"TO UNDERSTAND THE PATIENT'S JOURNEY, CURRENT NUTRITIONAL INTERVENTION, NEED STATE AND POTENTIAL OF GROVIVA ADVANCE IN PICU PATIENTS"

Dissertation Submitted to

The IIHMR University, Jaipur

for the partial fulfillment for the award of the degree of Master of Business Administration (MBA)

in

Pharmaceutical Management by

ANJALI PAWAR

Under the Supervision and Guidance of

Mr. Rahul Sharma

Associate Professor

School of Pharmaceutical Management IIHMR University, Jaipur

2023

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DECLARATION BY STUDENT

I hereby declare that this dissertation titled 'To Understand the Patient's Journey, current nutritional intervention, need state, and Potential of Groviva Advance in PICU patients' is the bonafide record of my original research work. I declare that it has not been shared with any other university or institution for the award of any degree or diploma. Information derived from published or unpublished work from others has been duly acknowledged in the text.

Name of the student: **Anjali Pawar**

Date: 26-05-2023

ABSTRACT:

The atmosphere of the pediatric intensive care unit (PICU) presents difficulties for the critically unwell child's enteral nutrition (EN) goals. With the complexity of care given to children who are extremely unwell, nutrition support in the PICU frequently conflicts. For various reasons, a sizable minority of eligible patients do not receive the best enteral nutrition. The stomach route is chosen due to its convenience of administration and lower cost compared to the parenteral route, and the early installation of EN is advised. Underfeeding has been proven to cause hypoglycemia, infections, dehydration, and an elevated risk of mortality in children, which are all symptoms of malnutrition. The length of hospital stays, and PIC stays were dramatically increased in children who were overfed. Large energy imbalances may be caused by both underfeeding and overfeeding PIC patients. An important objective of pediatric critical care is to provide adequate nutrition support therapy through the proper channel while accurately assessing the patient's energy needs to reduce medical costs, lengthen hospital stays, and improve patient prognosis. The following document illustrates the PICU environment, enteral feeding's advantages for PICU patients, and Groviva Advance's potential for PICU patients.

Acknowledgment

I would like to express my sincere gratitude and appreciation to all those who have supported me throughout the completion of this dissertation. Without their assistance, encouragement, and guidance, this accomplishment would not have been possible.

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I would like to express my gratitude to my family and friends for their love, encouragement, and understanding during this challenging journey. Their persistent encouragement, and faith in my competence have served as a constant source of inspiration.

Name of the student: Anjali Pawar

Date: 26-05-2023

TABLE OF CONTENTS

Chapter	Contents	Page no.
Chapter 1	Introduction	9
Chapter 2	Review of Literature	11
Chapter 3	Methodology	12
Chapter 4	Result	27
Chapter 5	Discussion	28
Chapter 6	Conclusion	29
Chapter 7	Reference	30

LIST OF FIGURES

Figure No.	Description	Page no.
3.1	Patient Journey to PICU	13
3.2	Role of the PICU team	15
3.3	Nutritional Interventions	15
3.4	PICU Nutrition algorithm	16
3.5	Classification of nutritional support	17
3.6	Types of feed in EN	18
3.7	EN Vs. PN	20
3.8	Guidelines on nutritional support	21
3.9	Guidelines as per ESPGHAN	21
3.10	Key criteria as per ESPGHAN	22
3.11	PICU Category	22
3.12	Requirements by HCPs	23
3.13	Drivers and barriers for prescribing PNS	23
3.14	Pack shot of Groviva Advance	24
3.15	Product strengths of Groviva Advance	25
3.16	Product Attributes of Groviva Advance	25
3.17	Attributes- Certi 5 Signature Nutrients	25
3.18	Problem-solving statements of Groviva	26

LIST OF TABLES

Table no.	Description	Page no.
2.1	Literature Review	11
3.1	Effects of critical sickness on the children.	14
3.2	Product Benefits	26

ABBREVIATIONS

	List of Abbreviations
EN	Enteral Nutrition
PN	Parenteral Nutrition
PNS	Parenteral Nutrition Supplement
PICU	Pediatric Intensive Care Unit
GI	gastrointestinal tract
ENS	Enteral Nutrition Supplement
WHO	World Health Organization
ETAT	Emergency Triage Assessment and Treatment
ENS	Enteral Nutrition Support
ESPGHAN	European Society for Pediatric Gastroenterology Hepatology and Nutrition
ESPEN	European Society for clinical nutrition and Metabolism
ESPNIC	European Society for Clinical Nutrition and Metabolism
ASPEN	American Society for Parenteral and Enteral Nutrition
SCC	Squamous cell carcinoma
MCT	Medium Chain Triglycerides
HCP	Health Care Personnel
BCAA	Branched Chain Amino Acids

Chapter 1: INTRODUCTION

A key objective of critical care is to provide the best nutrition support possible during critical illness. To achieve this, energy requirements must be carefully assessed, and macronutrients and micronutrients must be given via the most efficient way. Children (from one month to 21 years old) admitted to the PICU may already be malnourished to some extent. [1]

Within the first 24 hours after being admitted, children in hospitals usually pass away. Many of these fatalities might be prevented if sick children were identified quickly after they arrived at the medical facility and appropriate care started straight away.[2]

Children who are very unwell continue to be at risk for both under- and overeating. The PICU environment presents particular difficulties for the critically sick child's dietary goals. Nutritional requirement in the PICU can sometimes dispute with the complex care provided to seriously sick children, including various different procedures that require not taking the meals.

In the PICU, EN or PN is provided. Enteral nutrition administration to terminally sick patients has had a resurgence in popularity. Because of the perceived benefits of EN over PN, enteral nutrition delivery has become the standard technique for feeding terminally sick patients with a GI tract (when the food feed is possible). [1]

Malnutrition results in higher medical costs, longer hospital stays, and less favorable patient prognoses. Up to 40% of hospitalized patients suffer from "disease-related malnutrition," a special kind of undernutrition brought on by a coexisting illness. It is crucial to adopt preventative actions in order to help hospitalized children who are at exposure to malnutrition to match their goal energy levels. Oral meal intake, though, may not always offer the essential nutritional content in cases of acute sickness for a variety of reasons. The causes could be acute illness-related appetite loss, nausea, vomiting, early satiety, and swallowing difficulties. [3]

The most common life-threatening conditions among children in underdeveloped nations are identified using the WHO ETAT standards. Therefore, the following symptoms in children should be handled as extremity:

- Absent breathing,
- severe respiratory distress,
- central cyanosis,
- Shock indications (wea, rapid heartbeat and cold extremities); coma,
- seizures or,

- The most common life-threatening conditions among children in underdeveloped nations are identified using the WHO ETAT standards. Therefore, the following symptoms in children should be handled as emergencies.[2]

In pediatric critical care, the issue of what, when, and how to provide nutrition assistance has taken on a prominent role. The recommended method of nutrient delivery is enteral nutrition (EN), which is largely regarded as an essential part of treatment. It is impossible to predict a child's reaction to a disease, an accident, or both. Age, nutrition status prior to the sickness, and the severity, length, and severity of the disease or injury are some of the elements that contribute to it. Suboptimal nutrition coupled with a severe sickness may contribute to prolonged metabolic dysfunction, exacerbate the response to sickness, and put the child at danger of negative health outcomes, regardless of whether the severity of the sickness causes a nutritional drop/ collapse, or the child presents with a pre-existing malnutrition state. [4]

Groviva Advance is a scientifically proven high protein enteral feed child formula designed to fulfil the nutritional requirement of the severely sick child admitted in PICU where doctors want to shift the child from parenteral to enteral feeding. Groviva Advance is clinically proven for safety and helps in recovery of the children.

