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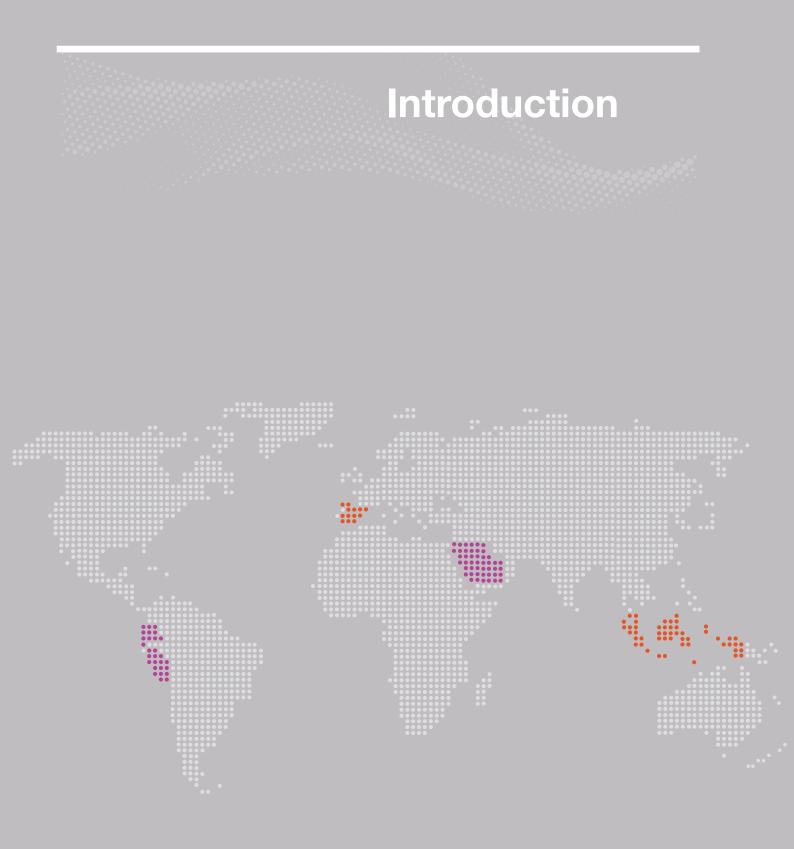
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Food is the key to health today and also tomorrow

The first years of life and especially the first two, constitute a window of opportunities to positively influence the immediate and future health of the human being, through an adequate and optimal diet. Nutrition in the first stage of life should have the objective of promoting health, and this allows an impact on the prevention of disorders and diseases in the short and long term.

Nowadays, we know that through diet, we can influence aspects as important as the development of the immune system, cognitive development or growth rate and the prevention of the main chronic diseases that children will face in the adult life (obesity and metabolic syndrome, cardiovascular disease, diabetes, allergies, neurodevelopmental disorders).

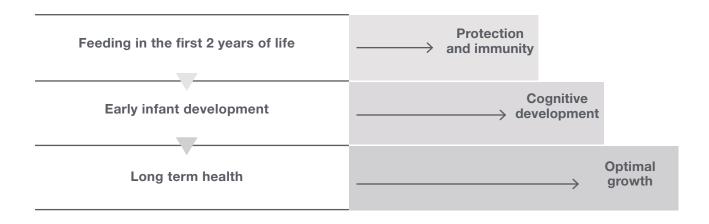
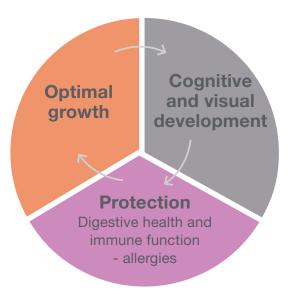
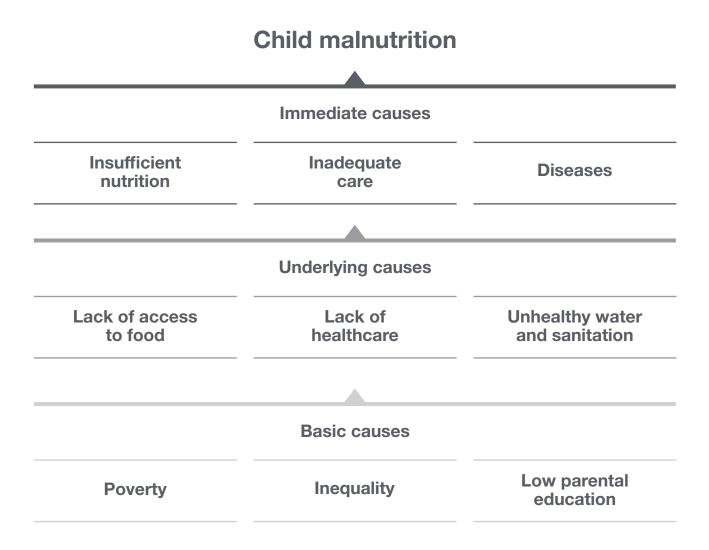


Figure: Health programming.

A correct and sufficient diet allows adequate growth and development (weight, height and body composition), and essential nutrients also contribute to cognitive and visual development as well as the maturation of the immune system, among others.



When the minimum requirements of energy and nutrients are not covered in the child, this leads to a situation of malnutrition generated by desnutrition. This fact may be due to one or more circumstances:



The causes that can lead to malnutrition are multifactorial and can present as macronutrient malnutrition, which is easily identifiable since it is quickly reflected in the evolution of anthropometric parameters, and the so-called hidden malnutrition is also very relevant. This derives from the deficit of micronutrients, which although it is more complex to identify, also has relevant repercussions on the child, as is the case of the deficiency of iron, DHA, iodine or vitamin D, whose deficit intakes are widespread not only in the countries with medium/low socioeconomic levels, but also in a large part of the developed countries.

Objective and structure

Laboratorios Ordesa has developed this monograph with the aim of deepening the study of the nutritional status of children of pediatric age from different social models and geographical locations.

The information presented in this document comes from the contribution of health professionals from five different regions of the world, who convey the current reality regarding pediatric malnutrition in their territory as well as their experience in managing this problem in pediatric consultation.

The document is divided into five chapters that belong to each of the participating countries: **Saudi Arabia, Ecuador, Spain, Indonesia and Peru**, and each chapter is subdivided into two sections:

1. Prevalence of malnutrition in the pediatric population

2. Use of pediatric nutritional supplements

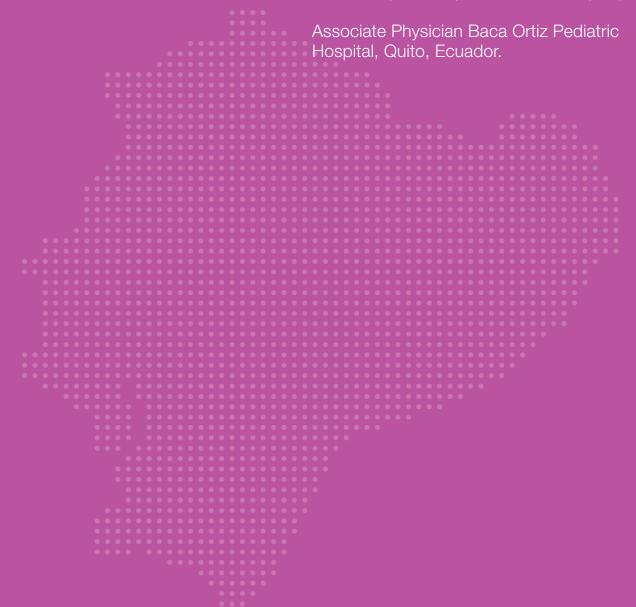
Due to the different realities in each country we can see very varied situations: in the set of the two sections, on the one hand, the current child nutritional situation and the trend in recent years are developed and deepened, and on the other hand, the different management, interventions and effective strategies that are being carried out in each of these countries. These actions are aimed at reducing child malnutrition and boosting the promotion of a complete and balanced diet. Finally, the use of nutritional supplements will also be reviewed as a measure to treat cases of malnutrition or to prevent it in cases of children with nutritional risk.

1

Ecuador

Dr Angelita Cabrera Aguilar

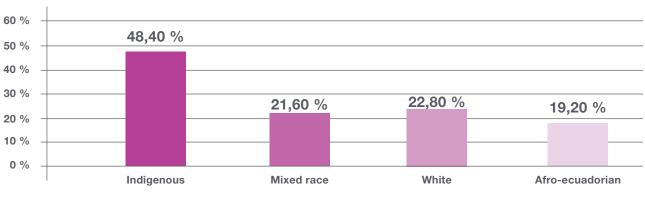
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1.1. Prevalence of malnutrition in the paediatric population in Ecuador

The educational level of the family, eating habits, ethnic factors, socioeconomic level, access to health services, and social inequity are the main factors that condition malnutrition, as they limit access to food in quantity and quality.

The indigenous group has the highest proportion of chronic malnutrition in children under 5 years of age, approximately half of their population^{1,2}.

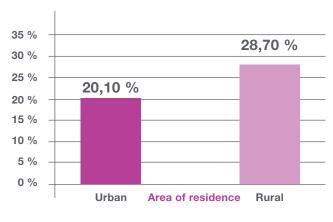


Chronic malnutrition by ethnic group

Figure 1.- Chronic malnutrition in Ecuador in children by ethnic group. Source: National Institute of Statistics and Censuses (INEC).

