Nutrition and Health Research Center
Research Protocol
Front of Pack Nutrition Labelling of processed foods for Mexican consumers

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Abstract

Introduction.
Chronic diseases related to diet are responsible for 80% of deaths in Mexico. Front of Pack Nutritional Labelling is a strategy that can contribute to improving healthy food choices among consumers. However, the FoPNL used in Mexico is not understood or used by most of the population.

Objetivo.
To design and evaluate FoPNL systems for processed foods that are easy to understand by Mexican consumers to promote healthy food choices.

Methods
Cross-sectional study with mixed methodology comprising three phases: 1) Design of FoPNL proposals, where the objective understanding and acceptability of current FOPNL systems in Latin America and other regions will be evaluated among Mexican consumers to design labeling proposals adequate for Mexican population, 2)Re-design of labelling proposals, where the objective and understanding of the labeling proposals will be evaluated to make the necessary adjustments, and 3) Efficacy of labeling proposals, where the efficacy of labels to improve healthy food choices will be evaluated using a randomized controlled trial of an on-line shopping simulation.

Expected results
Results will provide scientific evidence on the objective understanding and acceptability of a variety of FoPNL systems, which could be used by decision makers to promote new and better policies on FOPNL in Mexico, as well as researchers to design new research proposals.

1   INTRODUCTION

Non-Communicable Chronic Diseases related to diet, such as, obesity, Diabetes type 2 and cardiovascular diseases, are responsible for 60% of deaths around the world [1]. In response to the increasing trend of the burden of disease associated to diet, international organizations have suggested policies limiting the consumption of fats, sugars and salt as strategies to improve population intake. Front of Pack Nutrition Labelling (FoPNL) is an accepted strategy to provide nutritional information to consumers aiming to promote the informed selection of healthy foods (nutrients to promote or limit), ease comparison between foods from the same food category as well as from different food groups or categories, summarize the nutritional value of a product, provide information about the nutritional contribution of different groups, and encourage the reformulation of food products. FoPNL can contribute in the improvement of population dietary intake and, in the long run, reduce the risk of non-communicable chronic diseases in the population [2-4]. Different FoPNL have been developed around the world. In general, FoPNL can be classified as 1) Specific nutrient systems or 2) Summary Labelling systems (Table 1). Specific nutrient labeling systems show the content of certain nutrients based on the percentage of the daily

recommended value, such as Guideline Daily Amounts (GDA). They can use traffic light colors or words to indicate that a product has high, medium or low nutrient content, declare calories per serving, may contain a symbol based on captions "high in fiber" and in some cases nutrients to limit and encourage appear together, as is the case of multiple traffic light. Another example of nutrient-specific labeling system would be the warning system (such as Chile') that focuses on nutrients to limit.

Summary Labelling Systems provide information about how healthy a food product isby displaying a symbol, icon or score on the food product. In order to assign these symbols, the nutrient content of foods is evaluated using nutrient profiling systems based on cut-off points or algorithms considering different nutrients (positive and negative). Summary labelling systems can be classified as simple or gradient formats. Simple formats, as the "Green Key Hole", are only placed on products with fairly favorable nutritional composition. Gradient formats, as "NuVal", show a gradation of the "healthiness" of foods based on their nutrimental composition.

Current evidence of studies exploring the effectiveness of FoPNL on guidng consumers towards healthier food choices is inconsistent [2]. Most of the studies from European countries suggest that Multiple Traffic Lights are the most effective to increase healthy food selection [5, 6]. However, international research shows mixed results in relation to the ideal FoPNL to guide a healthy food selection [7]. Furthermore, few studies have explored the effectiveness of these strategies in Latin-American and Hispanic consumers [8-10].

Despite the above, different efforts have recently been made to implement a FoPNL in Latin-American countries, being the governments of Chile and Ecuador the leaders in the field [11]. In Mexico, in 2013 the Ministry of Health, launched the National Strategy for the Prevention and Control of Overweight, Obesity and Diabetes, wherein the implementation of a useful and easy to understand FoPNL was contemplated for Mexican population. [12]. Derived from that effort, GDA's were adopted as the mandatory FoPNL system [13]. However, previous evidence shows that Mexican consumers do not understand or use the label to make healthy food choices [14], and understanding of this label may depend on the characteristics of consumers [15, 16]. Additionally, the regulation includes a voluntary "Nutritional Distinctive". This distinctive consists on a summary labelling system that can be placed on food products that meet the established criteria if requested by food manufacturers. In spite of this effort, most of the food industry companies have not requested the distinctive.

The effectiveness of a FoPNL depends on different factors, among which the way consumers perceive the label is one of the most important [2]. Perception is influenced by undrestanding and acceptability of the label [2]. Even though experimental studies provide the best available evidence to assess the effectiveness of FoPNL, qualitative methodologies allow exploring in depth the perception of consumers of FoPNL [17]. The following project aims to extend available evidence related to the ideal FoPNL for Mexican consumers, using qualitative and quantitative methodologies.

Table 1. Classification of Front of Pack Labelling Systems

Labelling Systems	Examples
Specific Nutrients	
Guideline Dietary Allowances	Front of Pack Labelling System in Mexico
Multiple Traffic light	Front of Pack Labelling System in Ecuador Front of Pack Labelling System in England Front of Pack Labelling System in Chile
Summary	
Simple	Green Key Hole, Switzerland Choices International Foundation Program Pick the Tick, Australia and New Zeland
Gradient	Health Star Rating, Australia and New Zeland NuVal, United States
Mixed	
	GDAs+ Health Star Rating, Australia and New Zeland Colored GDA, England

2 BACKGROUND

2.1 FRONT OF PACK NUTRITION LABELLING IN THE PURCHASE DECISION PROCESS

The main purpose of Front of Pack labelling is to help consumers to easily and quickly evaluate the "healthiness" of a food product in the context of a full diet, and to compare nutriment levels in different products.