Chapter 2: REVIEW OF LITERATURE

Title of the Study	Author's name and Year	Learning
Approach to Enteral Feeding in the PICU	Nilesh M. Mehta, MD, DCH. 2009	In the PICU, nutrition support is provided either parenterally or enterally. Using EN While Critically Ill Has Many Benefits
Monitoring of gastric residual volume during enteral nutrition	Hideto Yasuda etal. 2019	Effects of malnutrition and EN treatment on PICU patients with malnutrition
Consensus Guidelines for Pediatric Intensive Care Units in India, 2020	PRAVEEN KHILNANI. 2020	Levels and Requirements of PICU Care
Paediatric emergency triage, assessment and treatment Care of critically ill children	World Health Organization 2016	Updated PICU treatment guidelines and pharmaceutical treatments.
Enteral Nutrition in the PICU: Current Status and Ongoing Challenges	Ann-Marie Brown. 2014	Whether present at admission or acquired during the PICU stay, malnutrition in the severely sick or injured kid is linked to higher morbidities and mortality in the PICU.

Table 2.1: Literature Review

Chapter 3: METHODOLOGY

Research Question:

- What type of nutrition should be given to PICU patients?
- When to give?
- How to provide nutritional support?
- What will be clinical outcomes?
- Key market drivers?
- Key market opportunities?
- Key market challenges?

Research Objective:

- To understand patient's journey in PICU stay
- To understand market opportunity
- To know outcomes and potential of Groviva Advance
- To understand Groviva in Lactose intolerance market.
- To know about Post-marketing Surveillance of Groviva advance

Study Area: PICU and its market analysis

Study Design: Observational study

Study Tool: Review articles, Research articles, Clinical studies, and Statistics.

Study Duration: 70 Days

Analysis: Understanding nutritional interventions in PICU and placement of Groviva advance in PICU Market.

Patient Journey

A child suffers from an accident/ trauma or medical emergency or requires surgery.

-Child is provided with oxygen support and canula to start fluids.

-Child is assessed for vitals (BP, HR, etc.)

-Medications, if required

Admitted to the hospital or brought to an emergen

When child is ready

Undergoes surgery or treatment for trauma.

Shifted/ admitted to PICU.

Intense monitoring

Assessment and initiation of nutrition

If patient is stable

Shifted to the ward for less intense monitoring for follow-up care.

Child Recovers

Released goes back home.

Figure 3.1: Patient Journey to PICU *(Source: Signutra USA)*

✓ **First Objective Met**

PICU:

Pediatric Intensive Care Unit is referred to as PICU. Children who are ill receive the best possible medical care in PICU. It makes it possible to provide skilled nursing care as well as ongoing monitoring of things like blood pressure, breathing, and heart rate. Additionally, it enables medical workers to administer more intense treatments like ventilators (breathing machines) and specific medications that are only safe to administer when closely monitored by a doctor. [5]

A child is admitted to PICU, if:

- Respiratory Issues
- Injury or trauma
- Metabolic disorders
- Congenital malformation
- GI Conditions
- Cancer/ Chemotherapy
- Organ Transplantation
- Poisoning. [6]

Impact of Critical Illness on the Children.

Impact	Challenges	Need
Physiologic stress response	The child is under the catabolic phase	greater calorie requirements
Nitrogen losses in the urine	Endogenous protein wastage	Huge quantity of protein
The child is suffering from pain, anxiety, fever	Unable to fulfill their nutritional requirements	Faster recovery
Compromised GI Tract		Ease of administration

Table 3.1: Impact of critical illness on the children. [7]

(Source of table: https://www.researchgate.net/publication/290446662_Nutrition_in_PICU)

PICU Team:

- Doctors
- Consultants or pediatric intensivists, PICU Coordinator
- Nurses
- Dietician

Role of PICU Team:

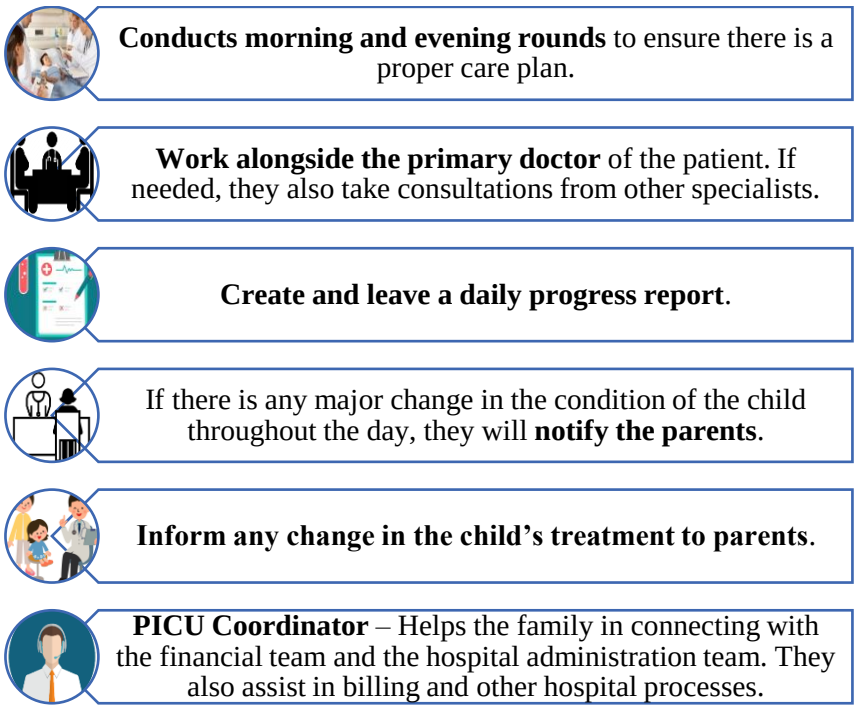


Figure 3.2: Role of PICU Team *(Source: Signutra USA)*

Factors Determining nutritional intervention.

