

A new era for diabetes-specific enteral nutrition policy: A scientific update



Position statement from the
International Special Dietary Foods Industries

ISDI Policy Statement*

ISDI recommends hospital nutrition care that aims to achieve and maintain glycaemic control. To this end, ISDI endorses use of diabetes-specific formulas (DSF), a category of foods for special medical purposes, as a safe, efficacious and cost-effective strategy to support the management of hospitalized patients with or at risk for poor glucose control. This leads to adverse health outcomes, while good control improves patient outcomes and cuts costs of care.

Evidence shows that use of DSF helps manage blood glucose levels, aiding recovery from illness or injury, and reducing health care costs.

**This policy statement is intended to create awareness of the value of DSF. Since DSF products may not be suitable for all hospitalized patients, their recommendation should be made by dietitians and physicians following careful consideration of each patient's medical status and dietary needs.*

Hospital patients are at risk for poor glucose control

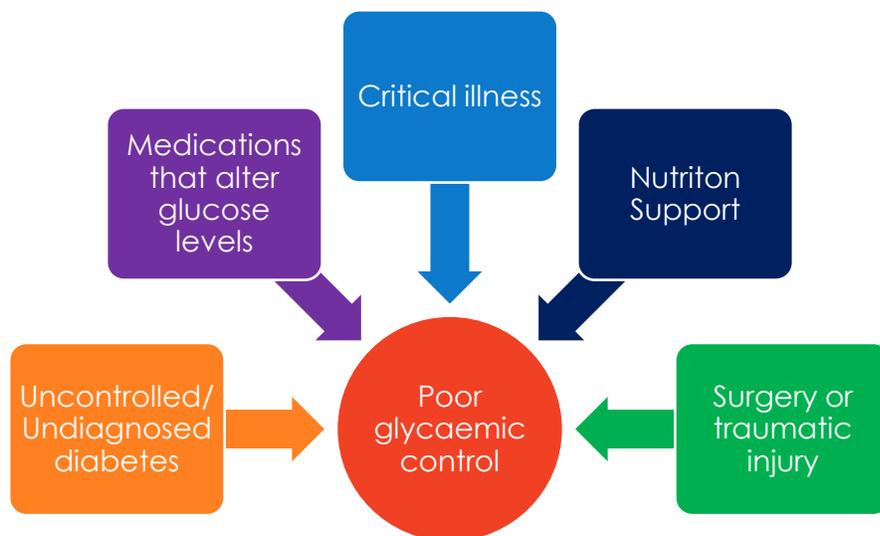
Hospitalized patients are at risk for poor glucose control — blood glucose levels that are too high, too low, or too variable. Abnormal glucose levels occur for a wide range of reasons; contributing factors include the presence of diabetes or pre-diabetes in admitted populations,¹ altered glucose metabolism due to treatment medications,² metabolic stress of critical illness,^{2,3} or stress responses to serious injury or surgery^{4,5} and nutrition support⁶⁻⁸ (Figure 1). While diabetes nutrition guidelines advise how food choices can help achieve normal glucose levels,^{9,10} patients who are hospitalized cannot always follow such diets due to illness or injury.

For hospitalized patients, the evidence on the importance of glycaemic control is clear. Poor control leads to adverse health outcomes, while good control improves patient outcomes and cuts costs of care.

Patients often require an enteral nutrition formula to be administered via a tube to help achieve nutrition goals, if they are not able to meet their nutritional requirements through oral dietary intake alone. In patients with or at risk of hyperglycaemia, initiation of an enteral tube feeding can be challenging, since enteral tube feeding is reported to be an independent risk factor for the onset of hyperglycemia.^{7,8,11-13} Diabetes-specific formulas (DSF) are considered a safe and effective strategy to help maintain glucose control while providing essential nutrition.^{12,14}

The evidence on the importance of glycaemic control for hospitalized patients is clear. Poor control leads to adverse health outcomes, while good control improves patient outcomes and cuts costs of care.¹⁴⁻¹⁸

Figure 1. Factors associated with poor glucose control in hospitalized patients



Diabetes specific formulas improve glucose control and outcomes

According to the 2017 American Diabetes Association standard of care, two key goals for nutrition therapy of hospitalized patients are to 1) Optimize glycaemic control and 2) Provide adequate nutrient to meet metabolic demands.¹⁹ Unlike standard formulas, DSF are designed specifically to help meet these goals. While both formulas are designed to provide nutrients to help meet metabolic nutrition requirements, only DSF are designed to help minimize glycaemic response. DSF have some of the following features in common as a way to provide nutrition with reduced glycaemic load, lower glycaemic index, and a higher proportion of heart-healthy fats in comparison with standard nutritional formulas:

