

# Possible Effects Of The Covid-19 Pandemic On The Prevalence Of Malnutrition-Anorexia Cases In A Pediatric Population. Using Big Data Tools.

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## ABSTRACT

The coincidence of COVID-19 and confinement on children's health has been studied. One possible cause of malnutrition is eating disorders.

Big data tools are currently a first-rate tool for assessing population changes and possible causes.

**Main objective:** To assess the possible changes in the prevalence of malnutrition in a child population after having suffered the confinement of COVID-19

**Material and methods:** Data collected from episodes of computerized medical records, studying the variables sex, age, weight, height, of a pediatric population comparing the situation just before COVID (2020) and after the social isolation measures were completely finished (2022) Using big data methods to study variables.

Using the Cole-Green LMS algorithm with penalized likelihood, implemented in the RefCurv 0.4.2 software (2020), which allows managing large amounts of data. The hyperparameters have been selected using the BIC (Bayesian information criterion).

To calculate population deviations from the reference, the reference was taken as being below 1.5 standard deviations from the average according to age.

**Results:** 66,975 computerized episodes of minors under 16 years of age and a total of 1,205,000 variables studied. The data and comparative graphs between districts of the population studied are represented with respect to the variables analyzed. Due to the COVID effect, an increase of 60 cases/10 5 inhabitants is recorded, in a heterogeneous way, being more in men than women, in rural areas in girls and in urban areas in the case of boys.

**Conclusions:** Big data technology allows for more efficient population studies, selecting populations most in need of health intervention, optimising scarce health resources. In this case, the active search for cases in certain neighbourhoods of the city should focus on boys and in certain municipalities on girls, since they may appear as hidden cases.

**Keywords :** big data, malnutrition, children.

## INTRODUCTION

Body mass index (BMI) is a common parameter to assess nutritional status (1-3). The assessment and detection of BMI

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changes are important for monitoring and controlling a child population (3-4). Although most of the work tends to focus on the so-called childhood obesity pandemic (2), we cannot forget another aspect of nutritional reality: low weight for height represented by a low BMI (3). In the world, the main cause of a low BMI is malnutrition associated with a lack of food intake due to a lack of resources (2-3) or the disease itself. However, in developed countries there is another situation to take into account, malnutrition associated with mental health. This is why when a case of low weight for height is detected in a child in our environment, the main differential diagnoses range from an underlying organic process, constitutional or functional thinness, nutritional problems of a socio-familial nature or mental disorders that lead to weight loss: anorexia, bulimia with a restrictive component, etc... (2-3).

Anorexia nervosa is one of the psychiatric pathologies with the highest mortality rates (5). It is defined as an exaggerated assessment of the volume and shape of the body, which leads to a relentless search for thinness. It is characterized by excessive voluntary weight loss, through a restrictive diet (5). The prevalence of anorexia nervosa in adults is 0.6% and has been increasing in the adolescent population (6). Anorexia nervosa classically presents in girls in early to mid-adolescence, with a higher prevalence in whites and above-average socioeconomic class (7-8).

The average age of presentation is 12.3 years (7). In our country the data are similar to those presented. What is common in most studies is that after the COVID-19 pandemic (8) there has been an increase in the prevalence of problems associated with the mental health of minors due to the measures taken by governments regarding the limitation of social relations (suspension of classes, social isolation, use of electronic devices...).

So much so that after the COVID-19 pandemic, it is estimated that disorders such as anxiety or depression have increased by between 25% and 27% (9). After the COVID-19 pandemic, the number of cases, hospitalizations and a decrease in the age of patients have increased, with a prevalence of anorexia nervosa rising to 4% in women and 0.3% in men (9).

To further complicate matters, the COVID-19 pandemic has accentuated the deficiencies of health systems and economic inequalities, especially among adolescents and young people (8-10).

Thinness, apart from being a manifestation of an underlying disease or a physiological condition, can reflect situations of risk of developing an eating disorder. Eating disorders have been associated with a high level of education, a family history of eating disorders, vigorexia, situations of family conflicts or even rejection of puberty itself (8-10). But we cannot forget that thinness can also express a situation of risk of social or economic exclusion from the family.

In Spain, according to a UNICEF report (11), the prevalence

of risk of social exclusion and child poverty could reach 28%. This could have a clear impact on the nutritional status of these minors.

