



Nutrition Procedures

This document provides information to help guide you to provide nutrition in your patients to ensure that the goal of 80% of what is prescribed is obtained.

Nutrition Prescription

Protein and energy targets will be achieved through any combination of EN, protein supplements, and PN or amino acids. The only difference between the nutrition prescriptions between the 2 study groups is that the protein goals are set.

Protein Target

In accordance with the study group the participant has been randomized to, the participant should be prescribed one of the two (2) following protein targets:

Lower Protein Dose	Higher Protein Dose
$\leq 1.2 \text{ g/kg/day}$	$\geq 2.2 \text{ g/kg/day}$

In both groups:

- Targets will be set using pre-ICU dry actual weight.
- For patients with BMI <20 or >30, ideal body weight based on a BMI of 25 will be used. Refer to the website to access a table that will help you calculate this body weight based on a BMI of 25.

Calorie Target

Although this trial is not about caloric dose, we want to encourage participating clinicians to be conservative in meeting energy targets and avoid overfeeding. Caloric goals should be the same in both groups and we recommend sites follow the SCCM/ASPEN clinical practice guidelines (McClave JPEN 2016).

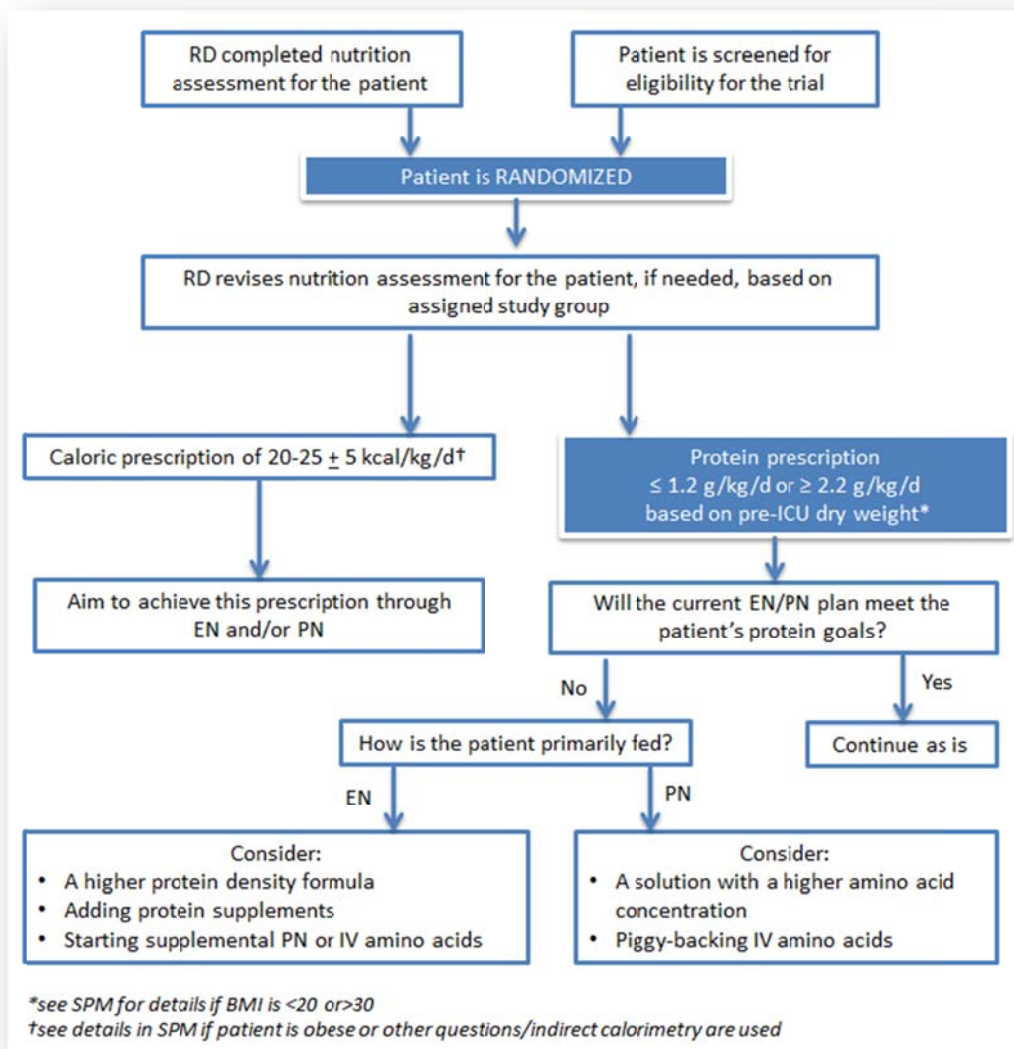
- For non-obese patients, we suggest that their caloric prescription be around 20-25 kcal/kg/day.
 - If the site chooses to use more sophisticated equations or indirect calorimetry, that is permissible.
- For obese patients, if indirect calorimetry is used, the goal of the nutritional prescription should be to provide energy not to exceed 65%–70% of measured requirements.
 - If indirect calorimetry is unavailable or not used, we suggest using the weight-based equation 11–14 kcal/kg actual body weight per day for patients with BMI in the range of 30–50 and 22–25 kcal/kg ideal body weight per day for patients with BMI > 50.