In their theoretical framework, Grunert and Wills suggest that for a FoPNL to be used correctly during food choice process, consumers are required to conduct a process of searching, exposing and perceiving the information presented on the labels [2]. Consumers' perception about the label will lead to information processing, which might be influenced by the acceptability and understanding of the label [2]. For that reason, both aspects (understanding and acceptability) could affect in an important way the use of the label.

According to Nielsen's conceptual model, (18) acceptability of a nutrition label is determined by different factors, including the liking, attractiveness and perceived cognitive load of the label. Label liking comprises different notions, including subjective preferences of consumers related to the label, or liking the label on the front of the food package. The attractiveness of the label is determined by the ease of identification (as an example, how easily consumers identify the label on the packaging) or perceived trust in the label, which could be improved by scientific or institutional endorsement [14, 19]. Perceived cognitive load refers to the perception of possible format defects that difficult understanding or cause discomfort [20].

Front of Pack labelling understanding can be evaluated using subjective and objective measurements. Subjective understanding corresponds to the extent in which consumers believe they have understood the label. Objective understanding is measured by evaluating the consistency between consumer's understanding and the information provided by the label [2], and provides a more accurate measurement that subjective comprehension, since subjective comprehension is susceptible to overestimation [2].

Strong evidence shows that the use of an acceptable and understood FoPNL by consumers is associated with higher nutritional quality food selection [21]. In this regard, summary FoPNL are perceived as easier to understand in terms of perceived cognitive load, but since attractiveness and liking of the labels seem to be subjective perceptions, these latter aspects differ between individuals and populations [22]. On the other hand, scientific information on the understanding of different FoPNL formats has not been consistent [22]. Thus, most of the studies from European countries suggest that the Multiple Traffic light is the most effective format to increase healthy food selection [5, 6]. However, international research indicates mixed results related to an ideal FoPNL to guide consumers to choose healthy products[7].

In addition, it is not clear how to achieve FoPNL use among consumers with different characteristics [23]. Different factors have been related to the habitual use of FoPNL, such as previous diagnosis of a chronic disease (for example Diabetes), interest in health, attitudes towards a healthy diet, beliefs around the relevance of nutrition labels in guiding food selection, self-efficacy, education degree and nutrition knowledge [23], emphasizing that motivation is considered a key factor for the use of FoPNL. Thus, FoPNL should be

implemented along with dissemination campaigns or education programs to promote the use of FoPNL in population [23].

2.2 FRONT OF PACK NUTRITION LABELLING SYSTEMS FOR PROCESSED FOODS

There are different proposals of front of pack nutrition labelling systems for processed foods. These can be classified in two large groups:

2.2.1 Nutrient specific labelling systems

2.2.1.1 Guideline Daily Amounts (GDA's)

GDA's provide numeric details on the nutrients content of a product in comparison to the nutritional requirements to promote an adequate health for an average person. This system allows the consumer to make food choices based on calculations on the required foods to meet the required amount of nutrients.

GDA's were developed in 2005, based on the 1991 report from the Committee on Medical Aspects of Food and Nutrition Policy (COMA), Daily Reference Values (DRV´s), and a report on salt published by its predecessor, the Scientific Advisory Committee on Nutrition (SACN). Both Committees (COMA y SACN) indicated that reference values were intended as intake targets at the population level for the generation of public health policies and not for individual use. Despite this statement, the Institute of Grocery Distribution (IGD) mentions that GDA's "help consumers to read nutrition information on the label in a context of their total diet" and add that consumers should be encouraged to "know the GDA´s" for each nutrient. Reference Values of GDA's are calculated for an average female adult, with average weight and physical activity level. It does not distinguish between adult men and children, which could lead to wrong interpretations on daily needs for specific nutrients.

In 2005, GDA's were adopted by different food companies and retailers as Nestlé, Kellogg's and Tesco. The most recent version of front of GDA's consists on five cells in a single color showing the amount per portion (defined by Food Industry) and the percentage of GDA's. In Mexico, GDA's are the official FoPNL [13] (Figure 1).

Figure 1. Example of Front of Pack Labelling of GDA's used in Mexico [13] .

2.2.1.2 Multiple Traffic light

Multiple Traffic Light system is a method to identify risky contents for health of some nutrients such as sugar, total fat, saturated fat and sodium (Figure 1). One of the first countries to embrace this system was the United Kingdom, who in 2007 published the technical guide of front of pack consisting on a multiple nutrition traffic light. This guide precises the basis identified by *The Food Standard Agency Board* (FSA) to help consumers make healthy food choices, identifying health risks through traffic light colors: red, yellow

and green [24]. To date, this scheme is voluntary and food industry is not obligated to use it.
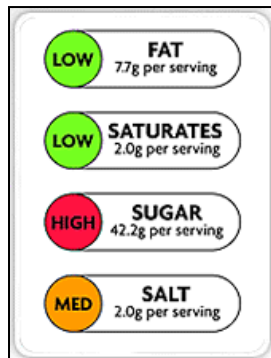

Figure 2. Traffic Light system used in United Kingdom.

2.2.2 Summary Front of Pack Labelling System

These Front of Pack labelling systems use a grading system based on pre-established criteria to evaluate the healthiness of a product. They are classified in two: simple or gradient format.

2.2.2.1 *Simple Format*

Simple Summary Front of Pack Labelling Systems give a symbol to the food products that meet certain pre-established nutriment criteria. There are different labels of this type, including the program "Pick the Tick" in New Zealand (Figure 3-A) [25], the "Nutrient Distinctive" in Mexico (Figure 3-B), or the international program *Choices* (Figure 3-C). Each one of these labeling systems set their own nutriment criteria. As an example, the program *Pick the Tick* evaluates the energy content, saturated fat, total sugar, sodium and fiber products through established criteria.