The electronic medical records of current health systems collect multiple variables in clinical practice, including anthropometric and sociodemographic data.

Different statistical techniques, such as machine learning, allow these data to be exploited from a large number of cases in an almost semi-automated way, providing data of great statistical value.

Although there are studies on this subject in different countries and even international series (10), there are no studies, at least in our environment and nearby population, that assess the situation of malnutrition in a child-youth population; and in no case has the use of new BIG DATA techniques been described for these studies.

## GOALS

### Main Objective

To describe the situation of the prevalence of malnutrition measured as a low BMI level in a pediatric population: Álava, Basque Country, Spain, using a new big data approach at two different historical moments, before and after the lifting of restrictions on social relations caused by the COVID-19 pandemic.

### Secondary objectives

To assess whether there is a causal relationship with the place of residence, average income per person in said district or neighborhood and immigration rate.

## MATERIAL AND METHODS

### Design

This is a population-based cross-sectional study.

### Study population

All minors under 18 years of age being followed up in the Basque health system, OSAKIDETZA, who present weight and height records in the electronic clinical history tool of OSABIDE GLOBAL (regional medical history management system) in the Alava area.

### Inclusion criteria

- Both sexes
- Ages between 0 and 18 years
- Be registered or present a registered address

### Exclusion criteria

- Not having data registered in the GLOBAL

### Epidemiological data

For this study, a reliable and official source is used on the

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variables average income per inhabitant, unemployment rate and immigration rate by district/neighborhood.

Available at: [https://www.eustat.eus/bankupx/pxweb/es/DB/-/PX\\_010154\\_cep1\\_ep06b.px/table/tableViewLayout1/](https://www.eustat.eus/bankupx/pxweb/es/DB/-/PX_010154_cep1_ep06b.px/table/tableViewLayout1/). (Accessed 08/29/2022).

By including the entire registered pediatric population, it is considered that it is not necessary to calculate the sample size. Data are recorded between 01/01/2020 and 30/03/2020; and the data are collected again using the same methodology between 01/01/2022 and 30/03/2022.

## Variables

- Main variables:
  - o Weight (Kgrs)
  - o Size (cm)
  - o Gender (Male, Female, Binary)
  - o Age (expressed in years and months)
  - o Date of registration
  - o Place of residence – district/neighborhood code
  - o Unemployment rate, per capita income by district

## Statistical analysis

The method based on Dirichlet processes (Dirichlet process, DP) is followed. In this project we will adopt this approach that allows to build Gaussian mixture models (GM). In addition, Gaussian mixture models based on Dirichlet processes (Dirichlet process Gaussian mixture models, DPGMM) are used. A set of populations is also analyzed using Gaussian mixture models based on hierarchical Dirichlet processes (Hierarchical Dirichlet process Gaussian mixture model, HDPGMM) [12]. Clusterings will be obtained that will inform us about the somatometric similarities and differences of the population based on the somatometric variables and the district in which they live (13), incorporating recent methodological innovations on databases similar to ours already described, [14-16]. The BMI calculation is performed as  $\text{weight/height}^2$  (Kgr/m<sup>2</sup>). These data are compared with the means and SDS of the studies published to date and reference of our population (4). Overweight is defined as less than 1.5 SDS with respect to the reference normality for age and sex (4).

The team proceeds to carry out comparative studies using the methodology already applied in previous studies by these same authors (Diez et al) (17): the so-called Hierarchical Dirichlet process Gaussian mixture model or method, applied to our population vs reference graphs from the Spanish 2010 study and used in the country.

It is assessed whether there are differences with a significance of  $p < 0.05$ . Due to the methodology itself, groups that allow for comparison are those that record at least 20 individuals with complete variables.

## RESULTS

Data have been obtained from a total of 67,270 minors.

The sum of all variables studied (some presented in this work and others reserved) amounts to 1,749,020 variables. We present in various tables the results obtained by sex, age and BMI and other variables.

Data from the National Institute of Statistics and EUSTAT indicate that 338,765 people lived in our territory, the province of Álava in the Basque Country – Spain, during the period studied.

The political territory is divided into 7 large districts or groups that include the municipal area of the city of Vitoria, the administrative capital of the Basque Country and main population centre, which brings together more than 255,000 inhabitants.