A study conducted in Ecuador in children aged 0-5 years showed that 25.3% had chronic malnutrition, 6.4% global malnutrition, and 2.4% acute malnutrition. Variables such as age, male sex, indigenous ethnicity, breastfeeding (in those under 6 months of age), prenatal controls, weight under 2500 g, birth order, maternal education, economic status of the family, source of drinking water, and area of residence were found to be associated with the probability of suffering chronic malnutrition³.

Children in rural settings are more likely to have chronic malnutrition or severe chronic malnutrition than those living in urban areas^{4,5}. There is a direct relationship between poverty and chronic malnutrition, which remains present to a greater extent in rural areas of Ecuador.



Chronic malnutrition by area of residence

Figure 2.- Chronic malnutrition in children by area of residence. Source: National Institute of Statistics and Censuses (INEC).

Chronic malnutrition in children under 5 years of age

Regions of Ecuador have very different rates of malnutrition. The national chronic malnutrition rate in children under 5 years of age was 23.0% in 2018^{6,7}. The region in Ecuador with the highest prevalence of chronic malnutrition in children under 5 years of age is the Amazon region⁸.

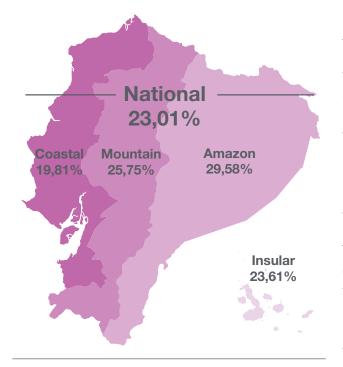


Figure 3.- Chronic malnutrition in young children under 5 years of age in Ecuador by region **Source:** National Institute of Statistics and Censuses (INEC).

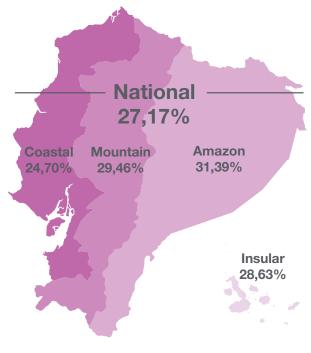
Chronic malnutrition in children under 2 years of age

The national chronic malnutrition in children under 2 years of age was 27.27% in 2018⁷ and was higher in the Amazon region, followed by the mountain areas, while the coastal region had the lowest prevalence.

Figure 4.- Chronic malnutrition in Ecuador by region in children under 2 years of age. Source: National Institute of Statistics and Censuses (INEC).

An additional conditioning factor to be analysed is the difference between the Andean region and the rest of the country. The Andean region (indigenous population) has up to 10% more malnutrition, and an important factor contributing to this would be diet, because diet in these areas is rich in carbohydrates, but with a low content in protein and micronutrients, vitamins and minerals⁹, prevalence of chronic malnutrition increases with the age of the child ^{5,10,11}.

Twenty-eight percent of children under two years of age suffer from this problem, evidenced by their low weight and height. The latest National Health and Nutrition Survey from the National Institute of Statistics and Censuses (INEC) shows that the chronic malnutrition rate in children under two years of age increased in Ecuador from 21.2% in 2004 to 27.2% in 2018.



Institutional support

Institutional support against malnutrition in Ecuador is mainly based on the strategies proposed by the Ministry of Public Health (MSP) to reduce the rates of pediatric malnutrition, as the latest surveys report that a quarter of children under 2 years of age, mainly indigenous children and those living in rural areas (INEC), had chronic malnutrition¹². The MSP of Ecuador, with the support of the **World Health Organization (WHO)**, has chosen to¹³ designate a number of resources to achieve a reduction in chronic malnutrition levels in children in the past 10 years, but the results have not been very satisfactory: although the prevalence of chronic malnutrition in children under 5 years of age has decreased, this reduction has not been maintained over time¹². The programs implemented include:

- Integrated Micronutrient Program: This tends to decrease maternal and infant nutritional anemia and vitamin A deficiency in children aged 6-36 months.
- **Nutritional Food Education Program:** Talks and workshops to guide the community, especially mothers of children under 5 years of age, to acquire healthy eating habits through ongoing education¹³.
- **Nutritional Food Surveillance System Program:** Assesses the nutritional status of vulnerable groups (children under 5 years of age) attending the Operational Units of the Ministry of Health.
- Food and Nutrition Program (Supplementary Feeding Program): This program aims at reducing the total prevalence of height delay (in children under 5 years of age) and decreasing the prevalence of chronic malnutrition in rural and urban areas¹².

Current healthcare policy

A nutrition and feeding program was created in 2013 to ensure a natural, nutritious, healthy diet with local products to reduce nutritional deficiencies³.

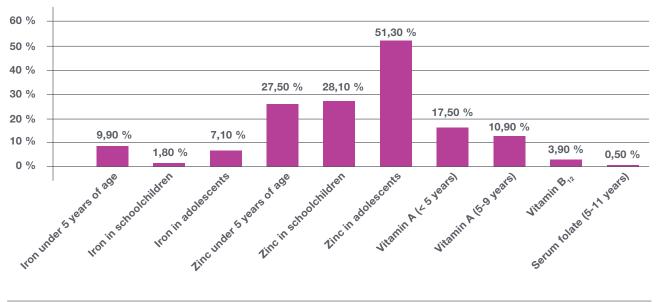
The aim was to improve the quality of life of the population and to eradicate chronic malnutrition, using as baseline the 2012 National Health and Nutrition Survey (ENSANUT), the main results of which showed that 25.3% of children under 5 years of age in Ecuador had chronic malnutrition. It is therefore imperative to have up-to-date information¹⁴. The age range is associated to the window of the 1,000 first days that are critical for life, since the basic development of children occurs at this stage, and it is considered that adequate height cannot be recovered in children after this period³.

1.2. Use of nutritional formulas or food supplements/ supports in Ecuador

Pediatric nutritional supplements

Nutritional supplements are food products intended to complement dietary intake by incorporating nutrients into the diet at concentrations that do not generate therapeutic indications or are applied to pathological conditions¹⁵. Special attention should be paid to the pediatric population with malnutrition or nutritional and growth problems derived from inadequate intake or secondary conditions.

Distribution of nutritional supplements to populations at greater risk is a complex task, but implementation of supplementation programs has been shown to have a significant impact on the improvement of the physical and intellectual capacities of children¹⁶, especially in those aged 1-10 years who do not have an adequate nutritional status and in which the need for energy and nutrient intake is higher due to a greater demand.



Micronutrient deficiencies in Ecuador Prevalence

Figure 5.- Micronutrient deficiency in Ecuador. Source: National Institute of Statistics and Censuses (INEC).

Under which criteria is use of NS recommended in children?

Nutritional supplements are mainly indicated when the child does not eat well or is at risk of malnutrition due to an unbalanced diet; to improve growth or physical and intellectual performance; in recurrent infections, particularly respiratory and gastrointestinal; in the event of hospital admissions for different causes, failure to thrive, or convalescence (after disease or surgery); when there is a lower intake of energy, protein, vitamins, calcium, iron, zinc, fiber, and folates. Use of nutritional supplements that provide a greater amount of energy and nutrients with a low volume of intake, together with nutritional education, allows for growth improvement and adequate recovery.

In Ecuador, deficiencies in iron, vitamins A, B and C, zinc, and folic acid are the most common. Iron deficiency is the most prevalent in children under 5 years of age, while zinc deficiency is most prevalent in preschool and school children and adolescents¹⁷. This deficiency is covered by taking nutritional supplements that also include additional amounts of the deficient micronutrient.

Maintaining an adequate micronutrient level is particularly important because of the significant changes occurring in growth and development. A diet deficient in vitamins and minerals will significantly contribute to morbidity and mortality throughout the pediatric age, particularly in children under 5 years of age¹⁹.

To achieve better adherence, it is recommended that nutritional supplements are given once daily, but depending on the degree of malnutrition, they may be recommended 1-2 times daily. To ensure the success of food supplementation in terms of prevention and recovery, children should be monitored for at least one year. Monitoring may be performed once a month, with a maximum of one control every three months to monitor changes over time by taking the anthropometric measures that are indicators to help assess nutritional status²⁰ before the children are considered eligible to leave a feeding program.²¹ The decision is made under the supervision of the pediatrician, especially once the child reaches the normal range of weight and height for his/her age and it is considered that he/she can stop using the supplements²⁰. The nutritional clinical history and anthropometric measures of the child should be included in order to allow for early identification of individuals at nutritional risk and, thus, for a quick start of the ideal nutritional therapy for each child, i.e. for an individualised nutritional therapy²².

Are there any aids for access?

A low percentage of nutritional supplements are provided free of charge in some MSP health units,²³ which can only be accessed through regular care²⁴. In most cases they should be purchased at the expense of every individual, which involves the limitation that the price may not be affordable for the entire population.

Treatment adherence

The best adherence to use of nutritional supplements is seen in private offices because of the better control and education by parents to meet the nutritional needs and the acceptance by children when they have a pleasant taste, which results in better adherence and therefore in an adequate treatment due to the possibility of better monitoring.

