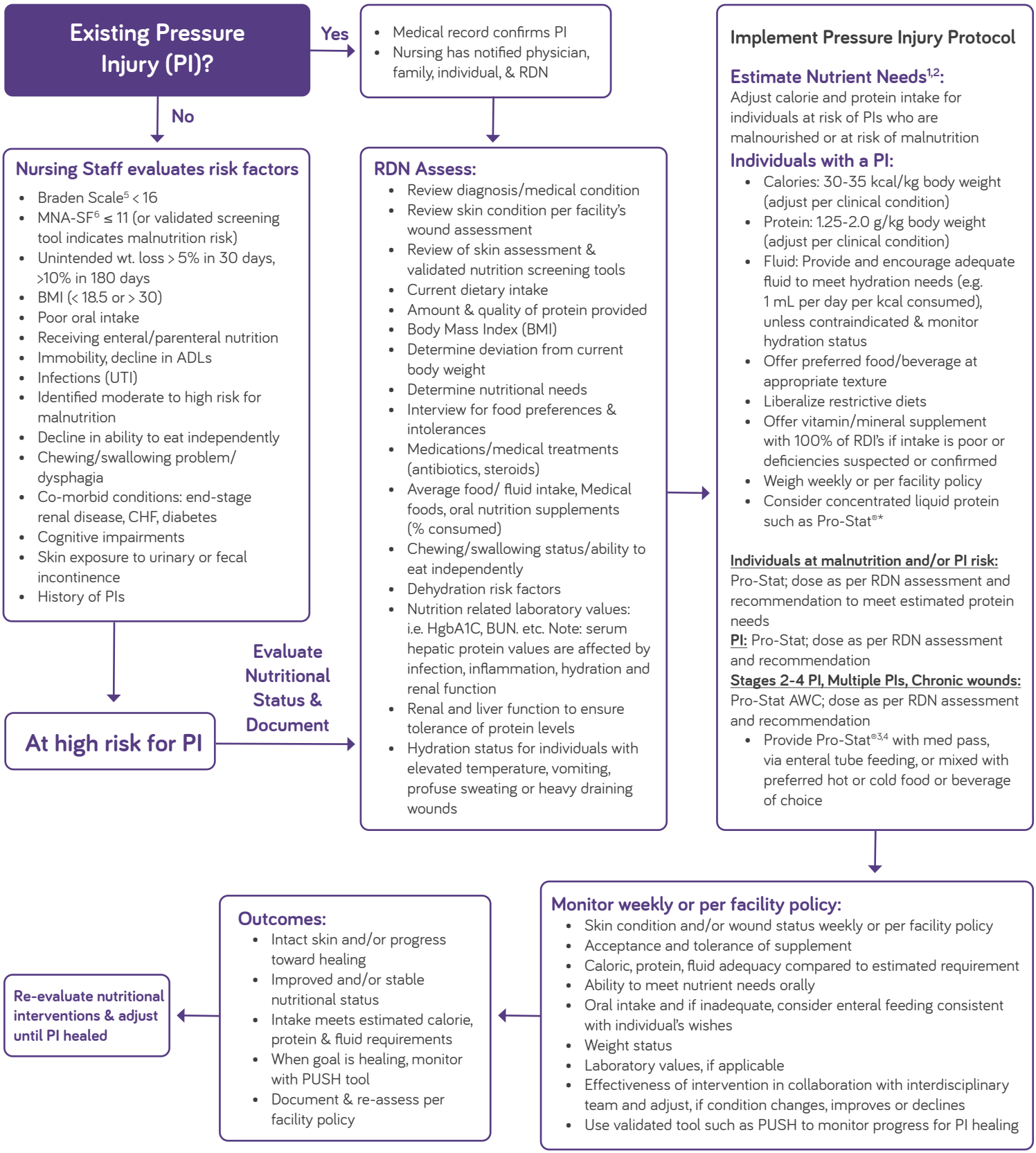
5. ADDENDUM I: GUIDE FOR NUTRITION MANAGEMENT OF PRESSURE INJURIES (PIS) FOR ADULTS IN ACUTE OR LONG-TERM CARE

FIGURE 1.