The Choices program has developed different general criteria for food categories for the content of trans fatty acids, saturated fats, sodium, added sugars, fiber and energy, which are adjusted according the country where are applied [26].
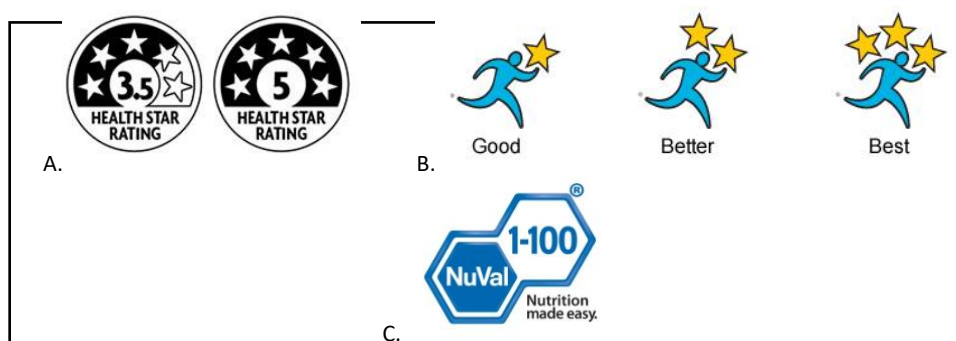

Figure 3. Different examples of Front of Pack Nutrition Labelling Logos A. Pick the Tick Logo in New Zealand. B. Nutrition Distinctive Logo in Mexico C. International Smart Choices Logo

Generally, the symbol is given to the products of food companies that meet the defined nutritional criteria. A license is given to display the logo on the pack of the approved products. Products are analyzed chemically by an independent laboratory of the manufacturer. If the products do not meet the criteria, companies are advised to reformulate the product composition of the product to obtain the logo.

2.2.2.2 Gradient Format

Gradient Labelling Systems evaluate the nutritional content of food products using aa nutritional profiling system and categorize the products from the healthiest to the less healthy. There are different examples of these Front of Pack labelling systems.

In Australia, government recommends the use of a five star system, where more stars indicate a better nutritional composition of the product, called *Health Star Rating* (Figure 4-A)[27]. In the United States, the Institute of Medicine recommends a similar Labelling System of three stars called *Guiding Stars* (Figure 4-B)[27]. In the same country, different supermarkets use the FoPNL called NuVal [28], which evaluates the nutritional content of more of 30 nutriments to promote and limit through the General Index of Nutritional Quality [29] assigning a value from 1 to 100, where a higher value indicates a healthier nutritional composition (Figure 4-C).

Figura 4. Different examples of Front of Pack Nutritional Labelling that use a gradient format. A. Health Star Rating: required FoPNL in Australia and New Zealand. B. Guiding Stars: FoPNL recommended by the Institute of Medicine in the United States.

2.3 Front of pack Experiences in Latin America

2.3.1 Chile

Due to the increase in overweight and obesity in the last decade in children from Chile, their government has taken a series of actions to handle this issue, including regulations for advertising aimed to children and front of pack labelling.(30) Regarding to labelling, article 120 bis, establish that if a meal or food product exceeds the amount of energy, sugars, saturated fats and sodium according to the guidelines shown in Chart 2, must carry a specific label emphasizing the nutritional characteristics exceeded in the product.   (31, 32).

Chart 2. Content of energy, sodium, total sugars and saturated fats limits in food.

Content Limits	Energy (kcal)	Sodium (mg)	Total Sugars (g)	Saturated Fats (g)
Solid Food (in 100g)	275	400	10	4
Liquid Food(in 100 ml)	70	100	5	3
***Decree 13/2015, Ministry of Health of Chile.**				

The development of the proposal of Front of Pack Labelling was recommended by the Ministry of Health to the University of Chile. To do this, researchers used qualitative methodologies (metaplan) and quantitative (point of sale questionnaires) to explore the design and image elements that helped to transmit the message of Front of Pack in a group

of Chilean consumers. Details of this investigation are presented in another document (33). In this way, the final proposal of Front of Pack Labelling consisted on a black octagon with the captions "High in…" for each nutrient that exceeds the established amounts according the guidelines shown in Table 2 (Figure 5).

Figure 5. Captions proposed by decree 13/ 2015, Ministry of Health of Chile.

This regulation came into force in June 2016, so the strategy falls short of results. However, information given in Ministry of Health networks, mentions that this strategy has had positive results since it has improved healthy food selection in Chilean consumers (34).

2.3.2 Ecuador

In August 2014, Ecuador government published an Agreement for the establishment of a mandatory Front of Pack Labelling for all processed food (food subject to technological operations for processing, modification and preservation)(35). The caption considers the content of transgenic statement when they go over 0.09% of the product, and require the placement of references on the components of fats, sugars and salt (sodium) through a red, yellow or Green horizontal bar, according their concentration level, along with the captions "High in…", "Medium in…" or "Low in…" respectively (Figure 6).

Figure 6. Equator Front of Pack Labelling.

The effectiveness of this study has not been evaluated yet, however, a study done in Quito city indicated that the traffic light label has become a Little seen instrument and with Little use according to shoppers.(37)

2.3.3 Mexico

In Mexico, in 2013 the Ministry of Health launched the National Strategy to Prevent and Control Overweight, Obesity and Diabetes, which considered the enforcement of a useful and easy to comprehend FoPNL to Mexican consumers [12]. Due to this effort, in 2014 the Agreement that establishes the GDA system as the required FoPNL in the country was published [13]. From June 30th from that year, all food products in the market –with a few exceptions- must have the Front of Pack Labeling according to the established guidelines.