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Indonesia

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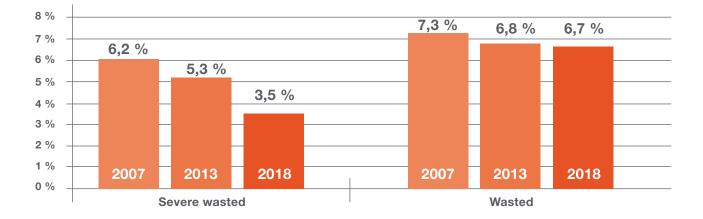
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2.1. Prevalence of malnutrition in the pediatric population in Indonesia

Total Indonesian population, based on recent Central Bureau of Statistics prediction is about 271 million people with around 10% of population is under-five children¹. Although malnutrition affects all age groups and occurs the entire life span, children are the vulnerable group. At present, malnutrition problems includes a spectrum of nutrient-related disorders, intra-uterine growth retardation and low birth weight, protein-energy malnutrition, iron deficiency anemia, vitamin A deficiency as well as iodine deficiency².

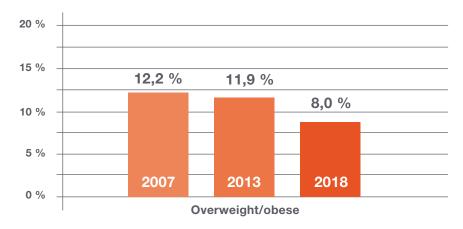
Based on the National Basic Health Research (NBHR) conducted by the Ministry of Health, the incidence of malnutrition in infants showed a decline trend over one decade $(2007-2018)^3$. Over ten years, under-five children who suffered from wasted and severely wasted (WHZ < -2 SD) decreased from 13.6% to 11.2% in 2018. It also revealed that more significant decrease occurred in severe wasted group compared to wasted population (Figure 1)³.



WHZ base on WHO growth chart Severe wasted = < -3 SD; Wasted = ≥ -3 SD and < -2 SD

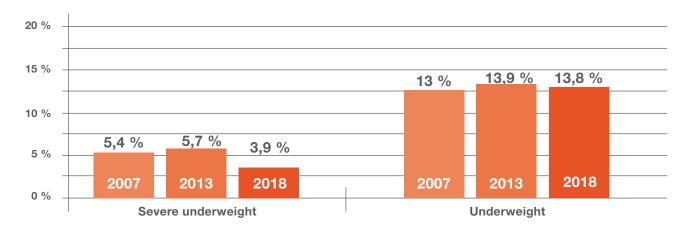
Figure 1.- Prevalence of wasted and severe wasted under-five children 2007-2018³.

The similar trend also appears in overweight and obese population of under-five children, as shown in figure 2:



WHZ base on WHO growth chart Overweight and obese = over +2 SD

Weight for age (WAZ) is one of important anthropometry index that typically use to assess the possible nutritional problems. Based on NBHR for one decade, the percentage of underweight and severely underweight children did not show a substantial decline (Figure 3)³.

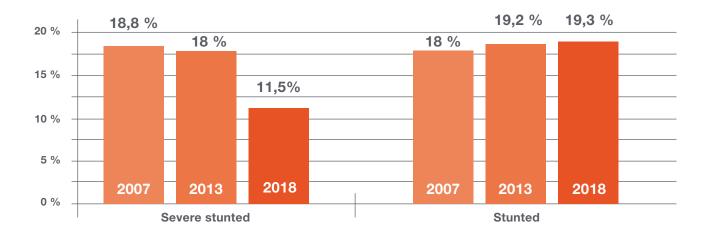


WAZ base on WHO growth chart Severe underweight = < -3 SD Underweight = ≥ -3 SD and < -2 SD

Figure 3.- Prevalence of underweight and severe underweight under-five children 2007-2018³.

Figure 2.- Prevalence of overweight and obese under-five children 2007-2018³.

The prevalence of stunting increased significantly from 36.8% in 2007 to 40.8% in 2018³. Stunting is often used as an indicator of chronic malnutrition and reflection of health and social problems. All effort should be focused on prevention action through monitoring child growth, because growth faltering is the earliest sign and highest contributor for stunting⁴. Although two thirds of under-five children have growth monitoring book, only half of them are regularly checked (Figure 4)³.



HAZ base on WHO growth chart Severe stunted = < -3 SD; Stunted = ≥ -3 SD and < -2 SD

Figure 4.- Prevalence of stunted and severe stunted under-five children 2007-2018³.

The main contributor of malnutrition in under-five children in Indonesia is inadequate of food intake, both in quality and quantity. For children under 24 months, breastfeeding and complementary feeding practices are the most important cause of the problem. Only about 30% of mothers maintain exclusively breastfeeding up to 6 months, despite higher percentage (50%) of mothers who provide breastfeeding initiation within one hour after giving birth³. Exclusive breastfeeding is difficult to maintain and tend to be discontinued early in Indonesia because the perception of breastmilk as being insufficient, or that babies who cried a lot or thin babies require additional milk formula or solid food. Furthermore, there is limited knowledge among mothers about appropriate management of lactation and optimal growth. On the other hand, inadequate government support related to breastfeeding practices.

The complementary feeding practices in Indonesia are still inadequate and inappropriate. Data showed that Indonesian children under 24 months, do not get a minimum standard acceptable diet. More than 40% of children have been given complementary foods before 6 months, and 28% are not following frequency recommendation, around 40% are not given adequate variation of food⁵. About 29% of children do not consume iron rich foods and another 14% do not intake vitamin A rich foods on a daily basis⁵.

Basically, factors affecting complementary feeding practices in Indonesia can be divided into behaviors of caregivers and environment systems. In term of caregivers, lack of knowledge about appropriate feeding practice is the main factor of the inadequate-administering behavior⁶. Although poverty in Indonesia is relatively declining, there are government programs for people living below the poverty line, but this is not yet impartial⁷. A survey in 2017 found that 38% of Indonesian population could not afford a diverse nutritious and healthy diet⁸. In some areas of Indonesia, local food alone cannot provide all the nutrient requirement of young child⁶.

Various studies have revealed that complementary foods consumed by Indonesian children are inadequate in protein and limited micronutrients content⁹. Studies also conclude that micronutrients problem occurred in each economic strata. Meat, fish, poultry, and eggs, as animal sources and fortified foods were suggested to fill the nutrient gaps of these problem nutrients. Iron, zinc, calcium, and niacin are the micronutrient deficits occurred in almost all age groups, socioeconomic strata and settings, as well as thiamine. On other hand, folate deficiency was only problem in periurban and urban middle socioeconomic groups¹⁰. In fact, there is no national and integrated program for home fortification of multiple micronutrients in Indonesia. Furthermore, the existence of additional feeding programs for toddlers and children of the school is considered unable to reduce the malnutrition problem¹¹.

According to Unicef global database, the proportion of malnutrition in children in Indonesian children 5-19 years of age tends to decrease by around 5-9% within 15 years. On the other hand the proportion of obesity increase around 5-7% within the same period¹². Another common problem in school children, especially adolescent girls, are iron deficiency anemia. The SEANUT study revealed the prevalence of anemia in children aged 2-12 years ranged from 10-15%. The study also showed high percentage of children with dietary intakes of energy and protein below Indonesian RDA, as well as vitamin A and C¹³.

2.2. Use of nutritional formula or food supplements/ supports in Indonesia

Healthy children have capacity to take diet voluntarily, but certain number of children who have acute or chronic condition may not achieve adequate amount of nutrients. Therefore they need oral or enteral nutritional support as supplemental feedings.

The common indication of oral or enteral nutrition supplementation are those who are:

• Only take **below 80% of calorie intake.**

- Weight faltering or weight loss
- Weight for height below 5 percentile or below -2 standard deviation.
- **Higher nutritional demand** (infection, congenital heart disease).
- Other special condition, such children with feeding problem or unbalanced diet condition¹⁴.

• Failure to thrive.

Nowadays, a lot of company join the Indonesia's market for iso-caloric and high density caloric formula. Most of formula targeted for 1-10 years-old children, only few product directed for below 12 months babies. These formula categorized as food for special medically purpose (FSMP), therefore parents cannot buy these products in the shop or supermarket. According to the most recent National Agency of Drug and Food Regulation policy, only pharmacy, hospital and health institution are allowed to provide special formula. These formula should be under medical supervision, therefore health professionals are the key person in recommending and monitoring the use of FSMP formula¹⁵.

The professional organization (such as Indonesian Pediatric Society) only makes a guidance for condition/disease that need special formula and recommends about the nutrients/ingredients and appropriate levels as well as indication, such as in the feeding problem algorithm as shown in picture 1⁶.

Feeding Problems Algorithm (Indonesia Pediatric Society - Nutrition & Metabolic Working Group, 2014)¹⁶ Elaborate Complain of feeding problem and manage **Red Flag** Mild-moderate malnutrition or wasted **Good nutritional status** (WHZ below -2 SD) (WHZ between -2 y + 2 SD) Inadequate Adequate Inadequate Adequate implementation implementation implementation implementation of Feeding Rules of Feeding Rules of Feeding Rules of Feeding Rules Parental Small Eaters Inappropriate Feeding Practice Misperception Feeding Rules education and implementation of pediatric nutrition care, **Feeding Rules Reassurance** monitor and follow up in 2 weeks of Feeding **Rules High Calorie Food** Include oral nutrition support (ONS) Adequate Inadequate implementation implementation of Feeding Rules of Feeding Rules Weight gain No weight gain Secondary etiology Primary etiology: lack of knowledge about child care and nutrition Volume/quantity problem Preference /quality problem (small eater) (food preference) **Education of Feeding Rules Feeding Rules** Picky Selective eater eater **High Calorie Food** \downarrow **Include ONS** Systematically introducing varied food

The implementation of this regulation is under transition period. In fact, previously some high density caloric formula can be purchased in the free market with or without medical supervision. But now, the government is considering to implement the regulation properly.