1. Cereda E and Munoz N, et al. In: Haesler E, Ed. Prevention and Treatment of Pressure Ulcers/Injuries: Clinical Practice Guidelines. 3rd ed. EPUAP/NPIAP/PPPIA, 2019: 94-114. **2.** Academy Nutr Care Manual (Academy of Nutrition and Dietetics. Nutrition Care Manual. https://www.nutritioncaremanual.org. Accessed Dec 13, 2021. **3.** Lee S K, Posthauer ME, Dorner B, Redovian V, Maloney M J, Pressure ulcer healing with a concentrated, fortified, collagen protein hydrolysate supplement; a randomized controlled trial. Advances in Skin & Wound Care. 2006;19(2):92-96. **4.** Hays et al. Effects of Whey and Fortified Collagen Hydrolysate Protein Supplements on Nitrogen Balance and Body Composition in Older Women. Journal of the American Dietetic Association. 2009;109(6):1082-87. June 2009. **5.** Bergstrom N, et al. Predicting pressure ulcer risk: a multisite study of the predictive validity of the Braden Scale. Nursing Research. 1998;47(5):261-9. **6.** MNA @ http://www.mna-elderly.com Accessed Jan 7, 2022.

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ADDENDUM II: PRESSURE INJURY PATIENT SCENARIOS

Patient Scenario #1

Stages 3 and 4 Pressure Injuries

Existing Pressure Injury (PI)?

Yes

- MT is a 159 lb male admitted to a rehabilitation center 6 months ago with a hip fracture and developed a stage 3 pressure injury on his hip & stage 4 on his coccyx.

Implement Pressure Injury Protocol

Registered Dietitian Nutritionist Assesses Patient Nutritional Intake & Weight History:

- The registered dietitian nutritionist interviews MT to assess his food choices and discovers that he loves sweets but not fruits or vegetables.
- He currently eats only 50% of his meals and has lost 16 lbs. (10%) since his admission 6 months ago.

Estimate Patient's Nutrient Needs:

- Based on the nutrition guidelines for a pressure injury, MT's protein requirement is 90-108 grams per day (72 kg x 1.25-1.5 grams protein per day).

MT'S TYPICAL DAILY MENU

	Protein*
Morning meal: 2 eggs 2 slices of toast 8 fl oz of milk	25 g
Noon meal: Meat sandwich (3 oz meat) Chips Soft drink	16 g
Afternoon Snack 2 cookies 8 fl oz of milk	9 g
Evening meal: 3 oz of meat Slice of bread A large serving of potatoes or corn Soft drink	27 g
Before bed meal: Popcorn Soft drink	2 g
50% of Meal Consumed = 39.5 g Protein	Total= 79 g

*http://fdc.nal.usda.gov. Jan 10, 2022

Assessment:

- Total daily protein intake = 39.5 grams per day does not meet estimated protein needs, does not eat a balanced diet, and a recent significant weight loss.
- **Patient is malnourished based on weight loss, poor oral intake, and PIs.**

Recommendation and Plan:

The registered dietitian nutritionist recommends the following:

1. Pro-Stat® AWC 30 mL (1 fluid ounce) three times daily in-between meals to meet his protein needs. Mix Pro-Stat® AWC in beverage of choice to increase hydration.
2. Continue Pro-Stat® AWC 30 mL three times daily until wound heals.

Pro-Stat® AWC is a medical food designed for the dietary management of wounds, and other conditions requiring increased protein needs in low volume. **Use under medical supervision.**

Pro-Stat contains 0% fruit juice.

Patient Scenario #2

Stage 1 Pressure Injury

Existing Pressure Injury (PI)?

↓ **Yes**

- FS is a 180 lb adult with a stage 1 pressure injury on her heel.
- Nursing has notified physician, family, individual, & RDN.

Implement Pressure Injury Protocol

Registered Dietitian Nutritionist Assesses Patient Nutritional Intake & Weight History:

- The registered dietitian nutritionist interviews FS and notes that she has a good appetite and tries to eat a balanced diet.
- Recent MD order for 250 mg Vitamin C twice daily and 10 mg Zinc three times daily.

Estimate Patient's Nutrient Needs:

- Based on the nutrition guidelines for pressure injuries, ST requirement is 102- 123 grams of protein per day (81 kg x 1.25-1.5 g per day).

FS'S TYPICAL DAILY MENU

	Protein*
Morning meal: 4 oz citrus juice or fruit 1 egg 1 slice of toast 1/2 cup cereal w/ 8 oz of milk	18 g
Noon meal: Large salad w/ 2 oz meat or cheese Crackers Serving of fruit 8 oz of milk	21 g
Afternoon Snack Ice cream Coffee	3 g
Evening meal: 3 oz of meat or fish Serving of rice or potatoes 1 slice of bread Vegetale and salad	21 g
Before bed meal: Peanut butter Crackers 8 oz milk	16 g
	Total= 79 g

*http://fdc.nal.usda.gov. Jan 10, 2022

Assessment:

- Total daily protein intake = 79 grams per day does not meet estimated protein needs, eats a balanced diet, and no recent significant weight changes.
- **Patient is not currently at risk for malnutrition.**

Recommendation and Plan:

The registered dietitian nutritionist recommends the following:

1. Pro-Stat® 30 mL twice daily in-between meals to meet her protein needs.
2. Discontinue daily micronutrient supplementation of 250 mg Vitamin C twice daily and 10 mg Zinc three times daily since FS is consuming a balanced diet.
3. Continue Pro-Stat 30 mL twice daily until wound heals.