However, the establishment of this FoPNL format as an official system in Mexico is not backed up with scientific evidence or previous exercises in Mexican consumers. Previous evidence suggests Mexican consumers might not understand or use the label to make healthy food choices [14], and comprehension level of the label might depend on the aimed group of consumers [15, 16]. This way, different civil society organizations have advocated for the revision of the Front of Pack Labelling sustaining that this one does not meet all the recommended criteria by the Pan-American Health Organization for Front of Pack Labelling.(8)

In parallel, the regulation includes a voluntary "Nutritional Distinctive". This distinctive consists in a summary labelling system that can be located on the food that meets the established criteria in the agreement and at the request of manufacturers. Just like the establishment of the GDA's as the official FoPNL, the design of the distinctive was not a result of an exercise based on scientific evidence. Despite this effort, most of the food industry companies have not welcomed the use of the distinctive.

2.3.4 Nutrient profiling systems for Front of Pack Nutrition Labelling of Food

The allocation of the Front of Pack nutrition Label for food is established through different criteria according nutriment composition of the same. These criteria are frequently a result of the use of a *specific nutrient profile*. The *Nutrient Profile* is a tool that allows to classify food depending on their nutrient composition and their contribution to the total diet balance, considering the benefit or risk potential to the population health [38].

2.3.4.1 Uses of the Nutrient profile

Assigning food in a category based on its nutritional content, has many applications besides the front of pack label. A nutritional profile can be used also as a tool to [38]: consumer education, regulating health and nutritional statements of food products, promoting the development of new products and reformulation of the existing ones, formulation of nutrition policies, regulation of advertising aimed to children, among others.

2.3.4.2 Ideal elements on a nutritional profile

In spite of the multiple purposes for which a nutritional profile can be constructed, its development must follow consistent, rigorous rules based on scientific evidence [39]. In these rules, the selection of nutrients to evaluate and reference amounts, the creation of an appropriated algorithm to calculate nutritional density, and the validation of a selected model against an objective measurement of a healthy diet are found. Therefore, every nutritional profile must be [39]:

- ***Objective*** – Based on scientific evidence

- *Simple* – Based on daily values and food portions that consumers can relate to their diet.
- *Balanced* – Based on nutrients to limit and promote.
- *Validated* – Against measurements of "healthy diet". Improve sense of writing.
- *Transparent* – Based on available algorithms and data to the public.
- *Aimed to consumers* – Possibility to guide to better food elections and healthier diets.

2.3.4.3 Characteristics of nutritional profiles

The development of a nutritional profile might consider several methodologies, standards and algorithms. Therefore, it is important to understand the wide range of nutritional profiles available now a day through the following characteristics:

2.3.4.3.1 Nutrients to evaluate

A nutritional profile must take account of the context for which it will be developed. The inclusion of nutrients to evaluate must be based on its importance in public health. There is indicating evidence of nutriments imbalance, and food groups in diet, can increase the risk to develop obesity, associated diseases (cardiovascular disease, diabetes, dyslipidemias, cancer, etc.) of importance to public health [40]. A nutritional profile can be developed based on [41]:

a) **Nutrients to promote.** Generally those deficient in population diet or known for their benefits in health.
b) **Nutrients to limit.** Nutrients consumed in excess represent a health risk. Generally fats, sugars and sodium.
c) **Mixed**. A combination of the above. These systems encourage consumers to consider food as a whole, or the total supply of nutrients, which is more consistent from a diet view point.

2.3.4.3.2 Evaluation system

The nutritional profile can apply specific criteria to evaluate the nutriment content in food by groups or use the same for all. Final score must balance nutrients to promote and limit. This can be achieved by a subtraction or quotient between the two types of nutrients. An example of a balanced algorithm is the Nutrient Rich Food Index [39], where the final score of the food is the result between the score of the nine nutrients to promote and the three nutrients to limit (Chart 1). Later, each food is assigned to a category of a scale of five categories based on this rating.

Another example is the nutritional profile, currently under development, from FSANZ, a derive from the UK FSA profile. This nutritional profile evaluates food to promote (% of fruits, vegetables, nuts, protein and fiber) and limit (energy, saturated fat, total sugars and sodium), giving a score to each one of them.

3 RESEARCH QUESTION

What FoPNL system has the best acceptability and understanding for healthy food selection in Mexican population?

4 JUSTIFICATION

Front of pack nutritional labeling is a strategy that can contribute to increase healthy food choices among consumers and nutritional quality of foods through product reformulation [42,43]. Front of pack labelling is particularly relevant in countries like Mexico, where more than 80% of the burden of deaths is attributed to chronic diseases [44]. Despite the former, the front of pack labeling system used in Mexico is not the most adequate for our population.

Per the latest National Health and Nutrition Survey, more than 75% of Mexicans ignore the number of calories required daily [44]. This information is required to interpret GDA's correctly. This survey also reports that only 23% of the population reads the label, and that only 9.7% uses this information to make healthy choices [44]. In this line, some studies have reported that GDA understanding among Mexican population is poor, even among populations with higher education levels and nutrition knowledge [14-16].

Based on the former, the current front of pack labelling system needs to be revised to identify other labels that could be more effective than GDA's, based on a better acceptability and understanding.

This study aims to fill this gap of knowledge by providing scientific evidence on the acceptability and understanding of a variety of front of pack labelling systems. This evidence could be used by decision makers to design public policies related to front of pack labeling, as well as other researchers to design new research proposals.

5 OBJECTIVES

5.1 GENERAL OBJECTIVE

To design and evaluate Nutritional Front of Pack Labelling Systems for processed foods that are easy to understand by Mexican consumers to promote healthy food choices.