It is common in our practice to follow routine steps before giving the nutritional support. First is the assessment. We identify the nutritional status, dietary intake and other conditions that affect the child status (allergy, neurologic impairment or growth and development problems). Then, calculate the calorie requirements and decide whether the child needs nutritional supplementation to ensure their optimal growth and development. We set the ideal body weight as the ultimate target for children and choose the appropriate route, which can be oral or enteral. The formula selection is based on the age, fluid and nutrient requirement as well as feeding route and gastrointestinal function and tolerance. Monitoring and evaluation is carried out every one or two weeks, in regard of tolerability and effectiveness of the volume and formula choices. Under special conditions, if there is a restriction of volume, we can use higher density formula to achieve nutrient requirement. In this phase, the palatability and child preference are the ultimate consideration to maintain the formula choice.

As nutritional supplementation is aiming for supplement feedings to ensure child's growth and development, the refore the duration of the usage of formula depends on the severity of the case. Those children who are in state of severe malnutrition probably need more than 8 weeks of supplementation, until they recover. In my experience, in mild to moderate cases the average of nutrition supplementation duration is within 4-8 weeks, with the supplemental volume around 500-600 ml per day for toddler, divided by 3 or 4 times a day.

The cost of commercial formula may exceed the financial resources for some families. Problems are more relevant once the child is discharged from hospital. Generally, these formulas are provided by the hospital. Unfortunately the government insurance program (BPJS) does not cover these kind of products. It is uncommon for pediatritians and other health professional to work closely with donation or charity program (wecare or kitabisa.com) or other insurer to ensure that patient obtains the best coverage possible.

On the other hand, for severe acute malnutrition (SAM) management in hospital and community in Indonesia, Ministry of Health always follows the World Health Organization (WHO) recommendation, which is divided into three phases: initial, rehabilitation and follow up treatment. (Table 1)¹⁸

Activity	Initial treatment		Rehabilitation	Follow-up
	days 1-2	days 3-7	weeks 2-6	weeks 7-26
Treat or prevent: hypoglycaemia hypotermia dehydratation	$\xrightarrow{\longrightarrow}$			
Correct electrolyte imbalance			\rightarrow	
Treat infection		\longrightarrow		
Correct micronutrient deficiencies	witho	ut iron — 🔒		
Begin feeding		\longrightarrow		
Increase feeding to recover lost weight («catch-up growth»)				
Stimulate emotional and sensorial development				
Prepare for discharge			\longrightarrow	

Table 1.- Time-frame for the management of a child with severe malnutrition.

Organization formula diets are F-75 and F-100; which is F-75 (75 kcal/100 ml) used during the initial phase, while F-100 (100 kcal/100 ml) is used for rehabilitation period¹⁹. These formulas prepared from the basic ingredients consist of: skimmed milk, sugar, cereal flour, oil, mineral mix and vitamin mix⁹. In community settings, WHO recommends using RUTF (ready-to-use therapeutic food) as part of management for rehabilitation period¹⁹.

Unfortunately, up until now we do not have RUTF as one of the management choices, so we still use F100 as the formula for SAM children who are already discharged from hospital. Health professionals from primary health care center in the nearest child's home are responsible to look after the SAM children. They also have to provide the appropriate nutrition (such as F100, Fe, folic acid, vitamins) and other medicinal drug (such as: antibiotics and anti-tuberculosis).

Lastly, it is not rare case to provide enteral nutritional supplementation at home.

The candidate for home enteral feeding should meet the following criteria:

- Medically stable
- Solution the feeding the feedi
- Available of payment source of formula and tube feeding equipment. They asked for control in outpatient clinic every week for follow up of feeding tube care as well as nutrition and medical monitoring and evaluation.

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3.1. Prevalence of malnutrition in the pediatric population in Peru

According to the World Health Organization (WHO), almost 160 million children under 5 years of age suffer stunted growth or chronic malnutrition. Overall, malnutrition is the cause of 45% of all deaths in this age group, particularly in the context of families with medium to low incomes levels, as a consequence of problems in acquiring sufficient nutritious foods^{1,2}.

A prevalence study based on the nutritional indicators reported by the Nutritional Status Information System (Sistema de Información del Estado Nutricional, SIEN) of the National Health Institute (Instituto Nacional de Salud) of Peru found 23.9% of all Peruvian children under 5 years of age to suffer chronic malnutrition in the year 2010, with a significant reduction to 18.0% in 2016 - though these figures only represent 79% and 77% of the population under 5 years of age projected for the years 2010 and 2016, respectively. The mentioned study also found that although the greatest decrease corresponded to the highlands and jungle regions, as well as the rural areas of the country, these zones continue to experience the greatest impact of the problem - a fact that reflects the healthcare inequalities in Peru. The prevalence in the rural areas doubled that recorded in the urban setting in 2016 (28.66% versus 13.22%), and the prevalence in the highlands and jungle regions in turn almost doubled that in the coastal areas (22.00% and 21.77% versus 12.58%)³.

One of the recent reports published by the SIEN shows that the prevalence of chronic malnutrition in children under 5 years of age during the period 2015-2019 continues to decrease year after year, reaching 16% in 2019¹⁸:

Evolution of chronic malnutrition in children under 5 years of age, 2015-2019 (percentage).

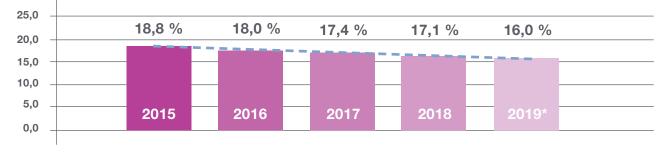


Figure 1.- Source: IINS-CENAN Sistema de Información del Estado Nutricional (SIEN). 2015-2018 SIEN Diresas, *2019 SIEN-HIS.

It is important to remain alert to the situation in the Departments of Huancavelica, Cajamarca and Loreto, which are the areas with the strongest presence of chronic malnutrition in children under 5 years of age during the period 2015-2019¹⁸. *Figure 2*.

Chronic malnutrition in **children under 5 years of age** according to departments, 2019 (percentage).

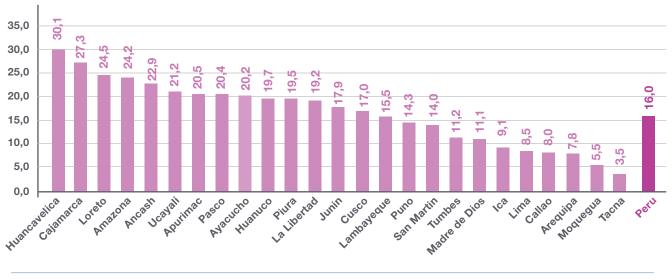


Figure 2.- Source: INS-CENAN Sistema de Información del Estado Nutricional SIEN - HIS - 2019.

Mention also must be made of the percentage decrease in the cases of chronic malnutrition in children under 5 years of age with respect to 2015 in some Departments of the coast and central highlands of the country¹⁸. *Figure 3.*

Chronic malnutrition in children under 5 years of age.

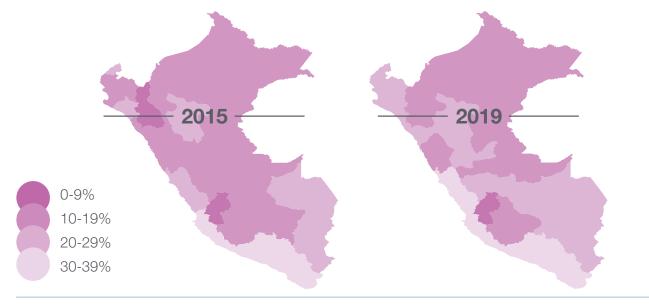


Figure 3.- Source: INS-CENAN Sistema de Información del Estado Nutricional (SIEN). 2015 SIEN Diresas, 2019 SIEN-HIS.

This important public health problem in Peru affects the more excluded populations, such as those living in rural areas, with poorer education and a lower income⁵. When these parameters are stratified according to area of residence, the tendency towards lesser chronic malnutrition in children under 5 years of age is seen to concentrate in the urban and rural settings. However, the risk of malnutrition in children living in rural areas is 3.6-fold (according to the NCHS standard) and 3.5-fold (according to the WHO) greater than the percentage risk seen in urban zones. This indicator moreover has not changed significantly since the year 2014⁴.

Regarding chronic malnutrition in infants under three years of age, the SIEN reports a national prevalence of 14.8% in 2019 - this representing a decrease with respect to previous years. Furthermore, in the same way as in children under 5 years of age, chronic malnutrition is more prevalent in the Departments of the jungle zones and highlands¹⁸.