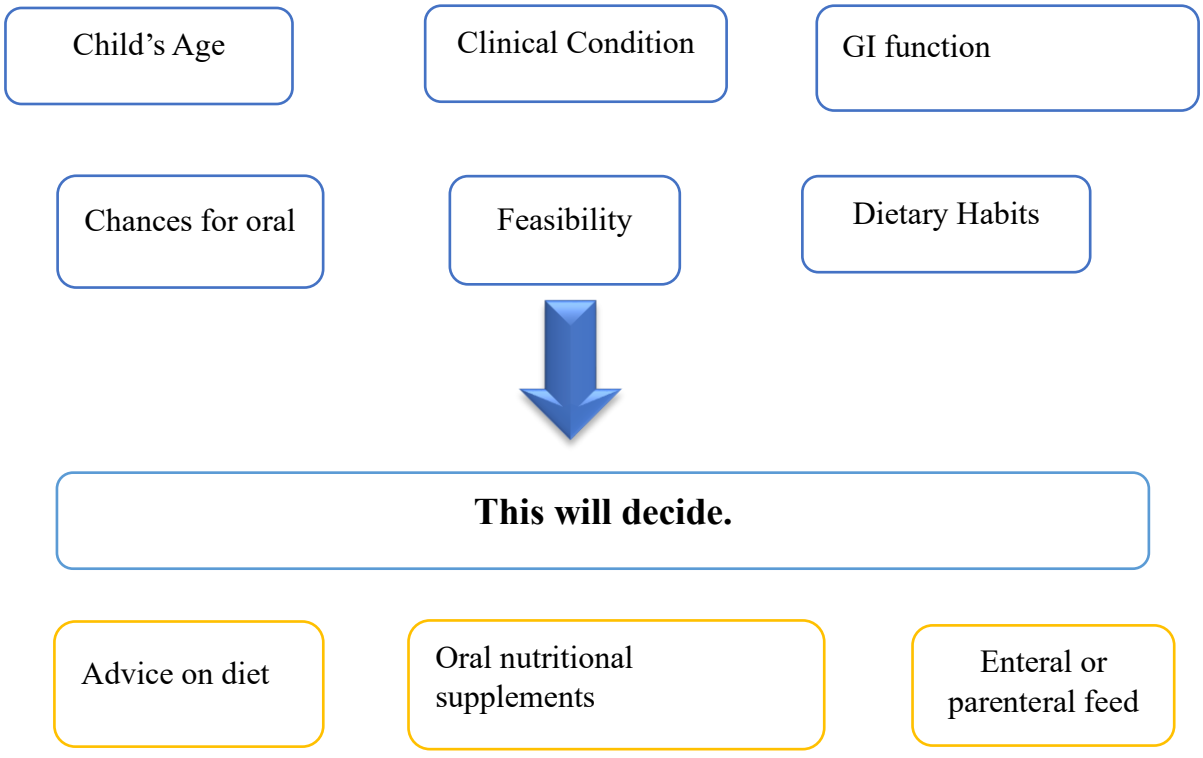


Figure 3.3: Nutritional Interventions. 8 *(Source: Signutra USA)*

Understanding Treatment Algorithm and nutritional intervention:

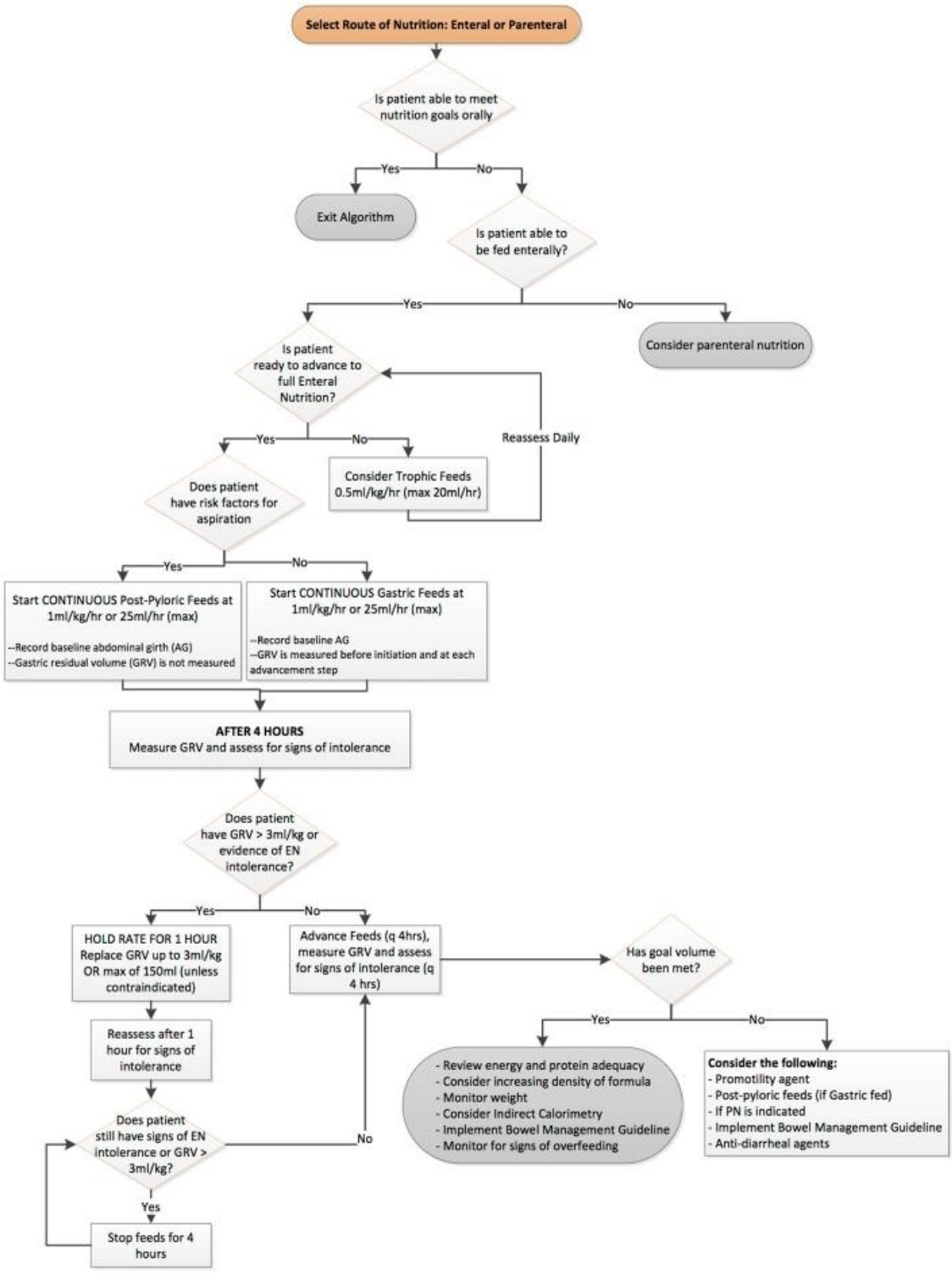


Figure 3.4: PICU Nutrition algorithm. [9]

(Source of figure: pubmed.ncbi.nlm.nih.gov/25045848/)

Importance of Nutrition in PICU:

Issues with Poor Nutrition

Malnutrition, critical disease, and inadequate nutrition result in:

- Prolonged need for ventilator
- Longer stay at PICU.
- Greater propensity for nosocomial infections
- A rise in mortality

Why do Children Admitted to PICU Face Poor Nutrition?