5.2 SPECIFIC OBJECTIVES

1. To design alternatives of Front of Pack Labels that are easy to understand and useful in guiding healthy food choices among Mexican consumers.
    a. To explore how several nutrient profiling systems classify a sample of food products currently available in the Mexican market.
    b. To explore the acceptability and understanding of Front of Pack Labelling Systems used in the international food market in a sample of Mexican consumers living in urban areas.
    c. To identify the graphic and language elements of the labelling systems that facilitate the understanding of the message of the labels towards healthy food selection.
    d. To design Front of Pack labeling proposals considering the graphic and language elements identified in the previous step.
2. To identify which of the proposed labels has the best performance, in terms of acceptability and objective understanding, in a sample of Mexican consumers.

a. To explore the acceptability and understanding of Front of Pack Labelling Systems used in the international food market in a sample of Mexican consumers living in urban areas.

3. To evaluate the efficacy of the two best labelling proposals to promote healthy food choices using an on-line shopping simulation in a sample of Mexican consumers.

6 HYPOTHESIS

A front of pack labelling system that takes into account the graphic and language elements considered by Mexican consumers as relevant for communicating the "healthy" message, will be effective in improving the nutritional quality of food choices during an on-line shopping simulation in this population.

7 METHODS

The study will be a cross-sectional type with a mixed-methods approach, meaning with qualitative and quantitative data collection and it will comprise three phases. Along the three stages, we will work in parallel with a graphic design team and an expert company in consumers researches in order to strength the research team and the resulting Front of Pack Labelling proposals of this Project.

7.1 PHASE 1. DESIGN OF FRONT OF PACK LABELLING PROPOSALS

This first phase of the project comprises three stages. The first stage intends to identify Front of Pack Labelling Systems currently used around the world. During the second stage the acceptability and understanding of the identified Front of Pack Labelling Systems proposals will be explored. The last stage will consist on the design of Front of Pack labelling proposals using the findings of the previous stages.

7.1.1 Stage 1. Identification of Front of Pack Labelling and Nutrient Profiling Systems

7.1.1.1 Review of literature

A scientific and gray literature research will be done to identify the Front of Pack Labelling Systems currently used around the world. From this first search, the research team will select by convenience the Front of Pack Labelling Systems to be explored in the next stage. All Front of Pack Labelling Systems currently used in Mexico and other Latin American countries will be included. In addition, Front of Pack Labelling Systems implemented in other countries that have shown effectiveness in improving healthy food choices will be selected. The final sample of Front of Pack Labelling Systems will not exceed a total of six systems, and will be representative of the main system categories: specific nutrients (for example: multiple or simple traffic light) and summary (for example Smart Choices). The selection will consider labelling systems that evaluate only negative aspects (such as fats, sugars and salt) of the food product, and those evaluating positive (such as fruit, vegetables, nuts or fiber content) and negative aspects.

In addition, a scientific literature research will be conducted to identify the nutrient profiling systems developed to date for the classification of food products based on their nutritional

content. The research team will select validated nutritional profiling systems and whose algorithm is public. The final sample of nutritional profiling systems will include those systems that consider only nutrients to limit as well as those that consider food to promote.

7.1.1.2 Classification of products by nutrient profiling systems

The performance of the identified nutrient profiling systems will be explored using a sample of food products currently available in the food market. The nutritional information of these products was collected as part of another research project included in the main research project. This data base has all collected information from 2014 to 2016

Classification exercises will be performed using STATA version 14.0. The following food categories will be included: 1) milk and dairy products, 2) sugary beverages, 3) salty snacks, 4) breakfast cereals, 5) ready to eat meals. The results will be evaluated by the research team, with expertise in nutrition, and will select the nutritional profiling system that better classifies food based on their nutritional content. Researchers will select three products of each food category. The nutritional content of these products should be different enough as to show a grading, from the healthiest to the least healthy. These foods will be used for the quantitative evaluation of acceptability and understanding of the labelling proposals.

7.1.2 Stage 2. Understanding and acceptability of Front of Pack Nutritional Labelling Systems among Mexican consumers

This stage comprises the assessment of the acceptability and understanding of the Front of Pack Nutritional Labelling systems selected in the previous stage. For that purpose, qualitative methodologies will be used (focus groups) aiming to explore the labels and to identify the graphic and language elements of the labelling systems that facilitate the communication of the central message of the labels. Qualitative methodologies are an ideal option to explore the consumers' perception regarding Front of pack labelling in depth [17]. Also, quantitative tools will be used to complement these areas.

Given that the research team lacks of a marketing background, which is needed to guide the focus groups in order to identify the desired graphic and language elements of the labels, as well as to comply with the timing of the project, focus groups will be led by the company Cuartel General de Comunicación y Estrategia SC (Headquarters of Communication and Strategy PP). The Company, hereinafter so-called Cuartel, has wide experience in marketing research through qualitative and quantitative methodologies. Cuartel has done more than 3000 studies in Communication, Image, Positioning, Use and Habits, Segmentation, Product testing, Proof of concept, Advertising evaluation, Price, satisfaction and loyalty. The Research team of the National Institute of Public Health will supervise the focus groups to ensure the fidelity of the methodology as well as the ethical principles of the research.

7.1.2.1 Participants and y recruitment

Initial contact and recruitment of participants will be done at different sale points, such as convenience stores, mini supers (Oxxo, Extra, 7 Seven), and retail stores located in different points of Mexico City. The selection of the sale points will be done by convenience, and will include those located in AGEBS (the Mexican equivalent for census tracts) classified as of intermediate socioeconomic level (3, 4 or 5) according to INEGI (National Institute of Statistic and Geography) [42].

An initial questionnaire will be used to explore elegibility criteria, including general demographic information (age, sex, information contact), consumption and purchase habits, as well as a series of questions to determine the individual socioeconomic level (Appendix 1). This rule is an algorithm developed by the Committee of Socioeconomic Levels and measures the extent in which the most important needs of households are satisfied by considering eight characteristics or possessions of the household and schooling of the person who most contributes to household expenses. The eight variables are: 1) schooling of the person who most contributes to expenses, 2) number of rooms, 3) number of bathrooms, 4) number of lamps/bulbs, 5)number of automobiles, 6) possession of a shower, 7) possession of a stove, and 8) Type of flooring. As a result, this rule produces and index that ranks households into seven levels, from A (highest socioeconomic level) to E (lowest socioeconomic level).