Actions against malnutrition in children in Peru

In 2014, the Government, together with the Ministry of Health, launched a national plan for the reduction of chronic malnutrition in children and the prevention of anemia in the country. The primary aim was to contribute to reduce chronic malnutrition in children and anemia in infants under three years of age through the strengthening of effective interventions in the intra- and inter-sectorial settings. Health campaigns and programs for children were established, with a series of objectives, such as:

1. Increasing the proportion of infants under three years of age with adequate Growth and Developmental Control (Control de Crecimiento y Desarrollo, CRED) according to age, with the supplementing of iron (multi-micronutrients)¹⁹. The Ministry of Health, through all its agencies at national level, regards CRED as a very important preventive measure, since its priority aim is to protect the optimum development of children under 5 years of age, and up to 11 years of age if necessary. Specifically, CRED can check whether the boy or girl is growing properly, i.e., gaining the required weight and height, and also allows the assessment of development - i.e., acquisition of the skills corresponding to the age of the child ^{20,7,8}.

2. Increasing the proportion of infants under 6 months of age with exclusive breastfeeding.

3. Increasing the proportion of infants under three years of age with full vaccination according to the age.

4. Reducing the prevalence of children with low birth weight.

5. Reducing common childhood diseases such as acute respiratory infections, acute diarrheal processes and parasitoses.

6. Increasing the quality of prenatal care and delivery in the institutional setting.

7. Increasing the number of homes with treated water supply¹⁹.

This process is accompanied by additional efforts and programs that have been conducted in recent years. Progress has been slow, though greater control and investment in the health and social settings can be expected to accelerate the reduction of chronic malnutrition in children in Peru.

3.2. Polymeric formulas/complements/supplements/ nutritional support in Peru

Nutritional supplements offer a complete formula and balanced nutritional profile. They may also be administered as a partial substitute or complement of the patient diet. Such supplements may be designed for use in the general population or may be adapted to the metabolic alterations and nutrient requirements of a population with a concrete disease condition²⁵. The purpose of these products in children is to complement their diet in circumstances requiring an extra supply of nutrients and energy (poor appetite, increased nutrient demand, unbalanced diet or recovery periods). Such interventions do not interfere with normal food intake and contribute to optimize nutritional status and development of the children¹⁷.

The current situation in Peru

The sociological and epidemiological data in Peru reflect a high percentage of children with stunted growth and an increased presence of infections, due to the lack of a complete and balanced diet^{3,24}.

The prevalence of malnutrition has tended to decrease over the last 5 years, though such progress may come to a standstill if sustainable long-term Government policies are not implemented. Chronic malnutrition is a multifactorial problem characterized not only by inadequate nutrient intake and infectious diseases (especially of a respiratory and gastrointestinal nature) but also by a broad range of social and economical circumstances⁵. In Peru, chronic malnutrition is closely linked to anemia, even before 6 months of age⁸. In this respect, multi-micronutrient supplementing in boys and girls between 6-35 months of age has been conducted in the country since 2009. This intervention was initially started in

the Departments of Apurímac, Ayacucho and Huancavelica with the aim of preventing and controlling nutritional disorders secondary to deficiency problems⁹. In 2011, the WHO recommended the use of multi-micronutrients in powder format to control anemia in children between 6-23 months of age living in countries with a prevalence of anemia of 20% or higher¹⁰.

The observed prevalence of vitamin A deficiency (11.7%) and nutritional anemia (33%) in children under 5 years of age in Peru confirms their importance as a public health problem in the country. Nutritional anemia has a number of causal factors, including particularly micronutrient deficiencies (iron, vitamin A, vitamin B_{12} , folates) and other factors such as infections (parasitoses, malaria, immune deficiencies) and disorders inherent to the red blood cell series⁶.

Micronutrients that include vitamins and minerals are essential for a high quality diet

In this regard, a diet rich in iodine, vitamin A, iron and zinc, together with maternal breast-feeding in early life, are crucial for the correct cognitive, neurological, skeletal and body development of the child. Over 40% of all children under 5 years of age living in developing countries throughout the world suffer anemia, and in almost one-half of these cases the underlying cause is iron deficiency⁷.

Nutritional support in the pediatric clinic

Children who eat poorly and do not have complete nutrition for a long period of time suffer nutritional deficits that can lead to inadequate growth, impaired mental capacity and frequent infections ^{22,23}.

Another influencing factor is reluctance on the part of the child to eat. In the absence of organic causes, this may be due to inadequate perceptions of the family environment¹¹, or eating disorders secondary to internal and/or external stimuli¹². Children that eat poorly are a major concern for parents, and in this regard eating problems are one of the most common causes of consultation in pediatric practice, since they are related to low nutritional supply, and lesser body weight and height²¹. Nutritional supports or complements must be indicated following adequate nutritional assessment of the patient, with monthly anthropometric controls in order to guarantee careful monitoring of the evolution of the child. Their formulation should include adequate macronutrients providing protein of high biological value and digestibility, as well as good tolerability (flavour is very important in children). Micronutrients must also be provided by the formulation, since they are essential for adequate neurocognitive development and growth of the child. The inclusion of prebiotics^{13,14} and probiotics is likewise advised in the formulation to ensure optimum development of the intestinal microbiota and digestive and immune systems^{15,16}.

In Peru, because of cost considerations, the use of such complements / supplements or complete polymeric nutritional support measures is largely confined to the private care sector, where pricing is often a limiting factor. These products are only distributed free of cost (through State funding, Ministry of Health) at institutional level in very concrete cases for children undergoing recovery or with special medical conditions, and the patients moreover must be included within regular health insurance or care coverage.

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4

Saudi Arabia

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4.1. Prevalence of malnutrition in the pediatric population in Saudi Arabia

The term malnutrition encompasses both ends of the nutrition spectrum from under nutrition (underweight, stunting, wasting and micronutrient deficiencies) to over weight in preschool and school aged children. Nutritional status is assessed in terms of anthropometry.

Height for age is used for assessing for nutritional status of populations, because this measure of skeletal growth reflects the cumulative impact of events affecting nutritional status that result in stunting and is referred to as chronic malnutrition.

Weight to height measurement or wasting is a **measure for acute malnutrition.** Another dimension of malnutrition is micronutrient deficiencies. Micronutrients of particular significance are:

- lodine
- Vitamin A and D
- Folic Acid
- Iron
- Zinc

Prevalence of malnutrition among the highest income countries is surprisingly high because malnutrition is not just a result of food insecurity. The prevalence of nutritional indicators in the form of underweight, stunting and wasting in children under 5 years of age is one of the ways of assessment of nutritional status of the population. This should be regularly practiced as a measure of public health status.

Deficiency of a single nutrient is an example of malnutrition, but deficiency of a single nutrient usually is accompanied by a deficiency of several other nutrients. Protein- energy malnutrition (PEM) is manifested primarily by inadequate dietary intake of protein and energy either because the dietary intakes of these two nutrients are less than required for normal growth or because the needs for growth are greater than can be supplied by what otherwise would be adequate intakes.

Historically, the most severe forms of malnutrition **marasmus** (non-edematous malnutrition with severe wasting) and **kwashiorkor** (edematous malnutrition) were considered distinct disorders. Non edematous malnutrition was believed to result primarily from inadequate energy intake or inadequate intakes of both energy and protein, whereas edematous malnutrition was believed to result primarily from inadequate protein intake.

On the other spectrum of nutrition, obesity is an important pediatric public health problem associated with risk of complications in childhood and increased morbidity and mortality throughout adult life. the prevalence of childhood obesity has increased.

Micronutrients are involved in fundamental functions in the body, such as growth, maintenance of health and metabolism. A vitamin can have several functions. Because our bodies cannot biosynthesize vitamins, vitamins must be supplied by the diet or as supplements.

In Kingdon of Saudi Arabia (K.S.A), a **big study was done to evaluate the prevalence of underweight,** stunting and wasting among children less than 5 years of age, number of children included was 15.516, 50.6% were boys.

The national prevalence of under 5 years age children of **overweight** was 6.1% and the national prevalence of under 5 years stunting is 9.3%^{1,2}.

The prevalence of moderate and **severe underweight, wasting and stunting** was defined as the population of children and toddlers whose weight for age, weight for height and height for age were below -2 and -3 standard deviations scores respectively.

Prevalence of **moderate underweight** was 6.9%, **severe underweight** was 1.3% and indicated a progressive increase in the prevalence of underweight with advanced age (Table 1). Moderate to severe wasting was 9.8% and 2.9% respectively (Table 2). Moderate to severe stunting was 10.9% and 2.8% respectively (table 3). The prevalence was lower in girls for all indicators. Comparison of the prevalence of nutritional indicators in selected countries demonstrates large disparity with an intermediate position for Saudi Arabia^{3,4,5}.

Age	Total number (%) <-2 SD			Total number (%) <-3 SD		
	Boys	Girls	Combined	Boys	Girls	Combined
<1	4.343	4.141	8.484	4.343	4.141	8.484
	(5,1)	(2,3)	(3,7)	(1,1)	(0,5)	(0,8)
1 a <2	1.283	1.228	2.511	1.283	1.228	2.511
	(5,5)	(2,9)	(4,2)	(0,8)	(0,4)	(0,6)
2 a <3	703	727	1.430	703	727	1.430
	(7,8)	(7,2)	(7,5)	(1)	(1,5)	(1,3)
3 a <4	716	787	1.503	716	787	1.503
	(7,8)	(8,8)	(8,3)	(2)	(1,5)	(1,8)
4 a <5	845	828	1.677	845	828	1.637
	(10,3)	(11,1)	(10,7)	(2,1)	(1,6)	(1,9)
Overall	7.890	7.711	15.601	7.890	7.711	15.601
	(7,3)	(6,5)	(6,9)	(1,4)	(1,1)	(1,3)

Table 1.- Prevalence of underweight by age and gender

Adapted from: El Mouzan MI et al. Prevalence of malnutrition in Saudi children: a community-based study. 2010³

Table 1 indicates a progressive increase in the prevalence of underweight with advancing age.

