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Marketing and Management

How do Speakers of English as a Second Language in Puerto Rico Interpret Over the Counter Labels

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Problem

The purpose of this quantitative research is to analyze how speakers of limited English as a Second Language (ESL) interpret Over the Counter (OTC) pain reliever drug labels in Puerto Rico.

Objectives

The objectives of the research are the following:

a. To analyze how ESL drug consumers process OTC pain reliever drug labels in Puerto Rico. The four factors that will be considered are dosage, intake frequency, drug interaction, and side effects.

b. To analyze how drug consumers in Puerto Rico process OTC pain reliever drug labels in Spanish using Spanish translation of the OTC labels.

c. To compare the consumers’ Spanish and English interpretation of OTC drug labels.

d. To identify the literacy information of OTC pain reliever drug labels possess that serve to enrich the Puerto Rican consumers’ interpretation of the instructions in English.

e. To explain the literacy information the OTC pain reliever drug labels should possess to satisfy the needs of Puerto Rican consumers.
LITERATURE REVIEW

Health related literacy issues include multi-facet and multi-dimensional scenarios throughout all levels of society (Bourdieu, 1977). This opens the scheme as to how consumer researchers must take into concern the literacy domain of the population they serve (Kirk, et al., 2000).

Fisher (2009) in the article “Family Health and Wellness” explains that generic medications have from 20% to 30% less pain reliever ingredient specially in over the counter drugs. This information is also provided by materials from the US Food and Drug Administration (FDA). This information is not communicated to patients. Pharmacist tends to place the Over the Counter (OTC) drugs next to non generic drug. Fisher highlights some indications written in the label that are difficult to understand such as: dosages, directions, and other information on drug labels. He mentions that if you take too much on OTC medication you will have health problems. It is essential to make sure that OTC drugs don’t interact with any of the prescription medications that a patient is taking. This requires a nation of health literate consumers. In the United States, Over the Counter drug labels are required to be understood by consumers who possess a functional level of the English language (Adkins & Corus, 2009).

Weiss (2001) in his article “Health Literacy: An important issue for communicating health information to patients,” explains that health literacy refers to an individuals’ ability to read, understand, and use the information necessary to obtain
adequate health care information in written form it requires some degree of health literacy. Limited health literacy is a widespread problem in all nations and it is mostly related to efficient reading skills. Deficient reading skills are associated among those with a limited educational background, but considerable research shows that limited reading skills exist even among those who have completed a formal education. Puerto Rico is a commonwealth of the US where English is learned as a second language (ESL). Spanish is the first language used throughout the academia, social, and cultural milieus. Over the Counter drug labels written in English and their interpretation by the drug consumers is a study that has not been performed in Puerto Rico. This leads the researcher to present a review of some of the data found in studies performed in the US and other countries. It is an issue that has become one of interests as OTC consumers and drugs increase at a fast rate.

The advance of OTC medicine terminology has been described as becoming more sophisticated over the years. Natalie Ross Adkins and Cohen Corus in their article “Health Literacy for Improved Health Outcomes: Effective Capital in the Marketplace” mentioned in Sondik’s (2007) article that more than one-third of the US population experience difficulties completing healthcare related tasks such as using charts, interpreting OTC drug labels, and following prescription instructions. The authors also refer to an annual 177.4 billion cost effect as attributed to medication noncompliance to drug information.

Researchers indicate that written material for OTC consumers have not intertwined with the understanding of their medications. Consumers prefer information
that helps them perceive the potential benefits and evaluate the harm drugs could produce (Raynor, 2010).

Mary-Margaret Scholtens, director of the Alternative Programs Providing Learning Experiences Group, mentioned in Raynor’s (2010) article, that scientific statistical has provided sufficient information about group related literacy rate. In her research she reviewed 70 quantitative and qualitative studies on health literacy issues and stated that 50% of American adults are unable to read at an eighth grade level; 46% of American adults cannot understand OTC drug labels; 50% of NASA employees are dyslexic; 60% of American prison inmates are illiterate and 85% of all juvenile offenders have reading problems. Raynor (2010) emphasizes that according to the Partnership of Clear Health Communication Organization, nearly half of all American adults have difficulty using and understanding health related written material. Thus one questions the problem this has on persons reading OTC labels.

A survey of Income and Program Participation quoted from Lee (2004) (Social Science and Medicine) states that Friedland in 1998 estimated that the cost of inadequate health literacy ranged from $30 billion in 1998 US dollars, or approximately 3.2 – 7.6% of individual healthcare expenditures in the United States. Because of the high cost impact the issues on literacy of OTC drugs and other health written materials have gained attention in national and international spheres (D’Alessandro, Kingley & Johnson-West, 2001; Kickbusch, 2001; Nutbeam, 2000; Wang, 2000; Weiss, 2001).

