

IMPACT

User Protocol

1. WHY USE IMPACT?

- Nutrition and Immunology

2. Who, When & How to Feed IMPACT*

- Trauma
- Surgery
- Pulmonary Disease
- Critically ill patients fed immune-enhancing formulas demonstrate:
 - 30% lower risk for infection (1,2)
 - 3 day shorter length of stay (1,2)
 - 2.5 fewer days on the ventilator (1,4)

- Sepsis/Infection
- Cancer
- Burn

3. References

*The information contained in this document is intended to provide guidelines for feeding the IMPACT product line. Individual patient needs must be considered when initiating enteral feeding with IMPACT.

1. WHY USE IMPACT?

The type of enteral formula selected is essential for the acute critically ill and injured patients since their nutritional needs are different than those of stable tube fed patients. Immune suppression and increased infection risk following surgery, trauma and critical illness can be minimized by adjusting specific nutrients in the diet. Early feeding of immune-enhancing formulas containing arginine, dietary nucleotides and fish oil, have been shown to help speed recovery, shorten hospital stays and reduce infectious and wound complications.¹⁻¹⁹

Studies have shown that providing enteral nutrition, in the critically ill patient, is the preferred route of nutrition support whenever possible. Adverse effects associated with parenteral feeding include gut atrophy, bacterial translocation and increased risk for infectious complications. It is therefore essential to provide enteral nutrition support in the early stages of critical illness in order to lessen these potential adverse effects. Ideally, early feeding of an enteral formula into the small intestine begins within the first 8-12 hours after surgery or within 24-72 hours after traumatic injury. Although the best time to begin early feeding is not known, most nutrition support experts agree that provided it is safe to initiate feeding, the sooner nutritional support is initiated the better the expected outcome.

IMPACT, the first immune-enhancing enteral formula, has been studied in approximately 2500 surgical, septic, critically ill and trauma patients. The results of 19 outcome studies including two meta-analysis demonstrate that patients fed immune-enhancing enteral formulas have on average a 30% lower risk for infection, are discharged 3 days earlier and are weaned from the ventilator 2-3 days sooner than patients fed standard high nitrogen formulas. With data like this, it makes sense to utilize these formulas in critically ill patients who are generally the most costly patients to the hospital.

What types of patients are appropriate for IMPACT? When do you use IMPACT? How do you use IMPACT? These are excellent questions that will be addressed in this pocket guide. This guide will help you develop protocols for successfully using IMPACT in your hospital. Use IMPACT appropriately and watch IMPACT make a difference in your patients.

NUTRITION AND IMMUNOLOGY

Nutrition support is an integral part of the therapy for critically ill patients. These patients have a characteristic metabolic response to injury whether their illness is secondary to trauma, burns, surgery, severe head injury, cancer, etc. This response is associated with an increase in metabolic rate and rapid loss of fat and muscle mass. If this response is prolonged, it has several adverse effects, including immunosuppression, decreased or delayed wound healing and loss of muscle strength. IMPACT® is an enteral formula designed to meet the needs of these patients. The patented combination of 3 ingredients contained in IMPACT; arginine, dietary nucleotides, and fish oil are outlined in detail to provide a clear understanding of how they function. Also there are brief descriptions of the types of immunity in order to understand the differences.

PATENTED 3 INGREDIENTS:

Arginine:

- A conditionally essential amino acid necessary for T-cell growth and replication.
- Promotes nitrogen retention and is a key nutrient for wound healing.
- Supplemental levels promote optimal immune function during times of metabolic stress.

Fish Oil:

- Contains the long-chain omega-3 fatty acids EPA and DHA important for optimal immune function.
- Adequate levels of EPA and DHA inhibit the immune suppressive and inflammatory effects of the n-6 fatty acids.
- IMPACT provides the proper balance of n-6 and n-3 fatty acids.

Dietary Nucleotides:

- Required by all cells, and are particularly important for cells with rapid turnover including mucosal cells, lymphocytes and macrophages.
- Normally provided in the diet or manufactured by the body in non-stress states.
- During stress states a dietary source is necessary to promote optimal growth and replication of T-cells.