Age	Total number (%) <-2 SD			Total number (%) <-3 SD		
	Boys	Girls	Combined	Boys	Girls	Combined
<1	4.290	4.109	8.399	4.290	4.109	8.399
	(12,3)	(10,8)	(11,6)	(5,6)	(4,4)	(5)
1 a <2	1.282	1.227	2.509	1.282	1.227	2.509
	(6,9)	(4,5)	(5,7)	(1,9)	(1,6)	(1,8)
2 a <3	698	727	1.425	698	727	1.425
	(12,3)	(8,4)	(10,4)	(3,2)	(2,8)	(3,0)
3 a <4	714	785	1.499	714	785	1.499
	(10,5)	(9)	(9,8)	(2,5)	(1,9)	(2,2)
4 a <5	893	826	1.710	893	826	1.719
	(12,6)	(10,8)	(11,7)	(3,5)	(1,9)	(2,7)
Overall	7.877	7.674	15.551	7.877	7.674	15.551
	(10,9)	(8,7)	(9,8)	(3,3)	(2,5)	(2,9)

Table 2.- Prevalence of waisting by age and gender

Adapted from: El Mouzan MI et al. Prevalence of malnutrition in Saudi children: a community-based study. 2010³

Table 2 depicts a prevalence of wasting of 9.8% and 2.9% for moderate and severe wasting respectively with an inconsistent pattern according to age. But with a consistently lower prevalence of wasting in girls.

Age	Total number (%) <-2 SD			Total number (%) <-3 SD		
	Boys	Girls	Combined	Boys	Girls	Combined
<1	4.336	4.123	8.459	4.336	4.123	8.459
	(10,5)	(5,2)	(7,9)	(3,3)	(1,5	(2,4)
1 a <2	1.278	1.225	2.503	1.278	1.225	2.503
	(12,5)	(11,1)	(11,8)	(3,80)	(3,3)	(3,6)
2 a <3	703	726	1.429	703	726	1.429
	(14,4)	(10,1)	(12,1)	(3,4)	(3,4)	(3,4)
3 a <4	716	787	1.503	716	787	1.503
	(11,7)	(12,8)	(12,3)	(3,4)	(2,5)	(3,0)
4 a <5	845	829	1.674	845	829	1.674
	(10,1)	(10,3)	(10,2)	(1,8)	(1,9)	(1,9)
Overall	7.878	7.690	15.568	7.878	7.690	15.568
	(11,8)	(9,9)	(10,9)	(3,1)	(2,5)	(2,8)

Table 3.- Prevalence of stunting by age and gender

Adapted from: El Mouzan MI et al. Prevalence of malnutrition in Saudi children: a community-based study. 2010³

Table 3 shows a prevalence of stunting of 10.9% and 2.8% for moderate and severe degrees, respectively. Although the overall prevalence was lower in girls, this pattern was not consistent according to age.

In Kingdom of Saudi Arabia, there are various social conditions, people are living very different social situations. In this way, doctors see most of the degrees of malnutrition: from mild, moderate, severe, under-nutrition, going to all degrees of obesity.

Nutrient deficiencies are related to both macronutrients and micronutrients. Most of micronutrient deficiencies include iron, calcium, vitamin D and zinc.

But even though there is an issue here, there are no institutional regulation or government policies. What is important to know is that health policies depend on doctor-parents relationship and the decisions that can be made between both about children's health.

4.2. Use of nutritional formula or food supplements/ supports in Saudi Arabia.

Complementary foods are combined with human milk or formula of infants and toddlers to provide the nutrients required for appropriate growth. The use of nutritional supplements is increasing.

In KSA, we follow the Pediatric Yorkhill Malnutrition Score (PYMS) as a reliable malnutrition screening tool. Our available tools are following growth parameters on growth charts and follow up investigation.

In KSA, various dietary complements are available for toddlers. Some of them are promoted in t.v. advertisements. They are complete formula with macro-nutrient caloric distribution similar to those recommended by balanced diet. They are indicated for kids with inadequate growth and development and for picky eaters. They contain the optimum required of proteins, fats (linoleic acid, alpha linolenic acid, DHA, MCT, saturated fatty acid and trans fatty acids) and a combination of probiotics and prebiotics that help the growth of intestinal microbiota reducing the susceptibility to infections and helping to regulate intestinal transit.

In Saudi Arabia, nutritional supplements are indicated for:

• **Convalescense:** following infection, trauma, or surgery.

• Picky eaters: inadequate nutritional intake.

• Unbalanced diet: deficient nutrients.

- **Increased nutritional demand:** sports and physical activity.
- Malnutrition risk: all autism spectrum disorders.

Nutritional supplements increase weight percentiles for height in healthy children with risk of malnutrition. It provides 50% of micronutrient requirements⁶.

A lot of companies join the Saudi market for isocaloric and high density caloric formulas. These formulas targeted 1-10 years old kids and are provided in pharmacies, hospitals and health institutes. These should be provided after proper assessment of the nutritional status, dietary intake and other conditions that can affect the child status like allergy and developmental problems. Then we calculate the caloric requirement and accordingly we decide whether the child needs nutritional supplementation to ensure their optimal growth and development. Monitoring and evaluations is carried out every 2 weeks in regard to tolerability and effectiveness of the volume and formula choice.

Cases of severe acute malnutrition are managed in the hospital in three phases:

Initial rehabilitation and follow up treatment. 2 Manage imbalance of electrolytes and micronutrients.



Management of dietary infections and other medical problems.

Adherence to these products is moderate in Saudi Arabia, it depends on the cultural and financial tolerability of the family.

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Spain

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5.1. Prevalence of malnutrition in the paediatric population in Spain

In Spain, there are several recent studies on the increase in childhood obesity as an expression of malnutrition due to excess energy intake. Thus, in a study in Galician schoolchildren in 2018, 14.8% were obese¹. However, there are few reports on malnutrition in children.

Paediatric malnutrition

may be due to diseases or social and environmental factor. With regard to malnutrition secondary to pathological conditions, there are studies on paediatric malnourished patients admitted to hospitals where the cause of malnutrition is secondary to chronic or severe childhood disease. Accordingly, in a multicenter study published in 2013 conducted in 32 Spanish hospitals with a sample of 991 patients, the percentage of malnutrition on admission was 7.8%².

As regards malnutrition from a socioenvironmental cause, the data source is usually based on population-based studies, particularly from schoolchildren.

a) Acute malnutrition

The indices relating weight and height (weight/height index and body mass index - BMI) can provide information about acute malnutrition. According to the Aladino study³ performed in 2015-2016 in over 10,000 Spanish schoolchildren aged 6 to 9 years, 0.4% to 0.8% of children were found to have a BMI less than 2 SD according to the WHO growth curves. In a cross-sectional study of 1,200 schoolchildren in Madrid, 5% of children were malnourished during the economic crisis, especially in families with both parents unemployed⁴.

b) Chronic malnutrition

When attempting to determine chronic childhood malnutrition in Spain based on anthropometric data from school studies, caution should be exercised when interpreting the data. Hence, as in other developed countries, inadequate height growth alone as an indicator of chronic malnutrition is not useful because its influenced by endocrine causes or constitutional growth delay and not only environmental causes such as emotional or financial deprivation.

Given this lack of studies, it can be assumed that the percentage of children in Spain with malnutrition due to environmental or socio-economic causes is very low, and this is probably the case. However, the

risk of child malnutrition due to lack of household income is not negligible and even more so in times of economic crisis. Thus, a clear risk of malnutrition due to lack of food intake was reported in 2013 in several Spanish autonomous regions. Currently, in Spain, with data from 2018, the persistent child poverty rate (i.e. the year under study and the previous two years) is 20.1% (one in 5 children), and this rate is much higher than the European average (around 12%), only behind Bulgaria and Romania⁵.

Food consumption

For a more reliable idea of the socio-economic situation of households, please refer to frequency of food intake and eating habits. According to the Aladino study mentioned above, the key findings are as follows:

Incorrect eating habits for breakfast:

- 15.5% of children have only milk, water or juice for breakfast.
- Only 2.8% have a quality breakfast, including at least one dairy product, one cereal and one fruit.

Fruit and vegetable intake:

• Percentage of children who never consume them or less than once a week: fresh fruit (8.2%), vegetables -excluding potatoes (15%).

Protein foods that are never consumed or less than once a week:

• Cheese (28.4%), yoghurts and fresh cheese (8.4%), eggs (26.6%), meat (4.2%), fish (16.7%).

Risk nutrients

The **ENALIA**⁶ study and the **ALSALMA**⁷ study can be used to determine the percentage of children with insufficient nutrient intake in Spain.

