

## **Process to implement new medicine guideline in Mexico**

This discussion paper describes the process to implement new guidelines in Mexico for medicine instructions/labelling centred in the user. The paper is divided into four sections: 1) the information design process developed by the Communication Research Institute (CRI) applied to a children's analgesic, 2) the seminar taught to pharmaceutical personnel, to regulatory officials and designers working at the laboratories, to convince them that a new way of approaching medicine instructions could be used, 3) the adjustment of CRIA's guidelines to the Mexican situation, and 4) conclusions. The paper also includes the proposal of a specifications table developed by the Centre for Advanced Studies in Design (CEAD) that comprises overall information for the designer about medicine instructions, It includes the whole process, from the identification of the correct medicine, to its use and disposal. The article ends with a critical analysis of the information design process used. *medicine insert, textual structure, graphic presentation.*

## **Introdução: implementation of a new code of ethics for over-the-counter medicines in Mexico**

2006 was a year of changes in Mexico: the struggle among three political forces to win the presidential elections was the main topic; every move, every decision was questioned thoroughly; every discussion was looked through a magnifying glass and used for political purposes. In the midst of this political turmoil, a great effort towards a better regulation of over-the-counter (OTC) medicines was taking place. The new code had to be signed before the possible change of the party in power could take place.

The process started three years before, through the association of different institutions with different interests in favour of the medicine consumers' well being. The Mexican Association of OTC manufacturers (Afamela) approached a group of experts that have been very active in Australia promoting the change of medicine instructions into clearer and better understood explanations. A relationship between the Medicine Labelling Group (an international organization, MLG), the Communication Research Institute of Australia (CRIA), —directed by David Sless—, Afamela, and the Centre for Advanced Studies in Design ([CEAD], an Information Design studio from Puebla, Mexico) began. This relationship ended successfully when the code of ethics and the guidelines were signed by the Mexican authorities in 2006. These documents were focusing on providing users with correct instructions for medicine use.

### **Over-the-counter medicines**

The over-the-counter medicines are referred to those medicines that do not need any medical prescription and that can be bought in any pharmacy or shop. The economic importance of these medicines is such that in 2007, 1700 millions US dls. were spent in OTC medicines in Mexico, covering a variety of 600 different products and recommended for 42 different illnesses (Bolaños, 2008). Besides, Mexico is one of 11 countries of pharmaceutical industrial volume (Kerlegand, 2003) in the world. This large amount of medicines consumed requires clear instructions for correct use and administration.

## **I. Information design process. First step**

One of the leading manufacturers of paediatrics analgesics in Mexico wanted to be the first laboratory to launch the new type of instructions and become an active participant of this change. CEAD was in charge of applying CRIA's design process (Sless & Shrensky, 2005; Sless & Wiseman, 1998) to improve the effectiveness of this medicine label.

The process consists of six steps that considers an overall view of the elements of the design problem centred on the user, the product, the legislation, the design label, and above all, testing the label with the final users. The stages of this process are:

### **1. Scoping**

Knowing everything related to the product and its context, as well as the functional analysis of the label; this means deconstructing the label to find out how each element is communicating with the user. This stage also includes the analysis of the different products that compete with the one under study. Designers can learn a lot from competitors, knowing how they are communicating and how they are improving their labels.

### **2. Benchmarking**

Consists of applying a diagnose test of the actual state of the medicine label and learn whether users can find and understand instructions to use it adequately. A quantifiable-qualitative research is developed that looks for 'deep and extended psico-emotional information, that is used to explain personal perception and the reasons that sustain attitudes and behaviours of a determined audience or group of people'. The qualitative study consists of in-depth individual interviews (Villegas & Covarrubias. 2003), observation of users interacting with the product and observations of the users' context; people interviewed that 'not only answer, but they are, make and share'. Sless suggests a sample of 10 participants, since he has confirmed that within the first 8 interviews the same label mistakes repeatedly appear. 'This number of participants not only helps in identifying problems, but also offers enough information to consider possible solutions'.

The label is tested with a specially designed question protocol that finds out whether participants can find and understand information to make good use of the medicine, from the moment they choose and identify the product, to the moment they dispose the product. Before testing, Sless establishes a minimum level of performance for Australia of 81%. This number results from: 90% of participants should find information, and 90% of them should understand the information to use the medicine easily and correctly, which results in 81% level of performance ( $.90 \times .90 = .81$ ).

### **3. Prototype development**

The label is modified to transform the weaknesses and mistakes found in the diagnose testing into well-understood and clear instructions. These modifications respond to the information and opinions of users' interactions with the label, observations and ideas of the interviewers and suggestions from medical doctors and health specialists.

### **4 and 5. Testing and refinement**

The redesigned label is tested again with the same type of users and with the same protocol to verify that at least 81% of the performance requirement was achieved. If not, further modifications and testing should be done until the required efficiency level is obtained.

## 6. Monitoring

Every label should be periodically monitored to verify that efficient performance is achieved.