- Lower carbohydrate content
- Higher proportion of carbohydrates that have a low glycaemic index and/or are slowly digestible, e.g. by replacement of high glycaemic-index maltodextrin, starch, and sucrose with low glycaemic-index carbohydrates such as digestion-resistant maltodextrin, isomaltulose, and sucromalt, non-hydrolysed starches among others.
- Fat content enriched in unsaturated fatty acids, particularly monounsaturated fatty acids
- Higher fibre content
- Clinically demonstrated to manage blood sugar levels of people with diabetes

Managing glycaemic response

Elia et al (2005) conducted a systematic review and meta-analysis on the impact of using DSF for nutrition (as oral nutritional supplements or as enteral tube feedings) for inpatients or outpatients with diabetes.²⁰ Compared with standard formulas, DSF significantly reduced the post meal rise in blood glucose, including lower peak glucose concentration and lower glucose area under the curve. Studies within the analysis found reduced requirements for insulin (26-71% lower) and fewer complications with diabetes-specific formulas compared with standard nutritional formulas.²⁰ Elia et al concluded that short- and long-term use of DSF as oral supplements and tube feeds are associated with improved glycaemic control compared with standard formulas.²⁰

Clinical evidence supports the use of diabetes-specific formulas to help:

- Improve glucose levels
- Reduce hypoglycaemia
- Reduce insulin requirements
- Reduced length of stay

A recent systematic review by Ojo and Brooke confirmed and extended the conclusion that DSF were effective for managing glycaemic status of hospitalized patients with diabetes on enteral nutrition tube feeding, as evidenced by improved postprandial glucose levels, HbA1c and insulin responses.²¹ In outpatients with type 2 diabetes, Huhmann et al showed that DSF provides improved glucose stabilization and management compared with a standard formula.²² DeLuis showed reduced glycaemic and insulinemic responses after a DSF, also when compared to a standard formula.²³ In these studies, DSF were found to safely and effectively lower high blood glucose levels without increasing risk of hypoglycaemia.

Reduced glycaemic variability

Glycaemic variability is often used as a marker for glycaemic control in clinical studies. Several recent studies have demonstrated the use of DSF had marked beneficial effects on reducing glycaemic variability compared to those receiving standard formulas.^{17,24,25}

Improved outcomes in acute and critical illness

Additional study reports demonstrate the effectiveness of DSF for blunting hyperglycaemia of stress-related metabolism in patients in acute and critical care

settings. Hamdy et al identified greater clinical benefits associated with DSF over standard formulas. The researchers conducted retrospective analysis of 85,481 inpatients hospitalized over a 10-year period (2000-2009) and demonstrated that DSF reduced hospital length of stay by approximately one day compared to standard formulas.²⁶

Mesejo et al showed improved glycaemic control (lowered insulin requirements, improved glycaemic control and reduced the risk of acquired infections) in critically ill, mechanically ventilated patients in 9 Spanish intensive care units (ICU) when they received diabetes-specific nutrition (compared to those who received standard enteral nutrition tube feeding).¹⁷

Reduced insulin requirements and reduced risk of hypoglycaemia

Several studies have demonstrated the use of DSF reduce insulin requirements as well as incidence of hypoglycemia.^{17,24,27,28} de Azevedo and colleagues showed the use of DSF as part of a carbohydrate restrictive strategy significantly reduced insulin requirements and incidence of hypoglycaemia in critically ill patients.²⁷ Han et al conducted a retrospective analysis of clinical outcomes data collected on patients with type 2 diabetes who were admitted to the ICU between 2009 and 2013 and were provided with DSF or non-diabetes-specific nutrition. Results showed that use of DSF was associated with significantly reduced insulin requirements, decreased mortality, and lower ICU costs.¹⁶

Endorsed by the nutrition expert group

A recently published European Society for Clinical Nutrition and Metabolism (ESPEN) expert group recommendations related to Carbohydrates and insulin resistance in clinical nutrition states.¹²

“Based on this available evidence, the ESPEN expert group endorses the utilization of DSFs for nutritional support of people with obesity and diabetes.”

Poor glycaemic control is common in the hospital and leads to poorer health outcomes

Poor glycaemic control is a common occurrence in hospitalized patients. Patients with diabetes have a 3-fold greater chance of hospitalization than those without diabetes;¹⁴ for people with diabetes, hyperglycaemia is often exacerbated during hospitalization due to illness or injury, its treatment, and changes in eating patterns. Other patients who experience hyperglycaemia in the hospital may not

have a diabetes diagnosis on admission, but the metabolic stress of illness, injury, or anaesthesia and surgery can lead to insulin resistance and hyperglycemia.^{11,29} In fact, reports suggest up to 80% critically ill patients in the hospital experience hyperglycemia.^{30,31} By contrast, the incidence of hypoglycaemia in hospitalized patients