The questionnaire will be applied randomly with a systematic skip (every 5 consumers) at the exit of the sale point, after a brief explanation of the study objectives and informed consent. Participants classified as typical C or lower C and meeting inclusion criteria will be invited to participate in focus groups (see below).

There will be a total of five focus groups with an average of 5 to 10 participants each, which often buy and consume (twice a week), at least two of the categories of prepackaged meals and bottled beverages of interest for the study (mentioned in section 8.1.1.2) and meet the following inclusion criteria:

- **Group 1:** Men and women 13 to 15 years old that visit the sales point by themselves, with a specific budget to purchase products.
- **Group 2:** Men and women 21 to 23 years old, who visit the sales point at least twice a week, purchase these types of foods and/or beverages, for their own consumption and/or their family.
- **Group 3:** Women, mothers of 3 to 12 year old children who visit the sales point at least twice a week, purchase these types of foods and/or beverages, for their own consumption and/or their family.
- **Group 4:** Men, fathers of 3 to 12 year old children who visit the sales point at least twice a week, purchase these types of foods and/or beverages, for their own consumption and/or their family.
- **Group 5:** Men and women 55 to 70 years old who visit the sales point at least twice a week, purchase these types of foods and/or beverages, for their own consumption and/or their family.

Group 1 participants (Men and women from 13 to 15 years) will be contacted only if they attend the recruitment points accompanied by a parent or guardian. Participants who meet the inclusion criteria will be invited to participate voluntarily in the focus groups, indicating the day, time, place and duration of the event, as well as the incentive they will receive in return for their participation. Candidates who agree to participate in the study will receive at least three reminders via text message or phone call about the date and location of the focus groups. Group 1 participants will be asked to attend with a parent or guardian.

7.1.2.2 Materials to evaluate label understanding and acceptability

The graphic design team will be asked to develop each of the Front of Pack labelling proposals in the following versions:

   a) Amplified option: Labels will be printed out in double letter size to explore the communication elements of each label (information, figures or hard data, texts, typography, colors, iconography, etc.).

   b) Real size: Real size food product dummies will be prepared to evaluate label understanding and acceptability. Dummies will reproduce real food products currently available on the Mexican market. These products will represent a range of foods with a gradient of nutritional quality (for example from the healthiest to the least healthy). Food selection will be done considering the categories previously mentioned and based on the food classification exercise done during the first stage of this phase of the study (section 8.1.1.2).

   Dummies will present all the elements of the frontal part of the package of real products, including other nutritional quality labels (such as nutritional or health declarations). However, other front-of-pack labeling system will be eliminated (for example GDA's or the Mexican "Distintivo Nutricional").

   c) Competitive environment: An image of store shelves or racks will be printed to evaluate the understanding and acceptability in a competitive environment. The image will present real food packages displaying one of the various labeling systems.

   The first focus group to be implemented will also work as a pilot group. Based on this experience the required methodological and time adjustments will be made. Treatment and dedication to this first group will be similar to the rest of the focus groups, including moderation of the focus group, audio and video recording of the session, audio transcription, information analysis and final results.

7.1.2.3 Procedures for data collection

7.1.2.3.1 Qualitative Information

Information will be collected according consumers' perspective using focus groups. Data on the different categories of the processes of interpretation of the label and the decision making on food selection will be collected. These categories were carefully selected considering previous experiences on the design of Front of Pack Labelling Systems [21], as well as the conceptual framework of acceptability of systems proposed by Nielsen (18). The Guide of Topics for the Focus Group is structured according these categories:

 a) Perceptions towards Front of Pack Labelling, food selection and health. Knowledge, attitudes, intentions and behaviors related to Front of Pack Labelling, food selection and health.

 b) Acceptability of the different alternatives of Front of Pack Labelling, both in their amplified size and real size, considering the following items:
   a. Liking of labels
   b. Attractiveness of labels
   c. Cognitive load of label processing

c) Objective understanding of the different alternatives of Front of Pack Labelling, both in their amplified size and real size, considering the following items:
   a. Ability to understand the design elements
   b. Ability to understand the main message
d) Usefulness of the different alternatives of Front of Pack Labelling, both in their amplified size and real size, considering the following items:
   a. Useful utility
   b. Motivational relevance
   c. Message for action
e) Graphic and language elements that facilitate the understanding of the message towards the selection of healthy foods, considering the following items:
   a. Size of the texts
   b. Information
   c. Typography
   d. Colors
   e. Iconography
   f. Ideal Front of Pack Labelling

Focus groups will have a duration of approximately two hours, and will be video and audio recorded in a digital file for its posterior transcription, codification and analysis. Before the focus groups starts, participants' informed consent to participate on the Project and to record the session will be obtained. The informed consent meets the AMAI ethics, information management politics and Cuartel's privacy terms, as well as the guidelines established by the Ethics Committee of the National Institute of Public Health (Appendix 2). Subsequently, the Guide of Topics will be applied for the Focus Group (Appendix 3).

7.1.2.3.2 Quantitative Information

Once the focus group Guide has been completed, a questionnaire evaluating the acceptability and understanding of the different FoPNL Systems will be applied (See Appendixes). The questionnaire has been designed considering the different aspects that determine the acceptability of a system (18), as well as previous experiences recently published exploring acceptability and understanding of a new proposal of Front of Pack Labelling in European consumers [21]. The questionnaire consists of 26 items divided in three sections: 1) Demographic Information. 2) Acceptability of the FoPNL Systems proposals, and 3) Objective understanding of the Front of Pack Labelling.

Acceptability: Participants will be asked to select the label that best corresponds to a series of affirmations. A total of four items will evaluate liking of the label, three items will evaluate the attractiveness of the label, and four items will explore perceived cognitive load.