- Difficulty in estimating nutritional needs of the individual children.
- GI Intolerance
- Fluid intake restriction
- Delay in initiation of EN
- Interruptions in EN to give medication or carry out sedation-needed procedures.
- Lack of routine nutritional assessment and monitoring

Nutritional Support- Classification

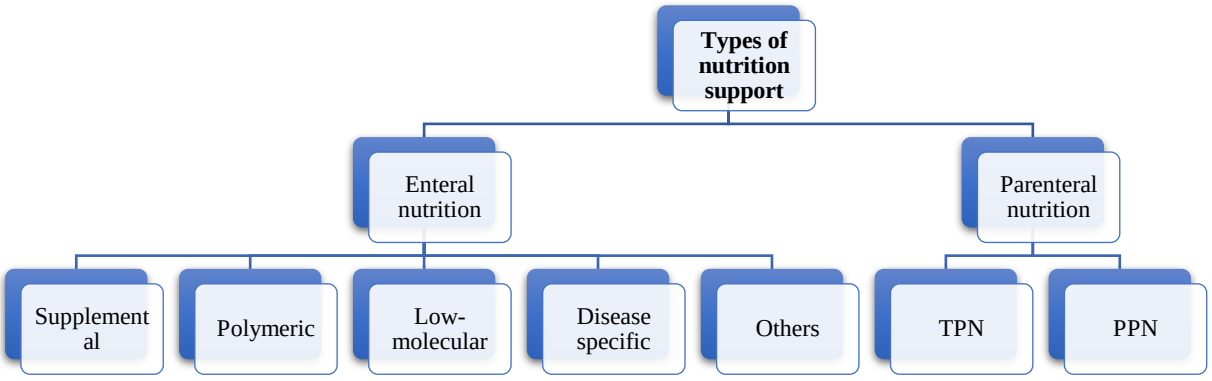


Figure 3.5: Classification of nutritional support. [8]

(Source of figure: https://pubmed.ncbi.nlm.nih.gov/20453670/)

Understanding Enteral and Parenteral Nutrition:

Traditionally, ENS has been interpreted as the administration of food postpylorically or into the stomach via a tube as opposed to the oesophagus.

Recent ESPEN recommendations state that regardless of the method of distribution, EN covers the use of dietary items for specific medical objectives.

Indications of Enteral Nutrition Support:

In a patient whose gut is not fully functional on its own, normal meal intake cannot satisfy energy and nutrient needs. The various conditions can be classified as: -

- Insufficient oral intake
- digestion and absorption issues
- Gastrointestinal motility issues
- nutritional needs and losses increasing.
- Failure to grow or ongoing malnutrition.
- Crohn disease.
- Metabolic diseases. [8]
- **Types of feed:**

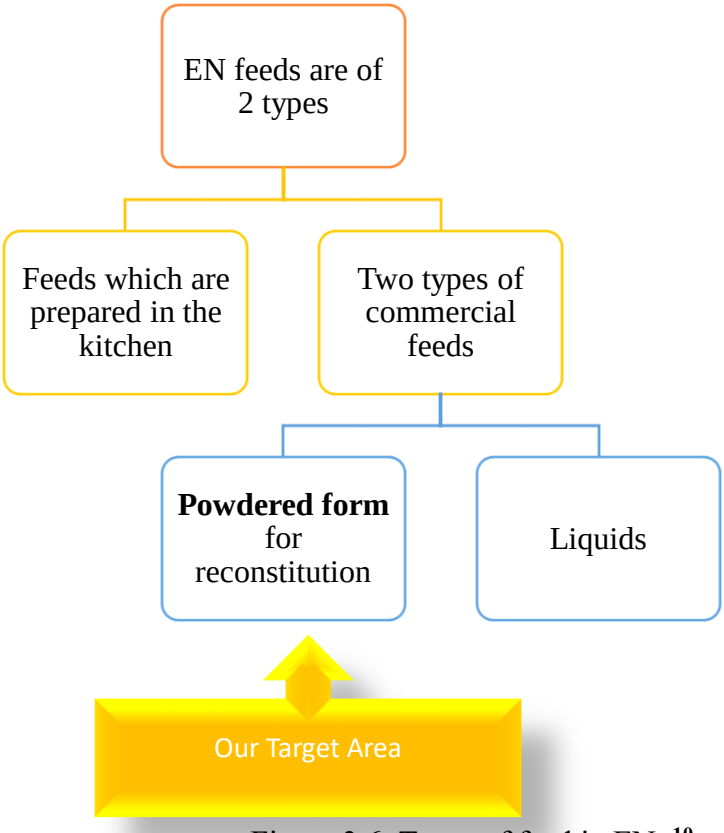


Figure 3.6: Types of feed in EN. [10]

(Source: https://pubmed.ncbi.nlm.nih.gov/33024380/)

Type of enteral nutrition formula based on nutrient profile:

- **Supplement feeds:** can be given in addition to regular food to boost the supply of nutrients and energy when necessary. Protein, energy, and other carefully chosen nutrients are concentrated in supplements.
- **Polymeric feeds**: serve formulations for oral & tube feeding as well, are frequently created with protein obtained via cow's milk, and are sufficient for the majority of patients. 1-2 kcal/mL, with or without fiber, is provided. Patients must be able to absorb whole macronutrients.
- **Low-molecular-weight formula:** which are derived from hydrolysates of the proteins and based on AA. They are recommended for patients with polymeric food intolerance. Tube delivery is the norm. Give 1.1 to 1.5 kcal/mL.
- **Disease-specific formulations** can be custom-made for some disorders using a range of parts and commercially available modules in hospital kitchens or at home, or they may be readily available. differ in terms of their protein, carbohydrate, fat, vitamin, and mineral composition.

What is PNS?

- Parenteral nutrition, also referred to as IV feeding, is a method for delivering nutrients to the body via veins.
- Parenteral feeding is given through tubing connected to a needle or catheter and comes from a bag holding the nutrients.