Cohen (2007) in her article “Helping Patients and Families Avoid Inadvertent Acetaminophen Overdose” showed “that of 307 unintentional over doses leading to
hepatotoxicity between 1998 and 2001; 25% of these patients were taking more than one acetaminophen-containing product.” Other examples of unintentional acetaminophen overdose of OTC drugs was reported to the Institute for Safe Medication Practices (ISMP) of particular concern are the 27,000 accidental childhood acetaminophen overdoses reported annually by the American Academy of Pediatrics. Another study performed by Kirk et al. (2000), “Connecting Pharmacy and Literacy: North Carolina Medication Information Literacy Project” involved pharmacy students who evaluated the comprehension of consumer-directed OTC medication information.

The United Kingdom Natural Health Services (NHS) has declared that increasing the number of OTC drugs across the developed world would help a patient to choose which drug to select for ailments. This could benefit the individual consumer. This way health consumer would be empowered in their health treatment. They also stress the fact that governments view OTC medicine as an effective way for shifting the costs of healthcare to the general population in national and international spheres. They conducted a study in 2000 that sought to identify a patient’s interpretation of side effects in relation to OTC drugs. This included a population of 188 volunteers from the general population, from the ages between 18 and 70 years with a large range of occupations and educational levels. The participants were tested by receiving information of the side effects of OTC drugs and a given booklet and pen to describe what they understood by reading the side effect labels. The Statistical Package for the Social Sciences (SPSS) was used. The researchers concluded that there was a need for health literature that explains the action consumers must take when there were adverse life-threatening occurrences.
They also mentioned Germany and Sweden as having their own description of side effects terminology and that these also led to a high estimation of health risk situations. This premise was reached by evaluating the terminology used on OTC drug labels in Germany and Sweden.

Over The Counter medicine has also been studied by Patel, Branck, and Arocha (2002), in their article “Errors in interpreting quantities as procedures: The case of pharmaceutical labels”. They found that subjects of different cultural and educational levels make multiple errors in cognitive processes while comprehending procedural texts on pharmaceutical labels. The subjects in the study were from Canada and Kenyan. Thirty mothers were instructed to read and interpret labels to be used for their children. The researchers took notes of the outcome and observed that when the subjects put into practice their interpretation of the dosage given, 3 out of 15 Kenyan subjects and 2 out of 15 Canadian subjects did not follow the correct dosage provided through the literature of the label. Another study included 878 participants from Kenyan and Canadian patients were given OTC literature to interpret and a comprehension score was calculated based on eleven questions obtained from the participant response form. This study demonstrated that OTC medicines were difficult to interpret by 72% of the subjects.

A national program of the Robert Wood Johnson Foundation “Hablemos Juntos” (Let’s Speak Together), 80% of ESL patients in the US have difficulty interpreting health literacy written information such as OTC drug labels, prescribed medicine, and person-to-person communication between the patient and healthcare personnel. It has been estimated that 12.5% of the US population will be constituted by Hispanics that will
reside in the US mainland. The inability to speak English is significantly relative to healthcare (Levy & Royne, 2009).

Research on health literacy issues, as it pertains to OTC drug consumers, is limited in national and international milieus. From the above discussion of health literacy consumers, one could assume that the development of health literature of OTC consumers in Puerto Rico is a critical issue in the development of a healthy nation.

To explain the previous premises the researcher will rely on Paulo Freire’s theory of literacy and Peter F. Drucker’s view of today’s global economic order. These scholars maintain that (1) the individual constructs and creates meaning through their sense of reality by internalizing signs and symbols in the environment, and (2) in order to bring about improved individual economic and literacy performance, tools must promote the teaching of languages in different international settings.

Learning languages and its pragmatic use relates to the following premises:

1. Growth in literacy occurs through the social event of learning to mean in different situations (Adkins and Ozzane, 2005; Bourdieu, 1992; Dewey, 1960; Luria, 1981; Merleau-Ponty, 1945; Vygotsky, 1936).


Thus one could infer that consumers could be seen as a sign, one that is not static but rather evolves constantly through the empowerment of health related literacy issues (Bourdieu & Wacquant, 1992; Adkins & Ozzanne, 2005).
Research reveals that one of the largest categories of OTC drug consumers is pain relievers. These OTC drugs have influenced consumers by many communication channels including healthcare professionals, pharmacist and advertising (Latta, 2008; Mitchell, 2008; Anderson, 2008). This leads me to research on OTC pain reliever drug labels consumer interpretation in English in Puerto Rico.