Objective Understanding. Participants will classify three products according to their nutritional quality, using the different FoPNL systems evaluated. For this purpose, images of three products of the same food category (previously selected during the exercises with the nutritional profiling system) displaying one of the FoPNL will be shown. Participants will classify the products according to their nutritional quality. No other nutritional information will be provided. The classification will be considered correct if all three products are ranked

in the expected order, based on their nutritional quality. The same five food categories used in the exercises of nutritional profiling explained in section 8.1.1.2 will be tested.

Demographic Information. Basic Information of age, sex, occupation, civil status, having children, schooling, interest in health, chronic diseases, as well as the geographical region of the participant using the zip code will be collected. In addition, questions used in the National Survey of Health and Nutrition 2016 will be included to collect information on socioeconomic level. For this questionnaire, the following 8 items will be considered to estimate the level of welfare condition of the participants: flooring, walls and ceiling material, number of rooms for sleeping, water supply, automobile possession, number of household goods (refrigerator, washing machine, microwave, stove, water heater), and the number of electronic appliances (television, radio, telephone, computer).

7.1.2.4 Incentive

At the end of the focus group, an electronic purse of the Walmart group of a value of $400.00 Mexican pesos will be awarded as remuneration for their participation on the Project.

7.1.2.5 Fieldwork

Focus groups will be led by previously trained personnel in leadership of focus groups. Two researchers with wide experience in qualitative methodologies will be involved in the moderation and analysis of the information obtained: one of the researchers will be in front of the group conducting the research dynamics, while the other one will remain behind Gesell dome observing the conduction of the groups, reactions of the interviewees and the whole verbal and not verbal language that us generated. The researcher behind Gesell dome will send notes to the moderator when considered necessary or when an investigator from the INSP considers necessary to investigate into a subject.

7.1.2.6 Data analysis

7.1.2.6.1 Analysis of quantitative data

The analysis will be carried out using the statistical package Stata version 14. Descriptive tabulation of demographic data will be made through an estimation of means and standard deviations (or medians and interquartile ranges in case of variables with non-parametric distribution) for quantitative variables, as well as proportions for categorical variables.

To evaluate label acceptability, the percentage of participants who selected each one of the proposed labels in relation to liking, attractiveness and perceived cognitive load of the label will be calculated. To compare the performance of the label in respect to objective understanding, the percentage of correct responses by labelling system, will be calculated. These ratios will be calculated also by food category and by sub-groups (for example, schooling, sex). The differences by category will be explored using Chi square tests.

7.1.2.6.2 Analysis of qualitative data

Cuartel will use audio recordings to transcribe the complete text of each performed group. Transcriptions will be organized in categories of information, generation units of descriptive, interpretative or inferential meaning that facilitate the analysis and interpretation of the results, first through the analysis and comparison within categories of meaning and later inter categories. Appendix 4 shows the arrays of results to use according to the interest categories

7.1.3 Stage 3. Design of alternative of Front of Pack Labels

Based on the results of previous stages, an image designer will be asked to design three front of pack labeling alternatives considering the language and design elements identified as relevant for front-of-pack labeling. The specific guidelines for the design of these proposals will be prepared by the research team in collaboration with Cuartel.

7.2 PHASE 2. RE-DESIGN OF THE LABELLING PROPOSALS

7.2.1 Stage 1. Exploration of acceptability and understanding

During this stage, acceptability and objective understanding of the labels designed by the reseach team will be evaluated using the same methodology as the previous phase. In other words, qualitative (focus groups) and quantitative (questionnaire) methodologies will be used to evaluate acceptability and understanding of the new proposals of Front of pack labelling.

7.2.2 Stage 2. Re-design of the labelling proposals

The research team will select the two labelling proposals best evaluated in terms of acceptability and understanding. For this purpose, the results of the focus groups and the questionnaire will be considered. If needed, the design team will be asked to work on those aspects of the labels that consumers found unacceptable or not understandable during the focus group, with the aim to develop two revised proposals.

7.3 PHASE 3. EFFICACY OF THE FRONT OF PACK LABELLING PROPOSALS

During the last Phase of the Project the efficacy of the re-designed front of pack labelling proposals will be tested in an on-line shopping simulation.

7.3.1 Design of the study

Three-arm randomized controlled trial without blinding

7.3.2 Participants

Participants will be 18 years old or older, who visit a sales point or retail store on regular basis (at least once a week) to make their food purchases.

7.3.3 Recruitment

Recruitment will be done through the Internet. In order to accomplish the required sample size, a company specialized in internet market segmentation in Mexico will be hired. This company will be responsible for disseminating and promoting the on-line shopping website. The recruitment strategy will be designed by this company based on eligibility criteria and sample size requirements to detect statistical differences between intervention groups (See section 8.3.7)

7.3.4 Intervention

The intervention will consist on an on-line purchase simulation with different labelling systems on food products. Participants will be randomly assigned to one of the three conditions using a randomization program: Control group, (no front-of-pack labeling), Label Proposal 1, and Label Proposal 2. Due to the nature of the intervention there will be no blinding of the intervention.

7.3.4.1 Virtual environment for an online shopping simulation

A supplier will be hired to develop a virtual environment for the on-line shopping simulation. The virtual environment will consist of five components or moments presented

in the following order: 1) Informed Consent, 2) Eligibility, 3) Collection of demographic data and shopping habits), 4) Virtual Store, y 5) Purchase feedback.

1) ***Informed Consent.*** Before data collection, participants will be asked to give their consent to be part of the study through an Informed Consent Letter (See Appendix). Participants will not be able to give their consent until they read all the consent form (scroll all the way down).