Enteral Nutrition Vs. Parenteral Nutrition

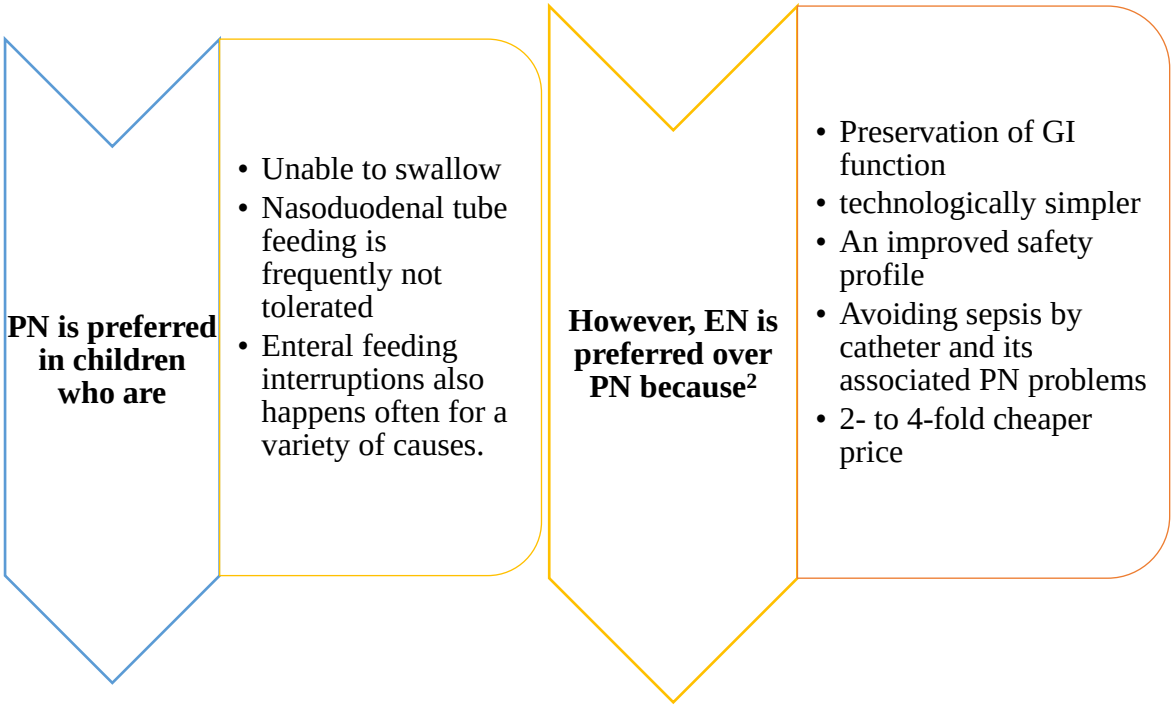
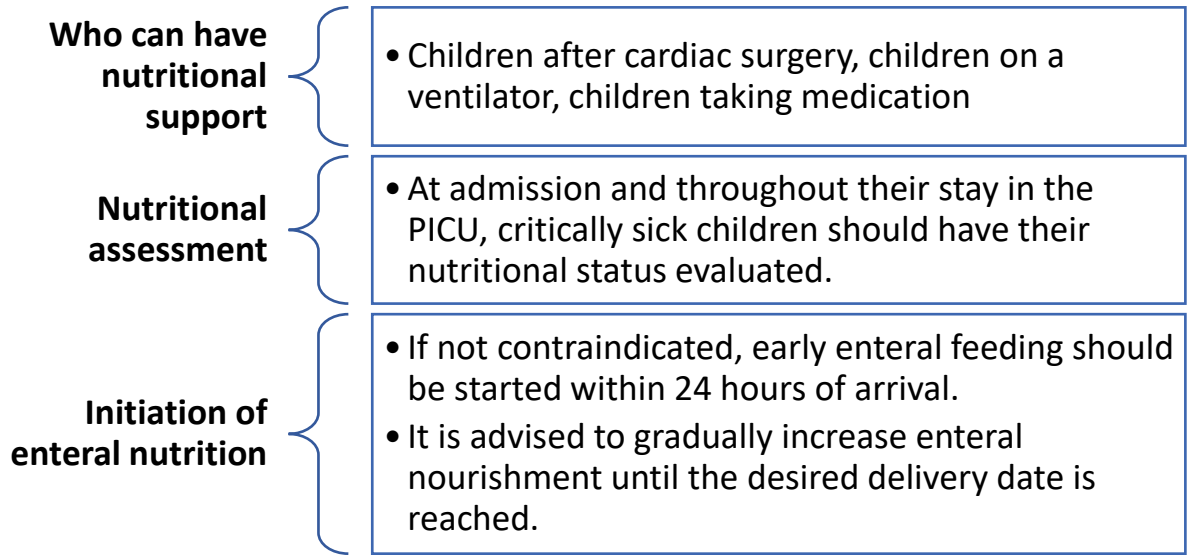


Figure: 3.7: EN vs. PN. [11]

(Source: https://pubmed.ncbi.nlm.nih.gov/31212639/)

Guidelines on Nutritional Support:



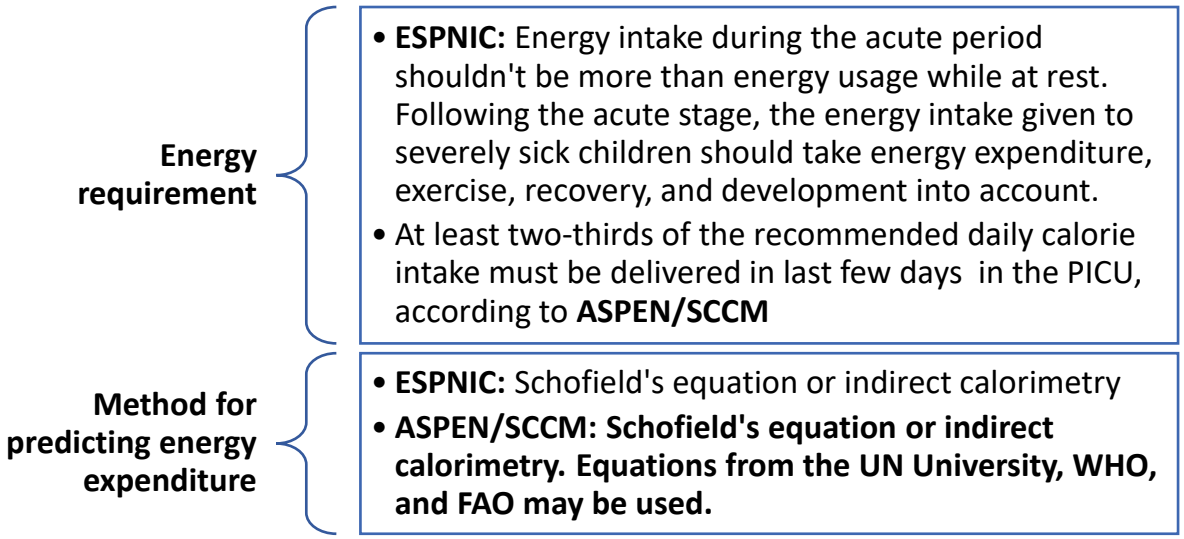


Figure 3.8: Guidelines on nutritional support. [12]

(Source: https://pubmed.ncbi.nlm.nih.gov/32077997/)

Guidelines for Enteral Formula (as per ESPGHAN)

Should provide a well-balanced combination of all the necessary nutrients
Only source of nutrition
Should majorly provide all of the people's recommended intakes for healthy people in the appropriate age range.
Delivered intravenously but can also be ingested
Adapted for age.
A 1 kcal/mL energy density. Children with higher energy needs can benefit from foods which have higher density.