Calorie Dose Clarifications

One of the most common questions is around calculating energy targets, particularly in obese patients is whether sites can use their own local way of calculating targets rather than the ASPEN recommendation?

The main point about energy targets in obese patients is **not to overfeed**. As a suggestion or guideline, we recommend the ASPEN guidelines but if you have something else that you use locally that works for you, and does not overfeed (should approximate what would be given if you used the ASPEN targets and not grossly exceed it), then that is acceptable.

Figure 4: Overview of Nutrition Procedures



Throughout the study the site should be monitoring compliance with the study protein target on a daily basis. We expect sites, based on their clinical experience, to be able to provide the protein goal allocated to each arm of the study. There is a built in daily nutritional adequacy tool in REDCap which



will help you monitor the adherence to the study intervention and the nutrition goals of 80%. This tool will allow you to clearly see how well you are complying with the treatment protocol and to make changes to improve your adherence. While we encourage you to use the nutritional adequacy calculator built into REDCap. Refer to the CRF instruction in the Data collection & entry section for details on how to make use of this tool.

Feasibility of Meeting Goals

Similar efforts should be used in both study groups to achieve at least 80% of the protein and calorie targets.

Refer below for several scenarios that have been developed to help the dietitians and study team members optimize nutrition delivery in study patients.

BMI = 20; Weight = 67kg

Meeting Goals with Enteral Formulas

	Lower Protein Dose (≤ 1.2 g/kg/day) Energy 25kcal/kg actual weight/day	Higher Protein Dose (≥ 2.2 g/kg/day) Energy 25 kcal/kg actual weight/day
Protein Goal (g/day)	≤ 80	≥ 147
Energy Goal (kcal/day)	1675	1675
Suggested Enteral Nutrition Products to Achieve Goals	Peptamen 1.5 ➤ 1.1 L (75g protein, 1650 kcal)	Peptamen Intense ➤ 1.7L (156g protein, 1700 kcal)
	Osmolite 1.0 + Juven ➤ 1.5L + 1 packet (81g protein, 1670 kcal)	Vital AF 1.2 + Juven ➤ 1L + 6 packets (159g protein, 1680 kcal)

Meeting Goals with Parenteral Formulas

	Lower Protein Dose (≤ 1.2 g/kg/day) Energy 25kcal/kg actual weight/day	Higher Protein Dose (≥ 2.2 g/kg/day) Energy 25 kcal/kg actual weight/day
Protein Goal (g/day)	≤ 80 (75)	≥ 147 (150)
Energy Goal (kcal/day)	1675	1675
Suggested Parenteral Nutrition Products to Achieve Goals	Clinimix 5.0/25 ➤ 1.5 L (75g amino acids, 1575 kcal)	Clinimix 5.0/20 + Clinimix 15.0 ➤ 1.5 L + 0.5 L (150g amino acids, 1620 kcal)
	Kabiven ➤ 2.0 L (68g amino acids, 1740 kcal)	Kabiven + Clinimix 15.0 ➤ 1.5L + 700 mL (156g amino acids, 1725 kcal)



BMI = 35; Weight = 100kg, weight at BMI 25=84kg

Meeting Goals with Enteral Formulas

	Lower Protein Dose (≤ 1.2 g/kg/day) Energy 11-14kcal/kg actual weight/day	Higher Protein Dose (≥ 2.2 g/kg/day) Energy 11-14 kcal/kg actual weight/day
Protein Goal (g/day)	≤ 100	≥ 185
Energy Goal (kcal/day)	1100-1400	1100-1400
Suggested Enteral Nutrition Products to Achieve Goals	Peptamen Intense VHP <ul style="list-style-type: none"> ➤ 1.0 L (92g protein, 1000 kcal) Peptamen AF <ul style="list-style-type: none"> ➤ 1.2L (91g protein, 1440 kcal) Vital AF 1.2 + Juven <ul style="list-style-type: none"> ➤ 1.0 L + 1 packet (89g protein, 1280 kcal) 	Peptamen Intense VHP + Prosource NoCarb <ul style="list-style-type: none"> ➤ 1.2L + 150mL (185g protein, 1500 kcal) Vital High Protein + Prosource NoCarb <ul style="list-style-type: none"> ➤ 1L + 210mL (193g protein, 1420 kcal)