Report suggests that up to 80% of critically ill patients experience hyperglycaemia in the hospital

may seem low (8% of those with diabetes), but this condition is very serious because it markedly increases risk of death.^{32,33}

As evidenced by the following study reports, uncontrolled glucose levels predispose hospitalized patients to adverse clinical outcomes:

- **7-times greater risk of perioperative infection** with hyperglycaemia in orthopaedic surgery patients (vs those with lower glycaemic levels).³⁴
- **Increased hospital length of stay (LOS)** in patients with exacerbations of chronic obstructive pulmonary disease who also had hyperglycaemia; LOS was increased by 10% for each mmol/L increase in mean glucose.³⁵
- **Greater risk for mortality** was reported for patients with penetrating-trauma injuries and hyperglycaemia, i.e., patients who died were 4—8 times more likely to have experienced hyperglycaemia than were those who survived.⁴
- **More than 2-times higher risk of mortality** among hospitalized patients with hypoglycaemia; hypoglycaemia can be spontaneous or can result from insulin treatment.³⁶
- Glycaemic variability in critically ill patients is recognized as a strong **predictor of mortality**.³⁷
- **Longer length of hospital stay, more frequent 28-day readmissions, and higher mortality rates** were all positively associated with hyperglycaemia at hospital admission in acute medical patients.³⁸

Diabetes specific formulas provide cost benefits

Goals of nutrition therapy in healthcare include ensuring patients receive adequate energy intake, thus improving the likelihood of better health outcomes. Recent data also indicate that glycaemia targeted nutrition therapy has the potential to reduce overall healthcare costs. Indeed, several clinical studies using diabetes-specific formulas (DSF) demonstrate reduced length of stay and lower hospital costs.

- Hamdy and colleagues evaluated the impact of diabetes-specific nutrition formula versus standard nutrition for tube-fed diabetic patients hospitalized for acute illness. The study was a 10-year, retrospective analysis of more than 85,000 hospital inpatients. Findings showed that those fed DSF had nearly a 1-day shorter stay in the hospital, and hospital costs were lower by about \$2500 US.²⁶
- Further, when type 2 diabetes patients hospitalized with critical illness in Taiwan were fed diabetes-specific nutrition formula (DSF) versus non-diabetes-specific nutrition formula (non-DSF), total ICU costs were significantly lower in patients fed DSF compared to those given non-DSF feedings (\$6700 US vs \$9200 US). Use of DSF was associated with shorter ICU lengths of stay.¹⁶

Summary statement

The evidence on the importance of DSF to support glycaemic control for hospitalized patients is clear. Poor control leads to adverse health outcomes, while good control improves patient outcomes and cuts costs of care.¹⁴⁻¹⁸ Unlike standard formulas, evidence support the use of diabetes-specific formulas to support glucose management and reduce cost.

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Appendix

What is glycaemic control?

Glycaemic control refers to physiological, nutritional, and medical means of altering blood glucose levels. Normally, the pancreas releases amounts of the hormone insulin that are proportionate with levels of glucose in the blood. In turn, this circulating insulin travels to target tissues (skeletal muscle, adipose, and the liver)

where it binds receptors on the cell surface and initiates signals to control glucose uptake, use, or storage in these cells. When insulin-mediated glucose disposal is well controlled by these normal physiological processes, blood glucose levels are normal, i.e., *euglycemia* is maintained (Table 1). However, many people, especially those who are hospitalized, experience glucose levels that are too high, too low, or too variable.

Conditions of poor glucose control can have serious adverse health consequences, so optimal glycaemic management is key to good healthcare practice.

Table 1. Blood glucose levels and glycaemic status

Terms used to talk about glycemia	Definition
Euglycemia	<p>The prefix <i>eu-</i> means <i>good</i> or <i>true</i>, so <i>euglycemia</i> refers to normal blood glucose levels or normoglycemia.</p> <p>The normal range for fasting blood glucose is 70—100 mg/dL (3.9—5.6 mm/L) or less than 180 mg/dL (10 mmol/L) after a meal. For individuals who are ill or injured, higher target ranges are sometimes recommended to avoid risk for abnormally low blood glucose levels.</p>
Hyperglycaemia	<p><i>Hyper-</i> means <i>over</i> or <i>above</i>; <i>hyperglycaemia</i> describes blood glucose levels that are above normal, as occur in people with untreated or poorly-controlled diabetes mellitus.</p>
Hypoglycaemia	<p><i>Hypo-</i> refers to <i>below</i>, <i>beneath</i>, or <i>under</i>; <i>hypoglycaemia</i>, below-normal blood glucose levels, can occur when insulin or other anti-diabetic medications are given at doses that exceed what is needed for uptake of glucose by target tissues (muscle, adipose, and liver). Less frequently, hypoglycaemia may occur spontaneously.</p>