**Hypothesis**

1. OTC drug consumers in Puerto Rico will differ in their interpretation of OTC drugs depending on whether the label is written in English or Spanish. The four (4) factors which will be used to interpreted their understanding are maximum dosage, frequency used, drug interaction, and side effects.

2. Puerto Rican OTC drug consumers understanding of drug labels will improve after taking the functional language courses from the PEECA program.

**METHODOLOGY**

**Population**

The sample to be considered from this research is 200 students from “Programa Experimental de Adultos (PEECA), an adult literacy program from the University of Puerto Rico, Río Piedras Campus in San Juan, Puerto Rico. The sample has been classified as limited literate in English and Spanish. The participant’s age ranges from 25 to 40 years old.
Data Collection

The population will be divided into 4 groups, 2 groups will correspond to the population before the 6 month functional language instructions in English and Spanish are given and 2 after. They will be provided with over-the-counter drug labels written in English and have participants write in Spanish their written interpretation of the said labels. Spanish written labels will be given to the participants with the same information and have the participants write their interpretation in Spanish.

The interpretation of understanding English and Spanish labels will rely on the following criteria:

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<tr>
<th>Factors</th>
<th>Understand</th>
<th>Does not understand</th>
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<tr>
<td>Maximum Dosage</td>
<td></td>
<td></td>
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<tr>
<td>Frequency Used</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drug Interaction</td>
<td></td>
<td></td>
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<tr>
<td>Side Effects</td>
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The following illustration represents the data collected matrix:
Analysis

Independent two-sample t-test

Given that the sample sizes it can be assumed that the two distributions have the same variance. The $t$ statistic to test whether the means are different can be calculated as follows:

$$t = \frac{\bar{X}_1 - \bar{X}_2}{S_{X_1X_2} \cdot \sqrt{\frac{2}{n}}}$$

A $t$ table will be used to structure and analyze the findings. Where:

$$s_{X_1 - X_2} = \sqrt{\frac{s_1^2}{n_1} + \frac{s_2^2}{n_2}}.$$  

Here $S_{X_1X_2}$ is the grand standard deviation or pooled standard deviation, $1 =$ group one, $2 =$ group two. The denominator of $t$ is the standard error of the difference between two means. For significance testing, the degree of freedom for this test is $2n - 2$ where $n$ is the number of participants in each group.

Conclusion

Other sources of methodologies as well as hypothesis could be answered using the data collected. For this study the researcher will rely on the hypothesis stated due to the fact that it’s the first study conducted with the consumer population of Puerto Rico.
BIBLIOGRAPHY


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Appendix
Advil® Tablets

Drug Facts

Active ingredient (in each tablet) Purpose
Ibuprofen 200 mg (NSAID)* Pain reliever/Fever reducer
*nonsteroidal anti-inflammatory drug

Uses
temporarily relieves minor aches and pains due to:
headache toothache backache menstrual cramps the common cold muscular aches minor pain of arthritis
temporarily reduces fever

Warnings

Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:
hives facial swelling asthma (wheezing) shock skin reddening rash blisters
If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you are age 60 or older have had stomach ulcers or bleeding problems take a blood thinning (anticoagulant) or steroid drug take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others] have 3 or more alcoholic drinks every day while using this product take more or for a longer time than directed

Do not use
if you have ever had an allergic reaction to any other pain reliever/fever reducer right before or after heart surgery

Ask a doctor before use if
stomach bleeding warning applies to you you have problems or serious side effects from taking pain relievers or fever reducers you have a history of stomach problems, such as heartburn you have high blood pressure, heart disease, liver cirrhosis, kidney disease, or asthma you are taking a diuretic

Ask a doctor or pharmacist before use if you are
under a doctor’s care for any serious condition taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin taking any other drug

When using this product
take with food or milk if stomach upset occurs the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

Stop use and ask a doctor if
you experience any of the following signs of stomach bleeding:
feel faint vomit blood have bloody or black stools have stomach pain that does not get better pain gets worse or lasts more than 10 days fever gets worse or lasts more than 3 days redness or swelling is present in the painful area any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use ibuprofen during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions
do not take more than directed the smallest effective dose should be used adults and
children 12 years and over: take 1 tablet every 4 to 6 hours while symptoms persist if pain or fever does not respond to 1 tablet, 2 tablets may be used do not exceed 6 tablets in 24 hours, unless directed by a doctor children under 12 years: ask a doctor

**Other information**
read all warnings and directions before use. Keep carton or card. store at 20-25°C (68-77°F) avoid excessive heat above 40°C (104°F)

**Inactive ingredients**
acetylated monoglycerides, colloidal silicon dioxide, corn starch, croscarmellose sodium, methylparaben, microcrystalline cellulose, pharmaceutical glaze, pharmaceutical ink, povidone, pregelatinized starch, propylparaben, sodium benzoate, sodium lauryl sulfate, stearic acid, sucrose, synthetic iron oxide, titanium dioxide, white wax

**Questions or comments?** call toll-free 1-800-88-ADVIL
LBL Document Number: LBL-00000027 (Version 31.0)
Lea cuidadosamente este folleto antes de la administración de este medicamento. Contiene información importante acerca de su tratamiento. Si tiene cualquier duda o no está seguro de algo pregunte a su médico farmacéutico. Guarde este folleto puede necesitar leerlo nuevamente.