2. Why, Who, When & How to Feed IMPACT*

- TRAUMA PATIENTS

WHY:

The National Safety Council estimates that 60 million injuries occur in the United States each year; of which approximately 50% require medical care and 6% (3.6 million) require hospitalization. Risk for infection is high in patients who survive severe trauma, and many require lengthy hospital stays and rehabilitative therapy.²⁰

Because trauma patients are generally young and well nourished, early nutritional support has not routinely been a high priority. Metabolic alterations following severe injury can cause the body to lose its ability to adapt to starvation. Evidence that early nutritional support is beneficial continues to accumulate.²⁰

The primary goal of nutritional support for trauma patients is to meet increased energy and protein demands, provide adequate nutrients for wound healing and maintain or improve host defenses against infection.²⁰ Studies have demonstrated improved outcomes in trauma patients fed immune-enhancing formulas containing arginine, dietary nucleotides and fish oil.^{1,2,4,6,7,10,13}

WHO:

Patient types appropriate for the use of IMPACT® may include but are not limited to:

- Blunt and penetrating trauma
- Stab wound
- Spinal cord injury (SCI) requiring vent
- Gunshot wound (GSW) Motor Vehicle Accident (MVA)
- Multiple trauma when patients are expected to be hospitalized for at least 5 days

WHAT:

The IMPACT line of formulas can meet all the needs of the enterally fed trauma patient.

- Adequate supplemental arginine for optimal support of immune function and promotion of wound healing.
- Supplemental dietary nucleotides required by all cells, especially cells with rapid turnover including mucosal cells, lymphocytes, and macrophages.
- Adequate, but not excessive, levels of omega-6 fatty acids to avoid suppression of immune function.
- A marine source of omega-3 fatty acids (EPA/DHA) for support of immune function.
- Supplemental glutamine for gastrointestinal tract nutrition.

- High protein for tissue synthesis and repair.
- Adequate levels of vitamins and minerals for wound healing, especially vitamins A, C, and zinc.

WHEN:

- Feed early – initiate within 24–72 hours of trauma.
- Determine enteral access route.
 - Place jejunal tubes (surgical G-J, surgical J, or NCJ) if abdominal surgery required.
 - Place post-pyloric NJ or PEJ if no abdominal surgery needed.
 - NG tube may be used if enteral feeding monitored closely.
 - Confirm placement of feeding tube prior to initiating feeding.

HOW:

- Start slow with full strength IMPACT at 25-50 ml/hr and advance 10-25 ml/hr as tolerated every 8-24 hours until goal rate or volume desired is achieved.
- Continue feeding for at least 5-7 days. May continue longer until risk for infection has passed and wounds are healing well.
- A minimum goal of 1000 cal/day of IMPACT is recommended.
- Transition to a high nitrogen formula such as Isosource Protein, Novasource GI Control, when patient is no longer at risk for infection.
- Pre-operative feeding with Oral IMPACT for 5-7 days (3 servings/day) has been shown to improve immune function more quickly following surgery and to reduce the risk for infection.¹⁶⁻¹⁸

2. Why, Who, When & How to Feed IMPACT

-SURGERY PATIENTS

WHY:

Despite improvements made in post-surgical care, infectious complications continue to be a major problem. Infections of surgical wounds represent roughly 10% of all hospital-acquired infections. The National Nosocomial Infections Surveillance System (NNIS) report of US hospitals found that 5-21% of deaths in surgical patients were related to wound infections.²⁰

Up to 50% of surgical patients are malnourished before or become malnourished following surgery. When compared with patients receiving parenteral nutrition, patients given early post operative enteral feeding, however, have been shown to have better outcomes. There were fewer infectious complications, better wound healing, and shorter hospital length of stay. Early enteral feeding after bowel surgery has been shown to significantly increase strength of anastomoses.²⁰