Figure 3.9: Guidelines as per ESPGHAN. [8]

(Source of figure: https://pubmed.ncbi.nlm.nih.gov/20453670/)

Key Criteria for Enteral Formula (as per ESPGHAN)

Most of the formulations should loncatin no lactose or a very small amount lactose in it, and they are all gluten free
It is preferred to have isoosmolality (300–350 mOsm/kg).
Dietary fibre is suitable for the majority of patients.
High-fat foods that contain more than 40% of their energy as lipids and, as a result, have lower glycaemic loading are advantageous for those with stress metabolism.
Patients with severe forms of conditions with the absorption as well as digestion of fats may benefit from MCT oils
Some long-chain omega-3 PUFA may have immune-modulating and anti-inflammatory properties.

Figure 3.10: Key Criteria as per ESPGHAN. [8]

(Source of figure: https://pubmed.ncbi.nlm.nih.gov/20453670/)

Understanding Category:

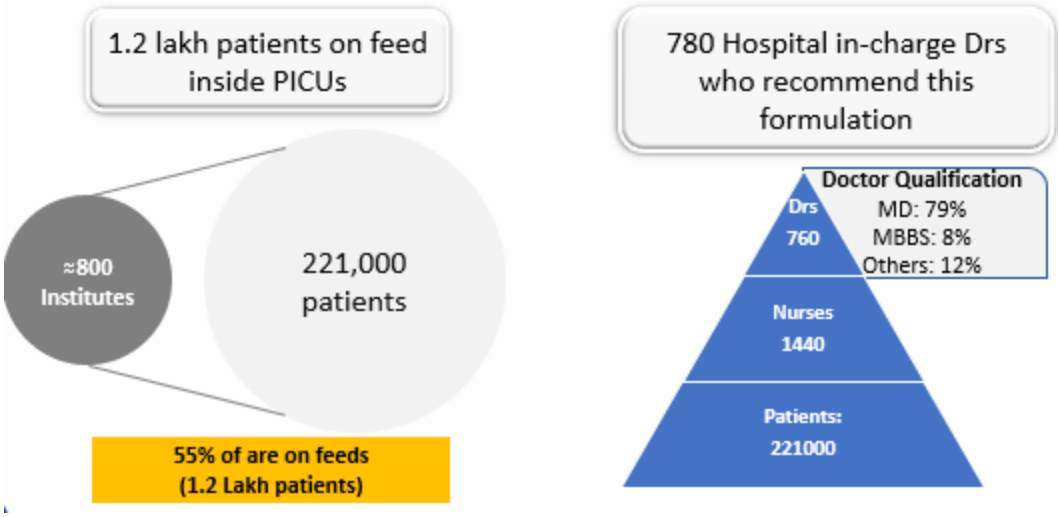


Figure 3.11: PICU Category. *(Source: Signutra USA)*

✓ **Second Objective Met**

Market Overview:

The total PICU market is estimated to be 69 Crs. Growing by 10%.

What do HCP's look for?

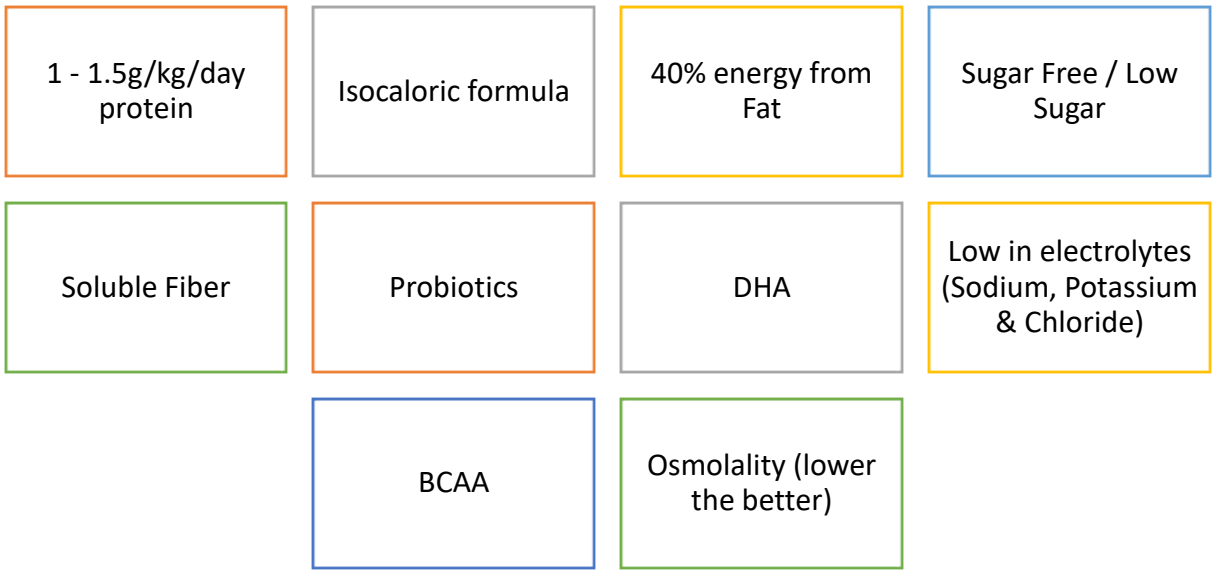


Figure 3.12: Requirements by HCPs *(Source: Signutra USA)*

Drivers and Barriers for HCP for using PNS.