The income of minors depends on the average family income. The average family income in the Basque Country is 47,005 euros in 2021. The total family income is obtained by aggregating the personal income of the family members, including minors. There are significant differences between districts (Source EUSTAT), with the towns in Álava having the lowest average income of the entire population in the region. The unemployment rate in the Basque Country is 7.5%, well below the average for the country, Spain. There are significant differences between districts (Source EUSTAT), with some towns in Álava and Vizcaya having the highest unemployment rates.

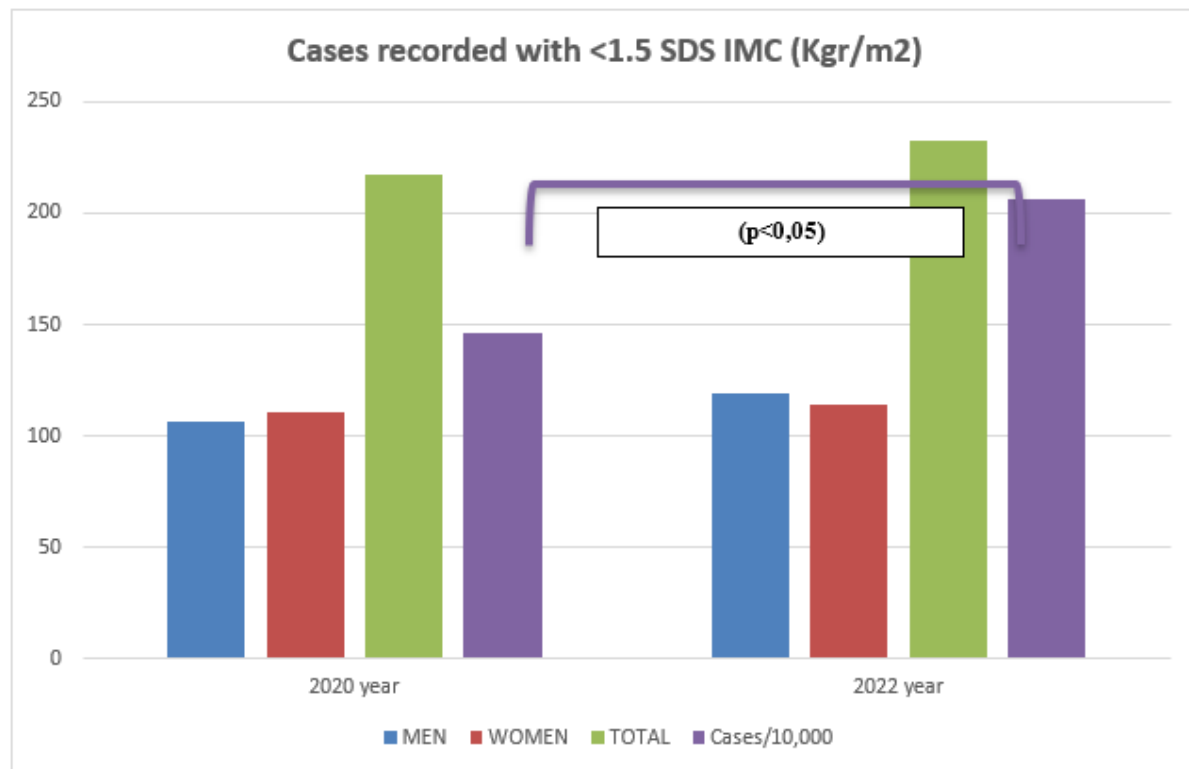
Regarding the rate of immigrant population in our territory. The average rate is 13% in the Basque Country, but Vitoria is one of the municipalities and the capital with the highest rate of immigrants in relation to the general population, 15%. There are districts of the capital that exceed 18% and localities that even reach more than 20%. Available on the web <https://www.vitoria-gasteiz.org/http/wb021/contenidosEstaticos/adjuntos/es/36/18/3618.pdf>. Dec. 2024 and on the EUSTAT website [https://www.eustat.eus/estadisticas/tema\\_131/opt\\_0/tipo\\_1/ti\\_actividad-ocupacion-y-paro/temas.html](https://www.eustat.eus/estadisticas/tema_131/opt_0/tipo_1/ti_actividad-ocupacion-y-paro/temas.html) and on [https://www.eustat.eus/elementos/ele0000200/migraciones-de-la-ca-de-euskadi-por-ambitos-territoriales-segun-clase-de-migracion-y-sexo/tbl0000255\\_c.html](https://www.eustat.eus/elementos/ele0000200/migraciones-de-la-ca-de-euskadi-por-ambitos-territoriales-segun-clase-de-migracion-y-sexo/tbl0000255_c.html) Dec. 2024. In the first quarter of 2020, pre-pandemic situation, a total of 217 individuals under 16 years of age (106 men, 111 women) were detected with a BMI < 1.5 SDS Kgr/m<sup>2</sup> for their age/sex. This figure represents 1.46% of all cases studied.