2) ***Eligibility.*** Participants will be asked to confirm they meet the established eligibility criteria. (See section 8.3.2)

3) ***Demographic data collection. The same*** initial questionnaire used in Phase 1 will be used to collect general demographic information (age, sex, information contact), consumption and purchase habits, as well as a series of questions to determine the individual socioeconomic level (Appendix 1)*.* Additionally, information on habitual expenses per week at the supermarket will be requested.

4) ***Virtual Shop.*** Participants will be randomly assigned to one of the three conditions of the interventions (no labelling, proposal 1 and proposal 2). Participants assigned to proposals 1 and 2 will receive a brief introduction to the corresponding label before entering the virtual shop. Once in the shop, participants will receive virtual money (equivalent to that reported on their usual spending per week). The virtual shop will emulate a real supermarket with the following sections: 1) milk and dairy, 2) beverages, 3) salty snacks, 4) bakery and cereals, 5) ready to eat meals and 6) checkout. There will be no restrictions on the order of access to the sections or the number of visited sections. Within each section, participants will be presented a variety of real products with a gradient in nutritional quality. The products will display the label corresponding to the intervention condition as well as the nutritional quality of the product. These products will be selected by the INSP research team (from the healthiest to the least healthy). Foods will be presented on shelves (emulating a real supermarket environment) and will have similar costs to real life. The price of the products will be derived from the food data base used in the first phase of the project. Participants will have the possibility to explore the frontal side of each product's package. As in previous stages, the frontal side will have all elements, including other quality labels (for example, nutritional or health claims), except for any other FoPNL system (for example GDA's or the Nutritional Distinctive). Participants will be able to buy as much food as they wish, based on their assigned budget. Once the purchases have been made, participants will proceed to the checkout area to make their payment.

5) ***Feedback purchase.*** Each participant will receive feedback on the nutritional quality of their purchases. Using a nutrient profiling system, the mean nutrtitional quality of the food products purchase will be calculated (see section 8.3.4). Based on this information, the participant will receive shopping tips for the selection of healthy foods based on the nutritional content reported on the back of the package.

7.3.5 Outcome

The outcome will be the nutritional quality of the products "bought" by the participants. Using a nutrient profiling system, the mean nutrtitional quality of the food products

purchase will be calculated (see section 8.3.4). Secondary outcomes will be energy and nutritional content in the shopping kart.

7.3.6 Analysis of the Data

The impact of the two label proposals will be evaluated using a linear regression model, where the outcome will be the mean nutritional quality of the products bought, whereas the independent variable will be the intervention group. The model will be adjusted for the main demographic confounders such as age, sex, civil status, having children and educational attainment and chronic disease. Differences will be considered statistically significant when $p < 0.05$. Analysis will be carried out using STATA version 14.0.

7.3.7 Sample size

Based on previous experiences [46], and considering a significance level of 0.05 and a statistical power of 80%, at least 273 participants per intervention group will be required to detect a difference of 0.3 points in the mean nutritional quality between intervention groups (Figure 7).

Figura 7. Tamaño de muestra necesario para detectar una diferencia mínima en nutrimental.
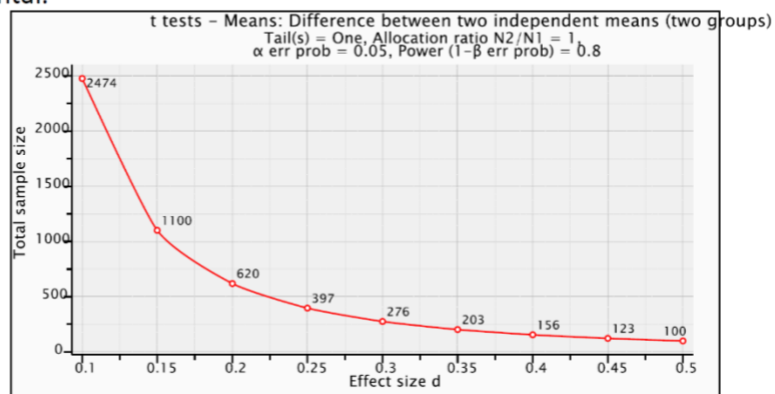
8 ETHICAL CONSIDERATIONS

This research proposal will be carried out considering the guidelines established by the Institutional Research, Ethics and Biosecurity Boards.

A written consent will be requested from all participants for the participation in focus groups, questionnaires and purchase simulations. Participants will receive a copy of the consent form with contact information of the head of the Ethics Committee, in case they have any questions or concerns regarding the project.

Each participant will be assigned an identification number that is not related to any personal information. Information collected as part of the research will remain confidential and it will only be known by the researchers. All field and digital records of focus groups will be kept in the office of the principal investigator, and access will be restricted to researchers of this study only. Audio files will be destroyed once transcriptions and data analysis are completed.

This study will not collect human biochemical samples in any of its three components, it does not imply any biosecurity risks for participants. Regarding ethical aspects, we consider

the proposal implies minimum risks for the participants, since the participants will provide their consent. At all times ethical principles of fieldwork will be respected: informed consent, autonomy and freedom to refuse to participate in the project.

9 LIMITATIONS

The sample for the three stages will not be representative of the Mexican population. Therefore, external validity of the results could be limited to people with similar characteristics of the sample. Nevertheless, previous experiences in Mexico show that understanding and acceptability of the different FoPNL alternatives does not differ by socioeconomic levels. We consider that the information collected will provide relevant information for the design and conduction of future studies in the topic of Front of Pack Labelling.

The use of online tools could have a low response rate, limiting the sample size and consequently statistical power to find differences. However, we have considered hiring an expert company in online market segmentation for the dissemination of the online shopping simulation, as well as through websites with a high traffic of users. By reaching a higher number of individuals we will have a better chance of meeting the required sample size.

The current study will not evaluate the effectiveness of the labelling proposal in a real environment. Therefore, results can only be interpreted as purchase intentions. The evaluation of effectiveness of a FoPNL in a real environment has political, logistic and economic implications that go beyond the scope of this Project.

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