Pro-Stat contains 0% fruit juice.

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7. PRO-STAT® PRODUCT INFORMATION

Pro-Stat®

A ready-to-drink concentrated liquid protein medical food providing **15 g of enzyme-hydrolyzed complete protein and 100 calories per 1 fl oz.**

Indications: For increased protein needs in low volume related to: pressure injuries, wounds (diabetic, venous, surgical burns) unintentional muscle loss, protein-energy malnutrition, low serum proteins, sarcopenia, dialysis, and fluid restriction.

Suggested Intake: 1-3 servings per day* (one serving = 1 fl oz, 30 mL)

Main Features:

- Clinically supported in 3 published trials to: manage wounds (1 study)[1], improve anabolism (1 study)[2], preserve lean body mass (1 study)[3]
- 15 g of protein and 100 calories per 1 fl oz
- Hydrolyzed for rapid absorption & efficient utilization[4]
- Available in 4 great tasting flavors: Wild Cherry Punch, Citrus Splash, Grape, & Vanilla

Lactose Free, Gluten Free, Soy Free. Ko*

Pro-Stat Ingredient list: Hydrolyzed Collagen Protein, Water, Glycerin, Malic Acid. Contains 2% or less: Potassium Sorbate (to help protect flavor), Sodium Benzoate (to help protect flavor), Sucralose, L-Tryptophan, Phosphoric Acid.

Wild Cherry Punch flavored version of this product contains 2% or less of each of the following: Natural flavors.

Citrus Splash, Grape and Vanilla flavored versions of this product contains 2% or less of each of the following: Natural and Artificial flavors.

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Serving Size: 1 fl oz (30 mL)

	Amount Per Serving
Calories	100
Fat	0 g
Total Carbohydrate	10 g
Total Sugar	0 g
Protein	15 g
Sodium	50 mg
Potassium	20 mg
Phosphorus	50 mg

Pro-Stat® AWC (Advanced Wound Care)

A ready-to-drink concentrated liquid protein medical food providing **17 g of enzyme-hydrolyzed complete protein and 100 calories per 1 fl oz, with added arginine, citrulline, cystine, vitamin C and zinc.**

Indications: For increased protein needs in low volume related to: stages 2 to 4 pressure injuries, multiple pressure injuries, hard-to-heal wounds (diabetic, venous, surgical burns), unintentional muscle loss, protein-energy malnutrition, low serum proteins and sarcopenia.

Suggested Intake: 1-3 servings per day* (one serving = 1 fl oz, 30 mL)

Main Features:

- Clinically supported in 1 published trial to promote pressure injury and wound healing[1]
- Providing 17 g of protein and 100 calories per 1 fl oz
- Contains added arginine, citrulline, cystine, vitamin C and zinc
- Available in 3 great tasting flavors: Wild Cherry Punch, Citrus Splash, and Berry Fusion.
- Hydrolyzed for rapid absorption & efficient utilization[4]
- For oral and enteral use

Lactose Free, Gluten Free, Soy Free. Ko*

Pro-Stat AWC Ingredient List: Hydrolyzed Collagen Protein, Water, Glycerin, Malic Acid, L-Arginine. Contains 2% or less: L-Citrulline, Phosphoric Acid, Ascorbic Acid, L-Tryptophan, L-Cysteine HCL, Potassium Sorbate (to help protect flavor), Sodium Benzoate (to help protect flavor), Sucralose, Zinc Sulfate.

Berry Fusion and Wild Cherry Punch flavored version of this product contains 2% or less of each of the following: Natural Flavors.

Citrus Splash flavored version of this product contains 2% or less of each of the following: Natural and Artificial Flavors

NUTRIENTS

Serving Size: 1 fl oz (30 mL)

	Amount Per Serving
Calories	100
Fat	0 g
Total Carbohydrate	7 g
Total Sugars	0 g
Total Protein (includes L-Arginine 3.2 g)	17 g
Vitamin C	175 mg
Zinc	10 mg
Sodium	35 mg
Potassium	20 mg
Phosphorus	50 mg

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1. Lee SK, et al. Adv Skin Wound Care. 2006;19(2):92-6.
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*Actual dosage is determined by clinician based on condition, estimated need and dietary intake.

NOTES

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