In the first quarter of 2022, post-pandemic situation, a total of 233 individuals under 16 years of age (119 men, 114 women) were detected with a BMI < 1.5 SDS Kgr/m<sup>2</sup> for their age/sex. This figure represents 2.06% of all cases studied.

Significant differences in both periods and sexes ( $p < 0.05$ ), with an increase of 60 registered cases/10,000 inhabitants between both periods.

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**Chart 1.** Representation of data for the BMI variable (kg) by sex. Reference to normal population (P50 Carrascosa study). The amount of population whose BMI is below 1.5 standard deviations from the mean for their age is indicated for both study periods 020 vs 2022.



The numerical results are shown in **Tables 1 and 2**. Using the cluster study statistical method, those districts that present results of less than 20 cases with data during the study period have been eliminated.

Assessing the distribution of cases, there has been an increase in these cases, especially at the expense of men (48 cases/10,000 inhabitants). Women contribute another 12/10,000 inhabitants to the total.

**Table 1.** Representation of data for the BMI variable (kg) in men by district. Reference: normal population (P50 Carrascosa study). The amount of population whose BMI is below 1.5 standard deviations from the mean for their age is indicated for both study periods 020 vs 2022, as well as the variation of cases in %.

| DISTRICT                 | Men 2020<br>% | Men 2022<br>% | DIFFERENCES<br>% variation |
|--------------------------|---------------|---------------|----------------------------|
| ABETXUKO                 | 0.00          | 3.90          | 3.90                       |
| JOY OF ALAVA (DULANTZI)  | 1.32          | 2.22          | 0.91                       |
| ARABIZKARRA I            | 5.34          | 5.92          | 0.58                       |
| ARABIZKARRA II           | 1.30          | 1.56          | 0.26                       |
| ASPARRENA (ARAIA)        | 4.00          | 4.00          | 0.00                       |
| OLD TOWN GASTEIZ         | 1.58          | 2.27          | 0.69                       |
| GAZALBIDE TXAGORRITXU    | 1.73          | 2.54          | 0.81                       |
| IRUÑA DE OCA (NANCLARES) | 2.63          | 4.55          | 1.91                       |
| KANPEZU                  | 4.76          | 4.00          | -0.76                      |
| HAVANA                   | 2.48          | 2.70          | 0.22                       |
| LABASTIDA                | 0.00          | 0.00          | 0.00                       |
| LAGUARDIA                | 0.00          | 1.19          | 1.19                       |
| LAKUA                    | 1.59          | 1.33          | -0.26                      |
| LAKUABIZKARRA            | 2.67          | 1.23          | -1.44                      |
| LEGUTIANO (VILLARREAL)   | 0.00          | 2.50          | 2.50                       |

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|                       |      |      |       |
|-----------------------|------|------|-------|
| OION                  | 0.99 | 0.62 | -0.37 |
| OLAGUIBEL             | 1.47 | 1.50 | 0.03  |
| OLARIZU               | 1.49 | 1.16 | -0.33 |
| OTXANDIO              | 0.00 | 0.00 | 0.00  |
| SALBURUA              | 1.28 | 1.38 | 0.10  |
| SALVATIERRA (AGURAIN) | 3.75 | 3.85 | 0.10  |
| Saint Martin          | 1.49 | 1.52 | 0.03  |
| SANSOMENDI            | 0.00 | 0.00 | 0.00  |
| Urcabustaiz (Izarra)  | 0.00 | 1.50 | 1.50  |
| ZABALGANA             | 2.89 | 1.26 | -1.63 |
| ZARAMAGA              | 1.27 | 3.13 | 1.86  |
| ZIGOITIA (GOPEGI)     | 0.00 | 1.61 | 1.61  |
| Zuya (Murgia)         | 0.00 | 0.00 | 0.00  |
| TOTAL                 | 1.57 | 2.05 | 0.48  |