The **ENALIA** study, conducted in 1,862 children and adolescents aged 6 months to 17 years between 2013 and 2014, reported an inadequate dietary intake of vitamins D (almost all of the population), E (particularly in those over 14 years, 71.3%) and folic acid (over 9 years, 51-68%). To a lesser extent, vitamin A, C and thiamine intakes (in women) were also inadequate in 5-13% of adolescents. Regarding minerals, intake was inadequate for iron (10%-14% between 6 and 12 months), iodine (8%-11% between 1 and 3 years), and calcium (more than 50% in patients over 9 years of age).

The ALSALMA study conducted in 2013 with information from Spanish children aged 7 to 36
months also showed the following risk nutrients: vitamins D, E, folic acid, calcium, iron and iodine.

Study	Highlights
Aladino ³ (2015)	 Incorrect or inadequate breakfast (15.5%) Low intake of fruits and vegetables (8-15%) Low intake of protein foods (8-28%)
Alsalma ⁷ (2013)	 Insufficient intake in children aged 6 to 36 months Vitamins D, E and folic acid Calcium and iodine Excess protein intake
Enalia ⁶ (2013-14)	 Insufficient intake in children and adolescents aged 7 months to 17 years: Vitamins D, E, A, C, thiamine and folic acid Calcium, iron and iodine Low carbohydrate intake and high protein and fat intake

Table.- Summary of the main population-based studies on dietary habits and risk nutrients during childhood in Spain

5.2. Use of nutritional formulas or food supplements/ supports in Spain

Paediatric nutritional supplements

Paediatric nutritional supplements are products with a complete formula and balanced nutritional profile that are included in the food category.

This type of product is aimed at children aged 1 to 10 years, particularly when there is an increased need for nutrient intake due to excess consumption or increased demand. The ultimate goal of their use is to supplement nutrition by providing extra nutrients.

Paediatric nutritional supplements should have a pleasant taste and should be able to be incorporated into other nutritious foods such as milk, soups or purées. In Spain, products under this name are not subsidised by the public health system.

In cases of greater severity and with a compromised nutritional status, complete diets or nutritional modules are usually used, in this case funded by the public health system and particularly for hospital use.

Nutritional supplements are mainly indicated for:

- Convalescence (after disease)
- Children who are poor eaters
- Unbalanced diet
- Increased nutritional demand
- Malnutrition risk



For what **type of children with diseases** are paediatric nutritional supplements targeted in Spain?

Recurrent upper respiratory tract infections are a common condition in young children, sometimes associated to hypertrophy of adenoid vegetations. Fever often aggravates the characteristics infection-induced anorexia. Another common condition of anorexia and increased losses occurs after trauma or at discharge from surgery. In these cases, a nutritional supplement in the **convalescence phase** allows more energy and nutrients to be taken with a low intake volume.

For what **type of healthy children** are paediatric nutritional supplements targeted in a country like Spain?

Nutritional supplements in paediatrics in Spain are mainly aimed at children with no disease who are poor eaters or with increased needs.

In the first group of **undereating children**, diets are poorly varied or monotonous. They are picky or fussy eaters who eat a limited number of foods, are unwilling to try new foods, have restricted intake of some food groups, and have strong preferences in other foods. These children have a potential risk of nutritional deficiencies and inadequate weight gain. Compared to good eaters, these children tend to eat insufficient amounts of fruits, vegetables, and meat, with the consequent lower intake of energy, protein, vitamin C, vitamin E, calcium, iron, zinc, fibre, and folate. The use of nutritional supplements in these children together with nutritional education has been shown to maintain weight during episodes of infections, improve growth and reduce the rate of respiratory infections⁸.

Children with a **highly unbalanced diet** where certain nutrients may be deficient should also be considered. These children who do not eat any kind of fruit or eat very few vegetables or do not eat dairy products will not take in enough vitamin C, folic acid or calcium, respectively.

In the second group **(greater nutritional demand)** are included healthy children who have increased energy and nutrient expenditure from regularly playing competitive sports.

Role of nutritional supplements in **paediatric** malnutrition risk

Use of nutritional supplements has been shown to increase weight percentiles for height in healthy children with **risk of malnutrition.**⁹ In addition, in children aged 3-4 years, daily intake of a nutritional supplement providing at least 50% of micronutrient requirements has been shown to increase nutritional weight indices for height, improve adequate intake of energy and protein, and provide greater dietary diversity without interfering with intake of natural foods¹⁰.

Another group of children who could benefit from nutritional supplements are children with **autism spectrum disorders**, particularly in its early stages. These are children with very restrictive and repetitive diets in which cases of scurvy due to lack of vitamin C, rickets due to vitamin D deficiency, dry eye due to vitamin A deficiency and optic neuritis due to vitamin B₁₂ deficiency have been reported primarily¹¹.

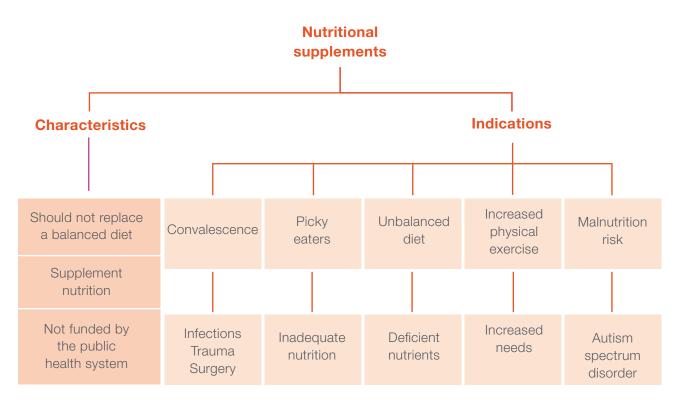


Figure 1.- Summary of the use of food supplements in Spain

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Vitafos[®] Scientific evidence

Vitafos® is a polymeric, hypercaloric normoprotein formula, of high nutritional value, gluten-free and lactose-free, which helps to meet energy and nutrients requirements in situations where diet is not enough.

One intake of **Vitafos®** provides 260 kcal, with a caloric distribution of macronutrients similar to the recommendations of a balanced diet.

Its pleasant organoleptic characteristics and easy dissolution, allows its administration both dissolved in water or added to different foods, to enrich different soups, creams and desserts.

Vitafos® has been on the market for more than 25 years, and it has been innovating its composition and adapting its formula to the latest international recommendations, to feed children from 3 continents that require an extra supply of energy and proteins in both physiological and pathological situations.

6.1 Scientific evidence of Vitafos[®] in pathological situations

Clinical impact of the use of a **hypercaloric formula** containing symbiotic and DHA in children with failure to thrive

The aim of the study was to analyze the clinical impact of **Vitafos**[®] (hypercaloric formula containing symbiotic (*Bifidobacterium longum infantis subesp. infantis* CECT7210 (*B. infantis* IM1[®]), fructo-oligo-saccharides) and docosahexanoic acid (DHA)) in children with non-organic failure to thrive. All of them obtained informed consent.

To achieve this objectives, a double-blind, multicenter clinical trial was held involving 7 Spanish hospitals, in parallel groups.

A total of 98 patients (55% male) were included ≥ 1 year with an average age of 5.17± 4.14 years, without differences between groups, with body mass index z-score (zIMC) \leq -1 (zIMC -2,2±0,7DE) and without organic disease, which were randomized into 2 groups: Experimental Group (intervention: hypercaloric formula with DHA and symbiotic (**Vitafos**[®]) and Control Group (control: same formula without symbiotic compounds or DHA).

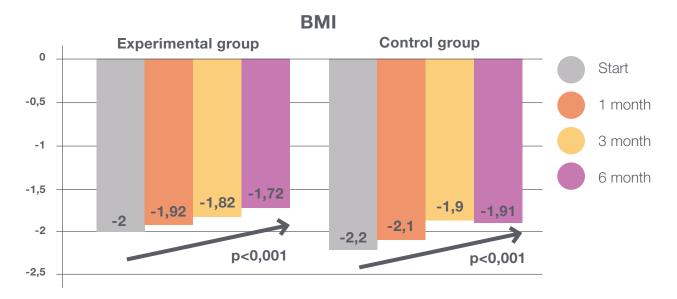
The follow-up time was 6 months, and nutritional variables (anthropometry and bioimpedance (BIA), digestive symptomatology and intercurrent infectious processes were collected.

In the case of clinical variables, fecal calprotectin (Cpf) analysis was performed by enzymoimmunoanalysis. In faeces, the count of total bifidobacteria and *Bifidobacterium longum infantis subesp. infantis* CECT7210 (BB CECT7210) was determined by quantitative technique Real-Time polymerase chain reaction (RT-PCR) (Applied Biosystems, Foster City, California).

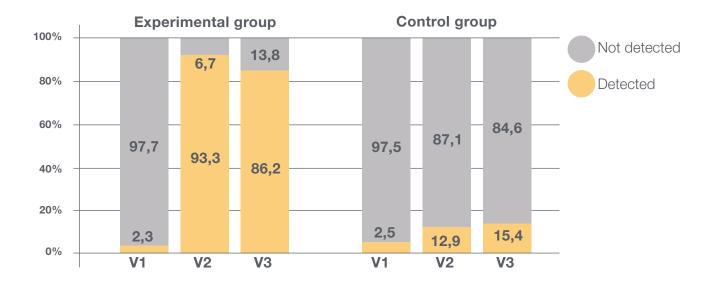
Regression for repeated measurements, Bonferroni correction, Poisson regression, Pearson correlation and Fisher test were used for the statistical study of the results.