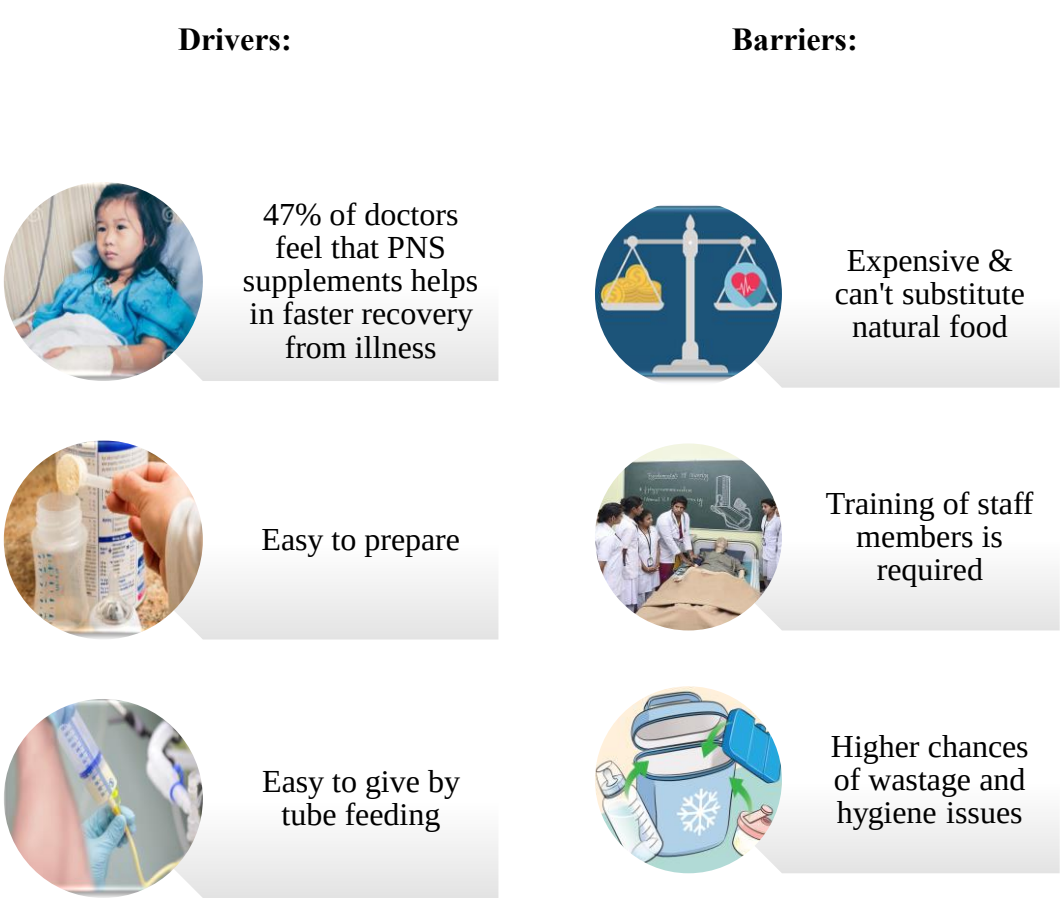


Figure 3.13: Drivers and Barriers for Prescribing PNS. *(Source: Signutra USA)*

Need, State and Potential Of Groviva Advance in PICU Patients:

Groviva Advance is a specialized high protein isocaloric enteral feed to be given through tube feeding or orally; to fulfil the nutritional requirement of critically ill children of 2 to 12 years of age admitted in pediatric ICUs for their faster recovery owing to

- Isocaloric formula
- Rich protein content
- High on energy
- Easy digestibility and absorption
- Support growth and immunity

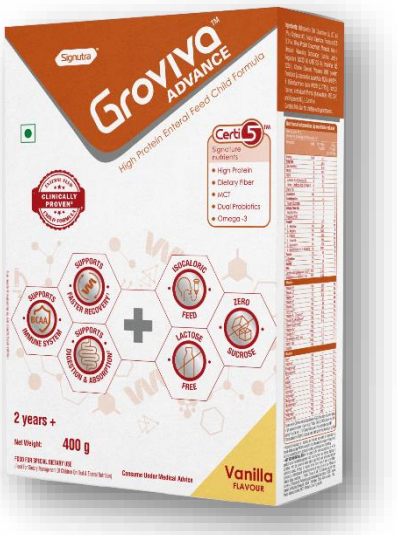


Figure 3.14: Pack shot of Groviva Advance

(Source: Signutra USA)

✓ **Third Objective Met**

Clinical Study of Groviva Advance:

The published study was titled, "Pilot Clinical Study to evaluate the safety and gastrointestinal tolerance of Groviva Advance in Hospitalized children requiring Isocaloric formula for enteral tube feeding."

The study was conducted at KIMS Hospital, Hyderabad with 31 subjects.

Outcome:

- Clinically proven efficacy
- well tolerated.
- No serious adverse events
- No episodes of recurrent diarrhea.

Product Strength:

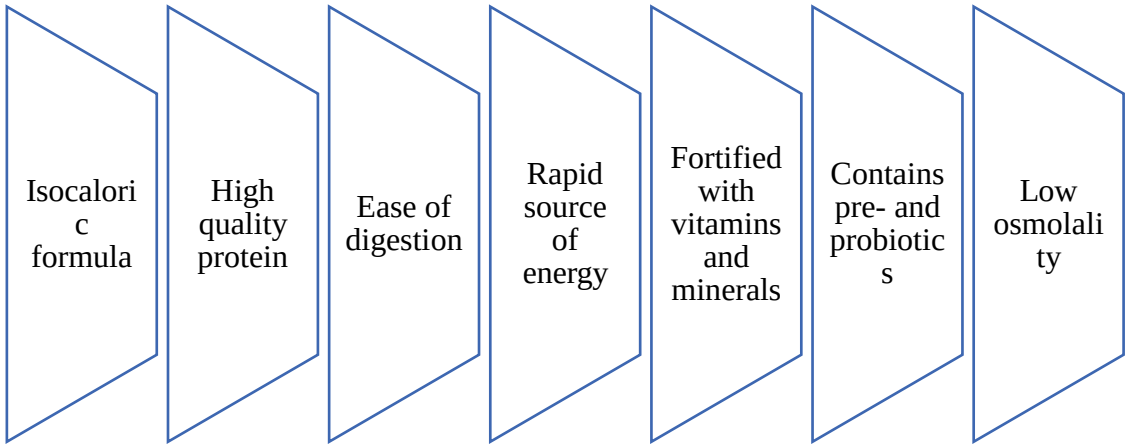


Figure 3.15: Product Strengths of Groviva Advance. *(Source: Signutra USA)*

Product Attribute:

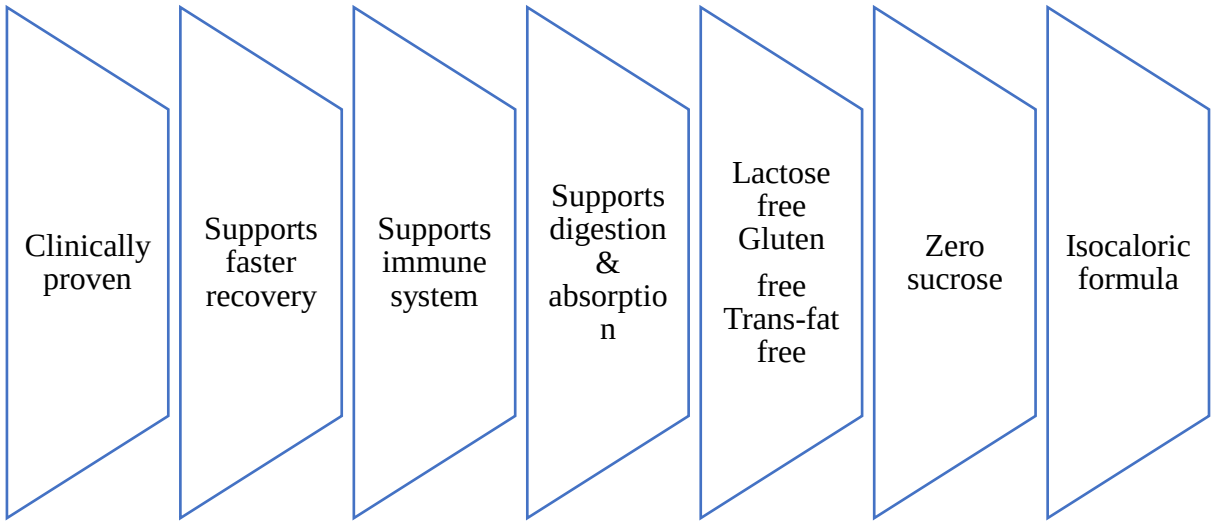


Figure 3.16: Product Attributes of Groviva Advance. *(Source: Signutra USA)*

Product Attribute- Certi5 Signature Nutrients:

Figure 3.17: Product Attributes – Certi 5 Signature Nutrients. *(Source: Signutra USA)*

Product Benefits:

High Protein	High-quality Protein helps improve lean body mass and is essential for muscle growth
Dietary Fiber	supports nutrient digestion and absorption
MCT	Medium-chain triglyceride oil is rapidly digested and absorbed and are a rapid source of energy.
Dual Probiotics	Probiotics (Lactobacillus acidophilus NCFM and Bifidobacterium lactis HN019) help maintain normal bowel function.
Omega- 3	These have higher anti-inflammatory properties, and supplementing with them can aid pediatric patients' recuperation.

Table 3.2: Product Benefits. *(Source: Signutra USA)*

What problem are we trying to solve?

For PICU

- Groviva Advance offers solution to the nutrition related challenges in children where doctor wants to initiate enteral feed
- Offers ease of reconstitution as dosage has to be accurate and nursing staff are not competent enough
- Isocaloric and right osmolality
- Supports faster recovery
- Takes care of gut microflora as it contains probiotics and prebiotics. Also, Easy to digest preteins enhances digestion and absorption
- Sugar free – beneficial for diabetic patients

For Lactose intolerance

- Takes care of lactose intolerance while fulfilling nutritional requirement of the children

✓ **Fourth objective met**

Figure 3.18: Problem-solving Statement of Groviva Advance. *(Source: Signutra USA)*

Chapter 4: RESULT

As the PICU patients requires lot of care and nutrition, so that appropriate nutrition should be taken into consideration while prescribing PN or EN. The choice always depends on the HCP's and their trust towards these supplements. As now-a-days HCPs are focusing more on EN for overall nutrition of the children, the EN should provide with the specific requirements as per ESPGHAN and should meet the RDA requirements as per the guidelines of ESPGHAN, ICMR, WHO ETAT.

So, PICU patients requiring EN should comply according to the age group, BMI of the children. The dosage should always be consistent and appropriate so as to avoid further problems. The dosage should always be as per the age group. If the child is undernourished or malnourished the dosage are set as per the doctor or dietician/consultant.

Groviva Advance also takes into account the goodness of high-quality protein, DHA, osmolarity, role of probiotics and goodness of MCT oils present in it. The fundamentals of Groviva Advance are Advance, Acquire. Achieve i.e., Advancing outcomes, Accelerating Delivery. As per the clinical study of Groviva Advance, it has clinically proven efficacy & safety in Indian patients, it is well tolerated with no serious adverse events and there are no episodes of recurrent diarrhea. It overcomes the limitations of kitchen feeds such as feed easily passes through a tube, is easy to administer, and easy to prepare. So, Groviva Advance is best suitable EN for PICU patients.

Chapter 5: DISCUSSION

As the nutritional requirements as well as food/ nutritional intakes are lower in patients who are severely ill and malnourished can cause a life-threatening condition to them. So, admission of those severely sick patients should be done immediately with PICU and those PICU protocols should be followed for better healthcare outcomes. The guidelines given by ESPGHAN is followed by every PICU hospitals for administration of the enteral feed to the severely ill children. These guidelines provide patients with utmost care and better health. Both the children undernourished and over nourished are at major risk of acquiring hospital acquired infections such as nosocomial infections, so enteral feeds can also help in preventing these types of infections.

In this study of the PICU environment, market, and nutritional interventions, the implications can be made that PICU is a major and growing segment owing to the big share in the market. So, Enteral feeding plays a major role in PICU as compared to parenteral feed due to more patient compliance, lesser side effects, and more benefits. So, HCPs are focusing more on the enteral feed as compared to parenteral ones which does not provide proper and adequate nutrition to the patient.

More Enteral feeds with different formula with all the guidelines should be introduced to increase the patient compliance. Osmolarity plays a major role when it comes to the enteral feed. Inappropriate osmolarity can lead to major hurdle and problems. So, the osmolarity is the major component to be looked at when going towards ENS.

So, the adaptation towards EN will provide consumers with the right nutrition as well as the right treatment.

Groviva Advance comes with the fundamentals of Osmolarity, highest protein, probiotics as well as DHA, which supports for overall recovery and better health outcomes of severely sick patients.

All of the objectives were met in this study- understanding of patient journey, market opportunity in PICU, Outcomes and potential of Groviva Advance in PICU patients, Monitoring Groviva Advance in lactose intolerance market. One objective which is not met is post-marketing surveillance of Groviva advance. This objective is not met because the product will be launched in next month into the market.

Chapter 6: CONCLUSION:

Malnourished and critically unwell children are more likely to experience serious infections and need a longer stay in the PICU. So, the focus of the dissertation was to determine the patient pool in the PICU and current interventions, and the future implications for the patients at the PICU. Groviva Advance is Pediatric Nutrition Supplement that is given in the enteral feed to the patients in the PICU and it is a clinically tested product with the best compliance, osmolarity, and high protein. So, more interventions can be made for the PICU patient pool so as to establish a better healthcare environment.

Chapter 7: REFERENCE:

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