**Table 2.** Representation of data on the BMI variable (kg) in women by district. Reference: normal population (P50 Carrascosa study). The amount of population whose BMI is below 1.5 standard deviations from the mean for their age is indicated for both study periods 020 vs 2022, as well as the variation of cases in %.

| DISTRICT                 | Women 2020 % | Women 2022 % | DIFFERENCES % variation |
|--------------------------|--------------|--------------|-------------------------|
| ABETXUKO                 | 1.45         | 1.23         | -0.21                   |
| JOY OF ALAVA (DULANTZI)  | 2.86         | 2.50         | -0.36                   |
| ARABIZKARRA I            | 0.80         | 2.01         | 1.21                    |
| ARABIZKARRA II           | 0.76         | 1.95         | 1.19                    |
| ASPARRENA (ARAIA)        | 5.00         | 5.50         | 0.50                    |
| OLD TOWN GASTEIZ         | 3.90         | 1.82         | -2.07                   |
| GAZALBIDE TXAGORRITXU    | 2.40         | 2.80         | 0.40                    |
| IRUÑA DE OCA (NANCLARES) | 0.00         | 0.54         | 0.54                    |
| HAVANA                   | 1.04         | 1.00         | -0.04                   |
| LABASTIDA                | 1.28         | 1.20         | -0.08                   |
| LAGUARDIA                | 0.00         | 1.52         | 1.52                    |
| LAKUA                    | 2.81         | 1.37         | -1.44                   |
| LAKUABIZKARRA            | 2.23         | 2.20         | -0.03                   |
| LEGUTIANO (VILLARREAL)   | 0.00         | 0.10         | 0.10                    |
| OION                     | 2.25         | 2.03         | -0.22                   |
| OLAGUIBEL                | 3.18         | 1.37         | -1.81                   |
| OLARIZU                  | 2.59         | 3.57         | 0.98                    |
| OTXANDIO                 | 2.35         | 4.35         | 2.00                    |
| SALBURUA                 | 1.45         | 1.32         | -0.13                   |
| SALVATIERRA (AGURAIN)    | 3.85         | 3.55         | -0.30                   |
| Saint Martin             | 1.64         | 1.29         | -0.35                   |
| SANSOMENDI               | 4.55         | 4.80         | 0.25                    |
| Urcabustaiz (Izarra)     | 0.00         | 0.10         | 0.10                    |
| ZABALGANA                | 1.77         | 1.59         | -0.19                   |
| ZARAMAGA                 | 2.25         | 1.93         | -0.32                   |
| ZIGOITIA (GOPEGI)        | 1.00         | 2.78         | 1.78                    |
| Zuya (Murgia)            | 2.17         | 2.20         | 0.03                    |
| TOTAL                    | 1.98         | 2.10         | 0.12                    |

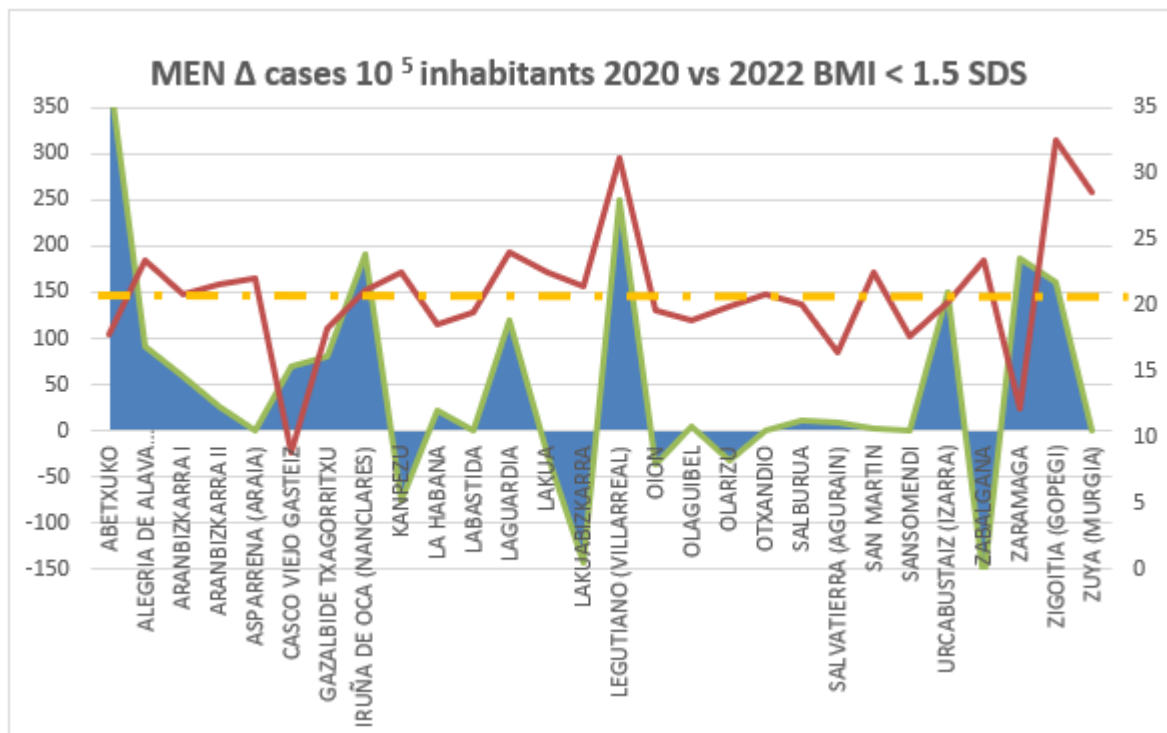
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Assessing the distribution of cases, there has been an increase in these cases, especially at the expense of men (48 cases/10,000 inhabitants). Women contribute another 12/10,000 inhabitants to the total.