1. Composición:
Cada comprimido recubierto contiene: Paracetamol 500 mg

2. Clasificación:
Analgésico Antipirético

3. Indicaciones:
Panadol Adultos contiene paracetamol que es un analgésico y antipirético.

4. Usos:
Panadol Adultos es efectivo para:
§ El tratamiento del dolor leve a moderado incluyendo: Dolor de cabeza, dolor de garganta, dolores musculares, fiebre y dolor después de una vacuna, dolores dentales, alivio del malestar de la gripe y del resfrío.
§ El alivio de la fiebre.

5. Contraindicaciones:
Contraindicado en personas con hipersensibilidad conocida al paracetamol o a algún ingrediente de la composición.
No debe administrarse a personas que sufran de enfermedad hepática o renal grave.

6. Efectos adversos:
Cualquier medicamento puede producir algunos efectos no deseados además de los que se pretende obtener, especialmente si se toman por un periodo prolongado de tiempo y/o en grandes dosis.
Panadol Adultos en general es bien tolerado, alivia el dolor sin producir acidez.
Sin embargo, si cualquiera de los síntomas siguientes aparece deje de tomar el medicamento y consulte al médico: Síntomas de alergias (ronchas, hinchazón, picazón), ojos o piel amarilla, diarrea, pérdida del apetito, náuseas, vómitos o deposiciones con sangre.

7. Advertencias y precauciones:
   a. No administrar con otros productos que contengan paracetamol, podría producir una intoxicación por sobredosis.
   b. No administrar más de 4 g diarios. La ingestión de una dosis superior a la sugerida puede producir náuseas, vómitos y dolor abdominal. En estos casos debe ir a un centro asistencial. En todos los casos de sospechar una sobredosis debe consultar al médico aún cuando no se presenten síntomas.
   c. El consumo excesivo de alcohol se debe evitar durante el tratamiento con Panadol, ya que el consumo simultáneo aumenta la posibilidad de toxicidad hepática.
   d. Embarazo y Lactancia: Consulte con su médico si puede tomar este medicamento.
   e. No administrar por más de 5 días en caso de dolor, por más de 3 días en caso de fiebre y por más de 2 días en caso de dolor de garganta. El uso prolongado y de altas dosis de paracetamol puede provocar severo daño hepático.
   f. Si está tomando este medicamento para el dolor de garganta, pero éste empeora, se acompaña de fiebre, es muy intenso o dura más de 2 días, se debe comunicar con su médico a la brevedad posible.
   g. En caso de ser diabético, mencione que está tomando este medicamento antes de efectuarse un examen de azúcar en la sangre, ya que el paracetamol puede alterar los resultados.
   h. El efecto de un medicamento puede modificarse por la presencia de una enfermedad, dando lugar a efectos no deseados, algunos de ellos severos. En caso de sufrir alguna enfermedad Ud. debe consultar al médico antes de ingerir este medicamento, especialmente en los casos siguientes: Problemas cardiacos, renales o hepáticos.
   i. No administrar a niños menores de 12 años sin antes consultar dosis al médico.
   j. Mantener a temperatura ambiente y fuera del alcance de los niños.

8. Interacciones:
   Como todo medicamento puede modificar el efecto de otros fármacos, por lo que se recomienda consultar al médico si está en tratamiento con otros medicamentos. Las drogas inductoras de las enzimas hepáticas (como por ejemplo anticonceptivos orales, propanolol, fenobarbital, fenitoína, carbamazepina) y alcohol pueden aumentar la hepatotoxicidad del paracetamol. El efecto anticoagulante de la warfarina y de otros anticoagulantes cumarínicos, puede verse aumentado por el uso diario, regular y prolongado de paracetamol, aumentando el riesgo de sangramiento; dosis ocasionales de paracetamol, no tienen efecto significativo. Debe leer la composición de otros medicamentos que está usando puesto que si alguno de ellos contiene paracetamol podría producir una intoxicación por sobredosis. En caso de requerir atención médica por otras razones no olvide mencionar que está tomando este medicamento.