Surgery, anesthesia, and blood transfusions suppress immune function and place the patient at risk for infection. Compared with patients fed a standard high-nitrogen formula, patients fed IMPACT® have been shown to have a quicker return of immune function, fewer infections and shorter hospital stay.^{1,2,5,8-14,16-19}

WHO:

Patient types appropriate for the use of IMPACT may include but are not limited to:

- Patients with cancer who undergo extensive surgeries such as head and neck surgery, GI, or colon
- CABG/Cardiovascular surgery
- Major Vascular surgery (AAA)
- GI Resection Surgery required secondary to trauma/MVA/GSW
- Wounds, fistulas, inflammation due to injury
- Surgery to repair fractures, bones and joints

WHAT:

The IMPACT line of formulas can meet all the needs of the enterally fed surgical patient.

- Adequate supplemental arginine for optimal support of immune function and promotion of wound healing.
- Supplemental dietary nucleotides required by all cells, especially cells with rapid turnover including mucosal cells, lymphocytes and macrophages.

- Adequate, but not excessive, levels of omega-6 fatty acids to avoid suppression of immune function.
- A marine source of omega-3 fatty acids (EPA/DHA) for support of immune function.
- Supplemental glutamine for gastrointestinal tract nutrition.
- High protein for tissue synthesis and repair.
- Adequate levels of vitamins and minerals for wound healing, especially vitamins A, C and zinc.

WHEN:

- Feed early – initiate within 24–72 hours of surgery.
- Determine enteral access route.
 - Place jejunal tubes (surgical G-J, surgical J, or NCJ) if abdominal surgery required.
 - Place post-pyloric NJ or PEJ if no abdominal surgery needed.
 - NG tube may be used if enteral feeding monitored closely.
 - Confirm placement of feeding tube prior to initiating feeding.

HOW:

- Start slow with full strength IMPACT at 25-50 ml/hr and advance 10-25 ml/hr as tolerated every 8-24 hours until goal rate or volume desired is achieved.
- Continue feeding for at least 5-7 days. May continue longer until risk for infection has passed and wounds are healing well.
- A minimum goal of 1000 cal/day of IMPACT is recommended.
- Transitioning to a high nitrogen formula such as Isosource® Protein or Novasource GI Control, when patient is no longer at risk for infection.
- When transitioning to oral diet, supplement daily with Oral IMPACT® (1-3 servings/day) if infection remains a concern.

2. Why, Who, When & How to Feed IMPACT

- PULMONARY DISEASE & VENTILATOR DEPENDENT PATIENTS

WHY:

On any given day, there are estimated to be over 11,500 chronic ventilator patients in U.S. hospitals. At a cost of about \$785 per patient day, this totals over \$9 million per day for care of chronic ventilator patients. The incidence of pneumonia is reported to be 25-58% in mechanically ventilated patients. Mechanical ventilation disrupts the lungs' normal physiologic barriers to infection making these patients up to 20 times more likely to develop pneumonia than those not requiring ventilator support.^{20,22}

Meeting nutritional needs and reducing the risk of infection are the primary goals for nutrition support in ventilator-dependent patients. Improved outcome has been observed in patients with pulmonary disease that were either well nourished or receiving nutritional support. Ventilator-dependent patients receiving nutritional support are more likely to be weaned from mechanical ventilation than those receiving no support.²⁰

Research indicates that patients who are septic, infected, or ventilator dependent and at risk for pneumonia benefit from receiving a formula that contains arginine, dietary nucleotides, and fish oil. Those fed these immune-enhancing formulas were weaned from the ventilator 2-3 days earlier than those on standard high nitrogen formulas.^{1,4,15}

WHO:

Patient types appropriate for use of IMPACT® may include but are not limited to:

- Respiratory failure requiring vent and increased risk for infection
- Acute respiratory distress syndrome (ARDS)
- Prolonged ventilation/difficulty weaning

WHAT:

The IMPACT line of formulas can meet the needs of the enterally fed ventilator-dependent, ARDS and COPD patients who are at risk for pneumonia and other infectious complications.