There appear to be differences in behaviour between districts, with a general increase observed in almost all of them among the male gender, with more heterogeneous behaviour among the female gender.

Having studied the variables BMI and per capita income separately for each district, an assessment is made of those districts in the territory that present a greater proportion of variation in cases 2020 vs 2022 of people with low BMI in relation to their age and sex according to reference standards Spain – Carrascosa 2010 (4).

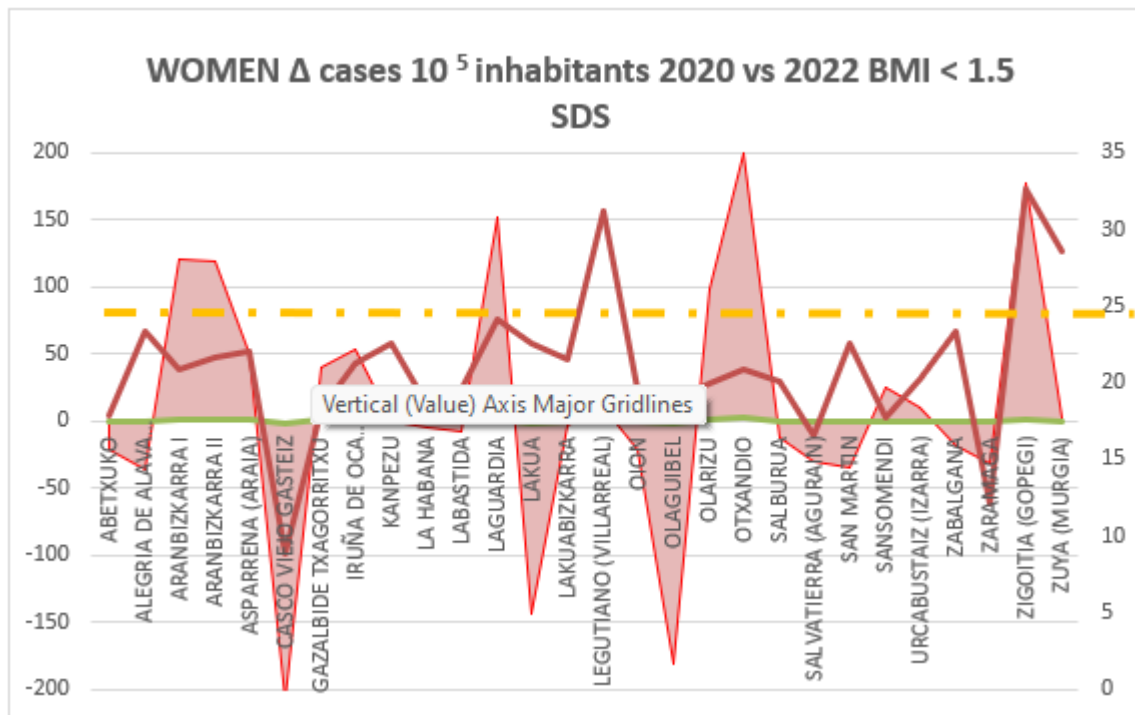
**Chart 2.** Men < 18 years old. Representation of the variation in registered cases with <1.5 SDS 2020-2022 in the BMI variable (blue area) per 10,000 inhabitants vs. per capita income (thousands € per inhabitant/year) (dark brown line) in said district. The orange line represents the average per capita income of the population, which is €19,366.