Meeting Goals with Parenteral Formulas

	Lower Protein Dose (≤ 1.2 g/kg/day) Energy 11-14 kcal/kg actual weight/day	Higher Protein Dose (≥ 2.2 g/kg/day) Energy 11-14 kcal/kg actual weight/day
Protein Goal (g/day)	≤ 100	≥ 185
Energy Goal (kcal/day)	1100-1400	1100-1400
Suggested Parenteral Nutrition Products to Achieve Goals	Clinimix 4.25/10 <ul style="list-style-type: none"> ➤ 2.25 L (95g amino acids, 1148 kcal) Kabiven + Clinimix 15 <ul style="list-style-type: none"> ➤ 1.5 L + 0.25 L (98g amino acids, 1455 kcal) 	Clinimix 4.25/10 + Clinimix 15.0 <ul style="list-style-type: none"> ➤ 1.0 L + 1.0 L (193g amino acids, 1110 kcal) Kabiven + Clinimix 15.0 <ul style="list-style-type: none"> ➤ 1.0L + 1.05 L (192g amino acids, 1500 kcal)

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BMI = 45; Weight = 134kg, weight at BMI 25=84kg

Meeting Goals with Enteral Formulas

	Lower Protein Dose (≤ 1.2 g/kg/day) Energy 22-25kcal/kg actual weight/day	Higher Protein Dose (≥ 2.2 g/kg/day) Energy 22-25 kcal/kg actual weight/day
Protein Goal (g/day)	≤ 100	≥ 185
Energy Goal (kcal/day)	1848-2100	1848-2100
Suggested Enteral Nutrition Products to Achieve Goals	<p>Peptamen 1.5 + Prosource NoCarb</p> <ul style="list-style-type: none"> ➤ 1.2 L + 30 mL (96g protein, 1880 kcal) <p>Perative</p> <ul style="list-style-type: none"> ➤ 1.4 L (93g protein, 1820 kcal) 	<p>Peptamen Intense VHP</p> <ul style="list-style-type: none"> ➤ 2.1 L (193g protein, 2100 kcal) <p>Peptamen AF 1.2 + Prosource NoCarb</p> <ul style="list-style-type: none"> ➤ 1.2 L + 150 mL (189 protein, 2100 kcal) <p>Promote + Juven</p> <ul style="list-style-type: none"> ➤ 1.7 L + 6 packets (190g, 2180 kcal)

Meeting Goals with Parenteral Formulas

	Lower Protein Dose (≤ 1.2 g/kg/day) Energy 20-25 kcal/kg actual weight/day	Higher Protein Dose (≥ 2.2 g/kg/day) Energy 20-25 kcal/kg actual weight/day
Protein Goal (g/day)	≤ 100	≥ 185
Energy Goal (kcal/day)	1848-2100	1848-2100
Suggested Parenteral Nutrition Products to Achieve Goals	<p>Clinimix 4.25/20</p> <ul style="list-style-type: none"> ➤ 2.25 L (96g amino acids, 1913 kcal) <p>Kabiven + Clinimix 15</p> <ul style="list-style-type: none"> ➤ 2.0 L + 200 mL (98g amino acids, 1860 kcal) 	<p>Clinimix 4.25/20 + Clinimix 15.0</p> <ul style="list-style-type: none"> ➤ 2.0 L + 700 mL (190g amino acids, 2120 kcal) <p>Kabiven + Clinimix 15.0</p> <ul style="list-style-type: none"> ➤ 1.5 L + 1.0 L (201g amino acids, 1905 kcal)

Protein Dose Clarifications

We prescribe glutamine as standard practice in our ICU: how should we give the glutamine? Should the glutamine be included in the protein dose? Or should glutamine be considered separate?

You should continue to give the glutamine based on your local clinical experience/practice. If a patient is given glutamine, the amount of associated nitrogen should be included in the daily protein dose.



What happens if an enrolled patient does not meet 80% of their protein prescription over their ICU stay?

There is no penalty if patient did not reach the protein goal or 80% each day, however, we expect that sites, based on their clinical experience, be able to provide the protein goal to patients allocated to each arm of study. We have built in a daily nutritional adequacy tool into REDCap to help sites monitor their adherence to the study intervention and nutrition goals. This tool will allow you to clearly see how well you are complying with the treatment protocol and make changes to improve your adherence.

NOTE: The most meaningful patients to the study are those that achieve a cumulative amount of protein of at least 80% of the target. We strongly encourage you to reach the protein goal of 80% each day, the reason being that in the efficacy **analysis**, we will only include those patients that achieve 80% cumulatively over the entire stay.