- If the patient is septic, infected, or ventilator-dependent and at risk for pneumonia: utilize enteral formula with all 3 immune-enhancing nutrients (arginine, dietary nucleotides and fish oil).
- Provide appropriate caloric support; avoid overfeeding.

WHEN:

- Provide early enteral feeding to prevent loss of muscles that support lung function—initiate within 24–72 hours of intubation.

- Determine enteral access route.
 - Place jejunal tubes (surgical G-J, surgical J, or NCJ) if abdominal surgery required.
 - Place post-pyloric NJ or PEJ if no abdominal surgery needed.
 - NG tube may be used if enteral feeding monitored closely.
 - Confirm placement of feeding tube prior to initiating feeding.

HOW:

- Start slow with full strength IMPACT at 25-50 ml/hr and advance 10-25ml/hr as tolerated every 8-24 hours until goal rate or volume desired is achieved.
- Continue feeding for at least 5-7 days. May continue longer until risk for infection has passed or the patient is extubated.
- A minimum goal of 1000 cal/day of IMPACT is recommended.
- Transition to calorically dense formula such as Isosource® Energy or Isosource Energy Fibre when patient is no longer at risk for infection.
- When transitioning to oral diet, supplement daily with Oral IMPACT (1-3 servings/day) if infection remains a concern.

2. Why, Who, When & How to Feed IMPACT

SEPTIC PATIENTS/INFECTION

WHY:

More than 500,000 cases of sepsis occur annually in the U.S. with a growing incidence in the number of antibiotic resistant gram-positive infections (ARGPI). The three most commonly infected sites are the respiratory tract, the urinary tract, and the bloodstream. The resurgence of ARGPI's is thought to be a consequence of the widespread use of broad-spectrum antibiotics. These antibiotic-resistant hospital acquired infections are often difficult to eradicate and can be deadly for a critically ill patient.²⁰

Chronic disease, critical illness, and malnutrition increase the risk for sepsis, all which compromise the immune system. The immune system is also suppressed following major surgery, trauma, or medical illness.

The primary goals of nutritional support are to meet increased energy and protein demands of the body and to maintain or improve the patient's host defense mechanisms against infection. Early enteral feeding of critically ill or injured patients reduces the occurrence of infectious complications when compared to parenteral feeding via a central line.

Arginine, dietary nucleotides, and fish oil enhance immune function in critically ill patients and have been shown to prevent additional infectious complications in septic patients. Septic patients fed IMPACT® have been shown to develop fewer infectious complications, are discharged sooner, and have better outcomes than patients fed standard high nitrogen containing formulas.^{3,11,13,23}

WHO:

Patient types appropriate for the use of IMPACT may include but are not limited to:

- Pneumonia
- Bacteremia
- MRSA
- VRE
- Patients with chronic or recurrent infections such as pneumonia or urinary tract infections
- Infected wounds or pressure ulcers

WHAT:

The IMPACT line of formulas are the only enteral formulas shown to help improve outcome in septic patients.

- Adequate supplemental arginine for optimal support of immune function.
- Supplemental dietary nucleotides required by all cells, especially cells with rapid turnover including mucosal cells, lymphocytes and macrophages.
- Adequate, but not excessive, levels of omega-6 fatty acids to avoid suppression of immune function.
- A marine source of omega-3 fatty acids (EPA/DHA) for support of immune function.
- Supplemental glutamine for gastrointestinal tract nutrition.
- Adequate levels of vitamins and minerals.

WHEN:

- Feed early – initiate within 24–72 hours of trauma.
- Determine enteral access route.
 - Place jejunal tubes (surgical G-J, surgical J, or NCJ) if abdominal surgery required.
 - Place post-pyloric NJ or PEJ if no abdominal surgery needed.
 - NG tube may be used if enteral feeding monitored closely.
 - Confirm placement of feeding tube prior to initiating feeding.