In the case of men, there is an increase of more than 13 total cases in 2022 compared to those detected in 2020. This means that compared to the total sample, the number of cases goes from 1.57% to 2.02%, which represents an absolute increase of 0.48% overall and therefore 28.66% from 2022 to 2020. This increase is heterogeneous according to the district/neighborhood of the city. There are districts with significant increases and above this average, such as Abetxuko, Alegria, Gazalbide, Legutiano, Zaramaga and Zigoitia. These districts are also mostly above an income per capita above the average for the territory; exceptions are Zaramaga and Abetxuko. Others, on the contrary, show a decrease in the number of cases detected, such as the districts of Kanpezu, Lakua or Zabalzana. These differences between districts and neighborhoods are significant ( $p < 0.05$ ).

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**Chart 3.** Women < 18 years. Representation of the variation in registered cases with <1.5 SDS 2020-2022 in the BMI variable (pink area) per 10,000 inhabitants vs. per capita income (thousands € per inhabitant/year) (dark brown line) in said district. The orange line represents the average per capita income of the population, which is €19,366.



In the case of WOMEN, we find a heterogeneous distribution across the districts.

There is an increase of 3 total cases in 2022 compared to those detected in 2020. This means that with respect to the total sample, the number of cases goes from 1.98% to 2.10%, which represents an absolute increase of only 0.12% overall and therefore 6.06% for the year 2022 vs 2020. This slight increase is also heterogeneous according to the district/neighborhood of the city.

There are districts with significant increases and above this average, such as Aramizkarra I and II, La Guardia, Olarizu, Otxandio, Zigoitia and Zuya. These districts are mostly located in rural areas and are around the average per capita income of the territory; the exception is the area of Zigoitia, with income much higher than the average. Others, on the contrary, show a decrease in the number of detected cases, such as the districts of Casco Viejo, Olaguibel and Lakua; these first two are well below the average income. These differences between districts and neighborhoods are significant ( $p < 0.05$ ).

## DISCUSSION

The possibilities of conducting epidemiological research studies using big data are multiplying, allowing for new strategies in health and healthcare intervention. Machine learning, with proven effectiveness in other fields (14-16) for the interpretation of a large amount of data generated in real life, is emerging as one of the tools to be used.

Somatometry in children in general, as a representation of the state of health; and the problem of eating disorders are a clear example of research opportunities using these techniques.

The effect of the COVID19 pandemic has been discussed by various authors previously (20-21), with various conclusions being drawn about the effects of confinement, social isolation and abuse of new technologies.

The pandemic not only led to an increase in the number of cases (21) but also in the risk of decompensation, suicides and hospitalizations (22) associated with eating disorders.

Other postulated causes are the relationship with the socioeconomic level of the family, the per capita income (23) and even the degree of stress that the presence of one of its members unemployed causes in a family (8-9,11).

UNICEF establishes that a child is considered to be at risk of poverty when the disposable income of his or her household does not reach a threshold that is based on 60% of the median income of all households in the country, also taking into account the composition of the household (11).

In our work we have taken these elements into account and have determined as variables to be studied in relation to a low BMI and that were accessible to this team of researchers, such as the average income level of the district and the immigration rate; the latter as an element associated with a greater number of children per family, lower family income and a higher unemployment rate.

In our work we found that there is an increase in the number

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of cases detected with low BMIs for their age range and sex in both sexes. Due to the methodology itself, these cannot be distinguished between true eating disorders, organic problems or malnutrition associated with the socio-economic situation of the family.

Children and adolescents living in urban areas appear to be more likely to present mental health problems (24-25), as they may be highly exposed to biopsychosocial stressors generated by the pandemic, such as family economic difficulties, limited access to basic services and social contacts, generating anxiety, distress and depression (26-28), in addition to increasing the likelihood of deterioration of family relationships and violence (29-32).