Results:

Throughout the study, nutritional parameters improved in both groups, but the gain of the Experimental group was higher.



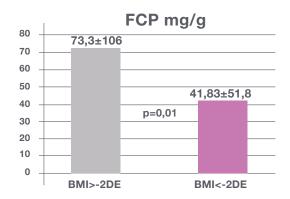
Significant differences (p-0.001) were found in the detection of BB CECT7210 between the two groups (Experimental:86.2% and Control: 15%), highlighting the survival of that strain throughout the digestive tract.



*p<0,05 a 3m 100 90 Experimental group ⁸³ 80 81 78 81 80 81 80 Control group *p<0,07 a 6m 60 ⁴⁶_44 40 20 0 LBM%N ECW%N BFM%N BCM%LBM TBW%N

Higher BB CECT7210 values correspond to a lower vomiting/per week incidence (p-0.013), lower prevalence of infectious processes (p-0.03), and higher LBM (lean body mass –BIA) (p-0.021).

Nearly half of patients with failure to thrive had fecal calprotectin figures above normal, suggesting a high inflammatory intestinal response. Younger children, with earlier diagnosis and increased malnutrition presented the higher FCP levels.



Conclusions of the study were that studied formulas were safe and effective, that the presence of BB CECT7210 (*Bifidobacterium infantis*IM1[®]) is related to fewer vomiting and infectious processes in better-evolving patients and that a positive nutritional impact has been observed with the presence of these symbiotic compounds and DHA in the formula in patients with failure to thrive.

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6.2 Scientific evidence of Vitafos[®] in physiological situations

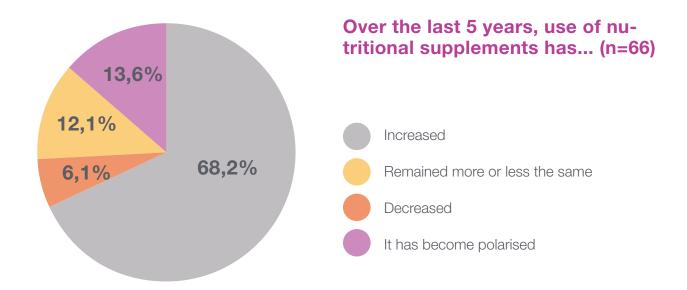
Supplilac study on the causes and effects of nutritional supplementation

The aim of the study was to deepen knowledge of the Saudi Arabian pediatricians use of the different varieties of nutritional supplements, to analyze the patient profile to which this type of preparation is recommended, as well as the prescribed administration guidelines, especially in the case of picky eaters.

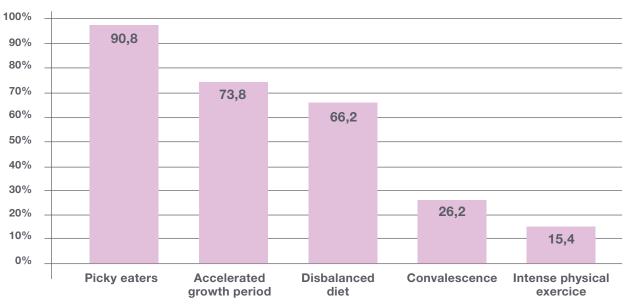
At the same time, retrospective information was collected on the efficiency and tolerability of **Vitafos**[®] in patients who had been prescribed the product, and degree of satisfaction with it.

Clinical practice questionnaires were completed by 66 paediatricians (68.3% male) of primary health and hospital care spread across the country with an average age of 47 ± 10.2 years.

General perception was that over the past 5 years the percentage of picky eater children has increased, and that so has done the use of nutritional supplements.



With regard to the main reasons for recommendation of such products, the most frequently mentioned were the following ones:



Paediatricians more frequently cited causes for nutritional supplements recommendation

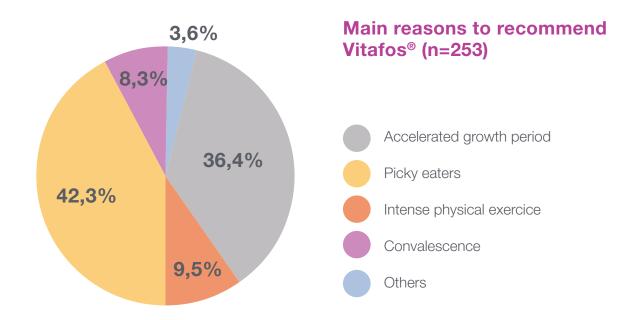
The average age from which pediatricians recommended nutritional supplements was 2.2 ± 2.2 years.



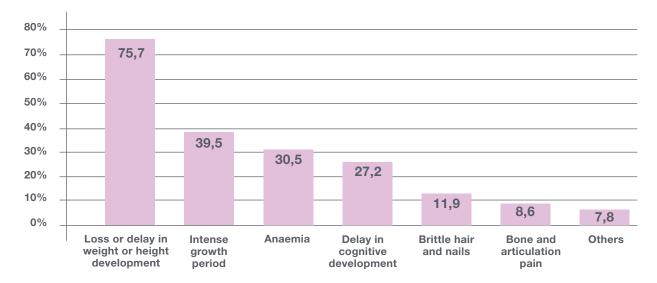
Age from which paediatricians begin to recommend nutritional supplements

In the specific case of retrospective analysis of patients who had been prescribed **Vitafos**[®] over the past 6 months, information was collected on 274 children (52.8% boys/47.2% girls) with an average age of 3.5 ± 2 years.

The main reason for prescribing the use of **Vitafos®** by pediatricians was that patients were classified as picky eaters, followed by the child being at an intense growth stage.



As for the symptoms of children, and which made pediatricians decide to recommend a nutritional supplement, the most common was weight loss or stagnation of growth.

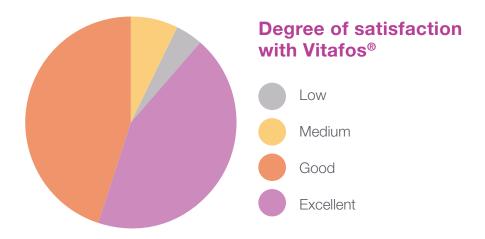


Main symptoms of the paediatric patients using Vitafos[®]

The average period of time required to see an improvement in symptomatology after beginning the consumption of the preparation was 40 ± 39 days.

In terms of growth during the period that the children were taking **Vitafos**[®], which on average was 5 months, it was 4 cm in the case of height and 2 kg in the case of weight.

Tolerability and digestibility of **Vitafos**[®] was valued as good or excellent by 88% of families, and the overall degree of satisfaction with the preparation was valued as good or excellent by 91% of them.



The main conclusions of the Supplilac study were the following ones:

Use of nutritional supplements by pediatricians is a common practice in physiological situations where an extra supply of energy and nutrients is required.

Vitafos[®] has demonstrated to be useful in supplementing the diet of the paediatric population, favoring growth by increasing both weight and size and presenting good tolerability and digestibility.



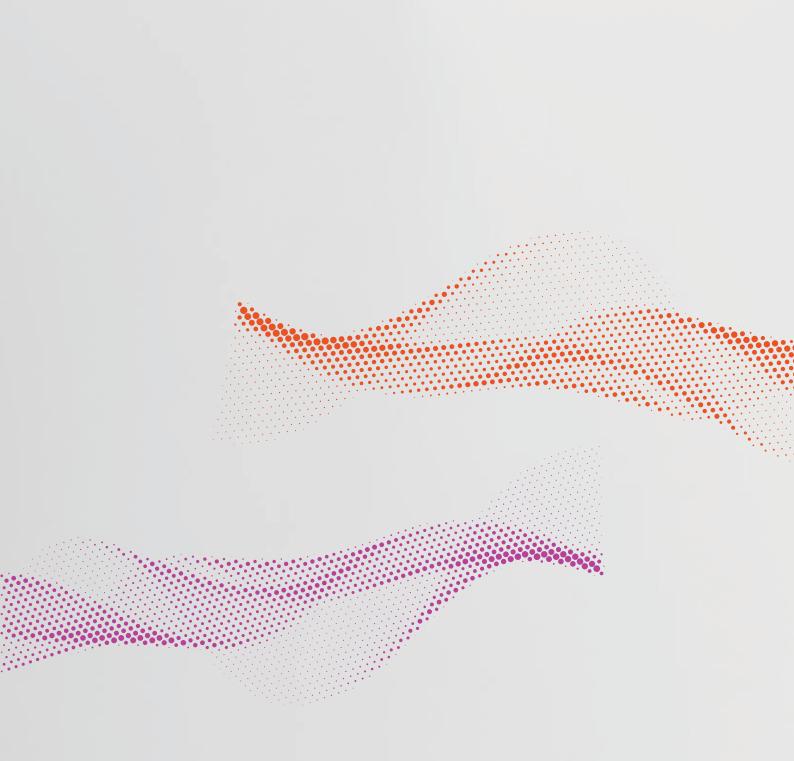
1. SUPPLILAC STUDY CAUSE AND EFFECT OF DIET SUPPLEMENTATION. In press.



This product can be consumed by celiac and lactose intolerant children · To be used under medical supervision. Do not use in children with galactosemia · Not for parenteral use.

www.vitafos.com/me





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