HOW:

- Start slow with full strength IMPACT at 25-50 ml/hr and advance 10-25 ml/hr as tolerated every 8-24 hours until goal rate or volume desired is achieved.
- Continue feeding for at least 5-7 days or longer until risk for infection has passed or patient is off antibiotics.
- A minimum goal of 1000 cal/day of IMPACT is recommended.
- Transition to a high nitrogen formula such as Isosource® Protein or Novasource® Energy when patient is no longer at risk for infection.
- When transitioning to oral diet, supplement daily with Oral IMPACT (1-3 servings/day) if infection remains a concern.

2. Why, Who, When & How to Feed IMPACT

- CANCER PATIENTS

WHY:

Many factors contribute to nutritional decline in cancer patients. Tumors may produce substances that suppress appetite; altered metabolism can cause wasting and loss of muscle mass; cancer treatment can produce side effects that result in decreased food intake. For example, fluid and electrolyte imbalance, malabsorption, anorexia, early satiety, impaired chewing and swallowing, nausea, and vomiting commonly lead to malnutrition.²⁰

Any degree of malnutrition affects the immune system adversely, increasing the risk of infection and impairing treatment efficacy and tolerance. Effects of malnutrition can range from weight loss to metabolic disturbances resulting in cachexia.²⁰

Nutritional formulas may be the sole source of nutrition or serve as a meal supplement or replacement for patients unable to consume an adequate oral diet. Enteral nutritional support helps normalize body protein levels, restore immune function, and promote weight gain. For the cachectic patient, the goal of nutritional support is to stabilize nutritional status.²⁰

Adequate nutritional support may improve tolerance to cancer treatment and decrease complications. Numerous studies have demonstrated reduced infectious and wound complications and hospital length of stay in surgical cancer patients fed IMPACT®. (See surgical cancer studies.) Pre-operative supplementation with Oral IMPACT has also been shown to enhance immune function and nutritional status in the surgical cancer patient.¹⁶⁻¹⁸

WHO:

Patient types appropriate for the use of IMPACT may include but are not limited to:

- Head and neck cancer
- GI/colon/pancreatic/hepatobiliary resection
- Appropriate before, during or after chemo or radiation therapy

WHAT:

The IMPACT line of formulas can meet the needs of most cancer patients who require enteral feeding or oral supplementation.

- Adequate calories and protein.

- Adequate levels of vitamins and minerals for wound healing, especially vitamins A, C and zinc.
- A formula containing all 3 immune-enhancing nutrients – arginine, dietary nucleotides and fish oil – as a nutritional adjunct to major surgery.

WHEN:

- Feed early – initiate within 24–72 hours of surgery or nutrition assessment demonstrating inadequate oral intake in patients undergoing aggressive chemo or radiation therapy.
- Determine enteral access route.
 - Place jejunal tubes (surgical G-J, surgical J, or NCJ) if abdominal surgery required.
 - Place post-pyloric NJ or PEJ if no abdominal surgery needed.
 - NG tube may be used if enteral feeding monitored closely.
 - Confirm placement of feeding tube prior to initiating feeding.

HOW:

- Start slow with full strength IMPACT at 25-50 ml/hr and advance 10-25ml/hr as tolerated every 8-24 hours until goal rate or volume desired is achieved.
- Continue feeding for at least 5-7 days. May continue longer until risk for infection has passed, blood counts are improved or surgical wound is healing well.
- A minimum goal of 1000 cal/day of IMPACT is recommended.
- Transition to a high nitrogen formula such as Isosource® Protein or Novasource GI Control when patient is no longer at risk for infection.
 - If patient able to take on oral diet, supplement daily with Oral IMPACT (1-3 servings/day) Consider pre-operative supplementation with Oral IMPACT, especially in malnourished patients who are at greater risk for infection following surgery.