In children and adolescents, it was observed that at the beginning of the pandemic, the prevalent diagnoses were anxiety disorders (33-35), possibly influenced by the knowledge of an increase in the number of infections, fear of getting sick, and facing grief from acquaintances. As the isolation of children and adolescents progresses, psychiatric symptoms begin to appear, due, among other aspects, to the relationship between isolation and loneliness with depressive disorder, social anxiety, self-harm, suicidal ideation, and eating disorders (24, 36-39).

In our work, which includes urban and rural areas, it is detected that the increase in cases in men occurs more frequently in urban areas with greater purchasing power predominantly. On the contrary, in women the greatest number of cases or increase in them occurs in rural areas and an urban area with high purchasing power. This could be related to what has been published, detecting that boys have suffered more in urban areas and districts with less purchasing power; however, the opposite has occurred in girls. This could be due to the fact that men have presented a greater dependence on social relations in urban areas (gang effect) and women in rural areas have suffered more in parallel unlike their male counterparts (26,28,30-32). These differences could be due to the way of relating that both groups, boys and girls, have, especially in adolescence and according to the rural/urban area.

Health resources are scarce and it is difficult to make decisions to determine which subsectors of the population to intervene in, to carry out campaigns or simply to actively search for cases of people at risk of malnutrition. BIG DATA is a quick and inexpensive way to obtain a real picture of the population situation, and therefore to determine where, how and why to invest these scarce resources (15-17).

We note that our study shows that there are situations of risk of malnutrition in our population, with towns, neighbourhoods or districts with an affectation rate of almost 4% of the entire child population in some of these districts.

This requires reflection on the methodology used (39) and the social nature of our population.

However, our work also shows that there may be situations not unrelated to the environment where a child lives that seem to condition his or her situation regarding the recorded weight (8,9,19-20). The relationship between income level, quality (and quantity) in food purchases, the possibility of attending extracurricular, educational, and sports activities (22) and in general the environment where a child grows up also seems to determine the possibility of suffering or not from a malnutrition disorder.

In areas with economic difficulties (11) the risk of child poverty becomes latent. Children from these vulnerable families are more likely to depend on third-party aid, school canteens, NGO support activities or social services (11). They also have less access to recreational, sporting and cultural activities, all of which could contribute to affecting their nutritional status. Child poverty in Spain undoubtedly affects multiple aspects of the lives of children and adolescents, from education to health and general well-being.

In our work we can detect that in urban areas, in the case of boys, the focus should be on detecting cases in urban areas in areas with less purchasing power and in rural areas with greater power. This is the opposite in the case of girls. In addition, our work shows that the increase in malnutrition has occurred asymmetrically, affecting more men than women in the period 2020-22.

There is a risk that there are hidden cases that have not reached the appropriate units and have been detected here during routine health checks.

This team of researchers therefore encourages our authorities to increase their knowledge of these variables and possible socio-demographic causes.

A low BMI can be the result of a situation of malnutrition due to a real lack of resources, or secondary to organicity or an eating disorder.

Knowing how and in what way to act in the face of the risk of a malnutrition disorder (23) allows not only to reduce the associated mortality, but also the number of resources used, such as hospitalizations and emergencies.

The use of big data is and will be in the coming years a first-rate tool in public health (29) in general for decision making in this area; and an opportunity to improve routine clinical practice in the most practical field.

## Biases And Limitations Of The Study

The main limitation of the study is related to the fact that the data used come from electronic medical records and therefore have not been generated for research purposes. Therefore, as described in the literature, errors may occur in the measurement and transcription of the data (Heude B et al. A big-data approach to producing descriptive anthropometric references: a feasibility and validation study of paediatric growth charts. *Lancet Digit Health*. 2019 Dec;1(8):e413-e423).

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The nature of this study allows it to be repeated periodically, detecting areas of improvement in different subpopulations.

## Ethical Aspects

The study has been prepared in compliance with the principles established in the Declaration of Helsinki (1964) latest version Fortaleza, Brazil 2013, in the Council of Europe Convention on Human Rights and Biomedicine (1997), and in the regulations on biomedical research, protection of personal data. Law 14/2007 on Biomedical Research

Study approved by the CEIC on 03/24/2023 with CODE File 2022-058

## Economic Report

The study will be conducted without funding. The tasks described in the project are undertaken by the principal investigator and his collaborators.

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