2. Why, Who, When & How to Feed IMPACT

BURN INJURY PATIENTS

WHY:

A major burn injury is the ultimate physiologic and metabolic stress. Age, percent total body surface area (TBSA) burn, and inhalation injury are strong contributing factors to mortality. Although burn care has advanced significantly in the past 50 years, infection continues to be a leading cause of complications and death in hospitalized burn patients.²⁰

Severe burn injury leads to rapid erosion of body mass. As much as 20% of body protein can be lost within two weeks. Early and aggressive nutritional support is essential to minimize the breakdown of body proteins, improve metabolic response, reduce infectious complications, and promote healing. This support is critical to successful therapy and survival.²⁰

Use of total parenteral nutrition has been associated with an increased risk of catheter-related infections. In patients with less than 20% TBSA injury, nutritional needs usually can be met by oral diet alone. For patients with greater than 20% TBSA burn injury, enteral supplementation or total enteral support is often required. Because burn injury results in a high risk for infections and wound complications, use of immune enhancing enteral formulas may reduce risk for secondary infections.²⁰

WHO:

Patient types may include but are not limited to:

- >20% TBSA burn injury
- Infection secondary to burn
- Mechanical ventilation secondary to burn injury
- Skin grafts healing/increased risk for infection

WHAT:

The IMPACT® line of formulas can meet all the needs of the enterally fed burn patients and those who require oral supplementation.

- High caloric intake.
- High protein – 20% to 25% of calories as protein.
- Increased intake of vitamin A, zinc, vitamin C and other water-soluble vitamins for wound healing.

- Source of supplemental arginine, dietary nucleotides and omega-3 fatty acids from fish oil to help support immune function.

WHEN:

- Feed early-initiate within 24-72 hours of burn or admit.
- Determine enteral access route.
 - Place jejunal tubes (surgical G-J, surgical J, or NCJ) if abdominal surgery required.
 - Place post-pyloric NJ or PEJ if no abdominal surgery needed.
 - NG tube may be used if enteral feeding monitored closely.
 - Confirm placement of feeding tube prior to initiating feeding.

HOW:

- Start slow with full strength IMPACT at 25-50 ml/hr and advance 10-25 ml/hr as tolerated every 8-24 hours until goal rate or volume desired is achieved.
- Continue feeding for at least 5-7 days. May continue longer until burns are healing and grafting is complete.
- A minimum goal of 1000 cal/day of IMPACT is recommended.
- Transition to a high nitrogen formula such as Isosource® Protein, Novaosource® Energy when patient is no longer at risk for infection.
- When transitioning to oral diet, supplement daily with Oral IMPACT (1-3 servings/day) if infection remains a concern.

References

1. Beale R et al. Crit Care Med 1999;27:2799-2805, 2. Heys S et al. Ann Surg 1999;229:467-477, 3. Galban C et al. Crit Care Med 2000;28: 643-648, 4. Atkinson S et al. Crit Care Med 1998;26:1164-1172, 5. Braga M et al. Crit Care Med 1998;26:24-30. 6. Weimann A et al. Nutrition 1998;14:165-172. 7. Chendrasekhar A et al. Crit Care Med 1997;25(1S):80, 8. Hasselman M et al. Int Care Med 1997;23(1):S136 9. Kemen et al. Crit Care Med. 1997;25:1489-1496. 10. Schilling et al. Nutrition 1996;12:423-429, 11. Gianotti et al. Arch Surg 1997;132:1222-1230. 12. Daly et al. Ann Surg 1995;221:327-338. 13. Bower, Cerra et al. Crit Care Med 1995;23:436-449. 14. Daly et al. Surgery 1992;112:56-76. 15. Wollschlager C et al. Am Rev Resp Dis 1990;141:334A. 16. Braga et al. Arch Surg 1999;134:428-433. 17. Snyderman et al. Laryngoscope 1999;109:915-921. 18. Senkal et al. Arch Surg 1999;134:1309-1316. 19. Tepaske et al. Presented at European Surgical Infection Society Meeting, Oslo, 6/1997. 20. Role of Nutrition in Disease Management, 1997, Novartis Nutrition 21. Gottschlich et al. JPEN 1990;14:225-235. 22. American Health Care Association 2000, www.ahca.org/brief/bg-sa.htm. 23. National Nosocomial Infections Surveillance (NNIS) System Report, Data Summary from 10/86-4/98 June 1998;CDC: National Center for Infectious Disease, Atlanta, GA.