Sless introduces a unique concept for testing related to those users who have problems understanding information; he refers to them as 'users at risk'. If a vulnerable group or 'user at risk' with physical, social, cultural and/or educational weakness can read and understand information, then the rest of the population can.

Applying CRIA's process, CEAD redesigned the paediatric analgesic label, following each step carefully and thoroughly, and testing it among a population of medium low and low socio-economic levels (C, D and D+). Many of the participants were considered as 'users at risk'. In this text, the author will only concentrate in some design issues of the label and the presentation of the information to the Regulatory Authorities<sup>1</sup>.

### **Application: analysis and redesign of an old Mexican Paediatric analgesic's Label**

#### **Analysis of an old Mexican Paediatric analgesic's Label**

The best way to become aware of the interaction problems that users have with medicines is through diagnose testing. Observing how people look for information, how they struggle to understand the correct dose, what are their comments about habits and myths on health issues, what words are difficult to understand, etc, give designers a range of insights on how to solve an information design problem.

Through 30 interviews-at-depth —10 interviews for each medicine presentation— with mothers with children age 3 months-12 years old of medium and low socio-economic level, CEAD found various problems in the label. Those related to information organisation and language use will be explained in this text.

#### *Problems of content and organization of information*

The most important problems found were:

1. Information with similar topics was distributed within different sections of the label, e.g. information about kidney and blood problems was repeated with different words under various headings:

- Precautions: 'In patients with kidney or renal damage, consult your doctor'

- Secondary reactions: 'it can produce alterations in kidney or blood'.

2. The label did not explain thoroughly how to administer the medicine. Mothers could not easily tell how much medicine they should give their child. This was a very delicate issue because the pharmaceutical laboratory was modifying the drug concentration and also wanted mothers to administer the medicine by checking the weight of the child. The introduction of a new label would help people realise that it was not the traditional medicine they were used to and that they would need to read the label.

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<sup>1</sup> For further information on the complete process applied to the redesign of the paediatric analgesic label, see González de Cossío, M., 2008 Nuevas etiquetas de medicamentos para apoyar la automedicación en México. El caso de un analgésico pediátrico (New medicine label to support self-medication in Mexico. The case of a children's analgesic) Salud Pública de México, vol 50, special issue (forthcoming).

Through the interviews CEAD found out that people would find the adequate dose through the child's age information.

3. This analgesic carried three different presentations regarding age differences: drops for children 2 months-2 years old; solution for 1-8 years old; and tablets for children 2-7 years old. However, the label did not inform about these presentations; when CEAD visited the drugstores and pharmacies in suburban areas, found that only the tablets—which is the traditional presentation that has been in the market for more than 6 decades— were shown at the counter. The other two presentations were rarely sold and were therefore kept inside the shelf. See image 1.

### Old label of the pediatric analgesic



**Image 1.** Old label of the pediatric analgesic. The difficult words used, the pink background, the white upper case type, the difficult organization of the text were factors that contributed negatively to the legibility and comprehension of the medicine instruction.

#### Problems of language use

Complicated language and unfamiliar terms was the most common problem of the label:

- The label had 15 complex and technical words that were difficult to understand. For example, hypersensitivity (changed into 'very sensitive'), renal (changed into 'of the kidney'), hepatic, contraindications (people thought it meant contradictions), anti-pyretic, over-dose, paediatrics, etc.
- The label used abbreviations not understood by users at risk, such as ml, mg, kg.
- The label had a help-line with a 0-800 free telephone line. However, several people did not understand they could call without any charge.

### *Problems of layout*

Problems related to the distribution of elements within the label were of various types. Information was distributed in a limited space causing reading difficulties.

- The long text was compressed into a narrow space
- The text had no separation between paragraphs
- The forced justification of the text altered space affecting rhythm and reading speed
- The very small font had legibility problems
- The text was not organized under headings
- The lack of colour contrast, white text on background with pink gradation interfered while reading

### **Redesign of the paediatrics analgesic label**

The modifications of the label solved the problems found in the diagnose testing. The redesign included:

1. Difficult or technical terms were substituted to simpler and everyday life words, as follows:  
hypersensitivity changed into 'very sensitive'  
renal changed into 'of the kidney'  
hepatic changed into 'of the liver'  
contraindications changed into 'precautions'  
anti-pyretic changed into 'fever relief'  
over-dose changed into 'took too much'  
paediatrics changed into 'children's', etc
2. A section was especially devoted to *How to administer the medicine*<sup>2</sup> (M), using a numbered list of steps that the mother had to follow. Here is the example of the new 'tablets' label
  - 2.1 Look for the dose according to the child's weight. If you do not know it, check the age.
  - 2.2 Make the child chew the tablet.
  - 2.3 If necessary, repeat the dose every 4 hours, but no more than 4 times per day.
  - 2.4 Do not use M for more than 3 days.
3. A new section was included for the different age presentations of the analgesic. Those abbreviations that were of interest to the user were changed into familiar terms, e.g. kg was substituted by kilos.
4. Text was organised into lists and under simple headings (Hartley, 1994) such as:

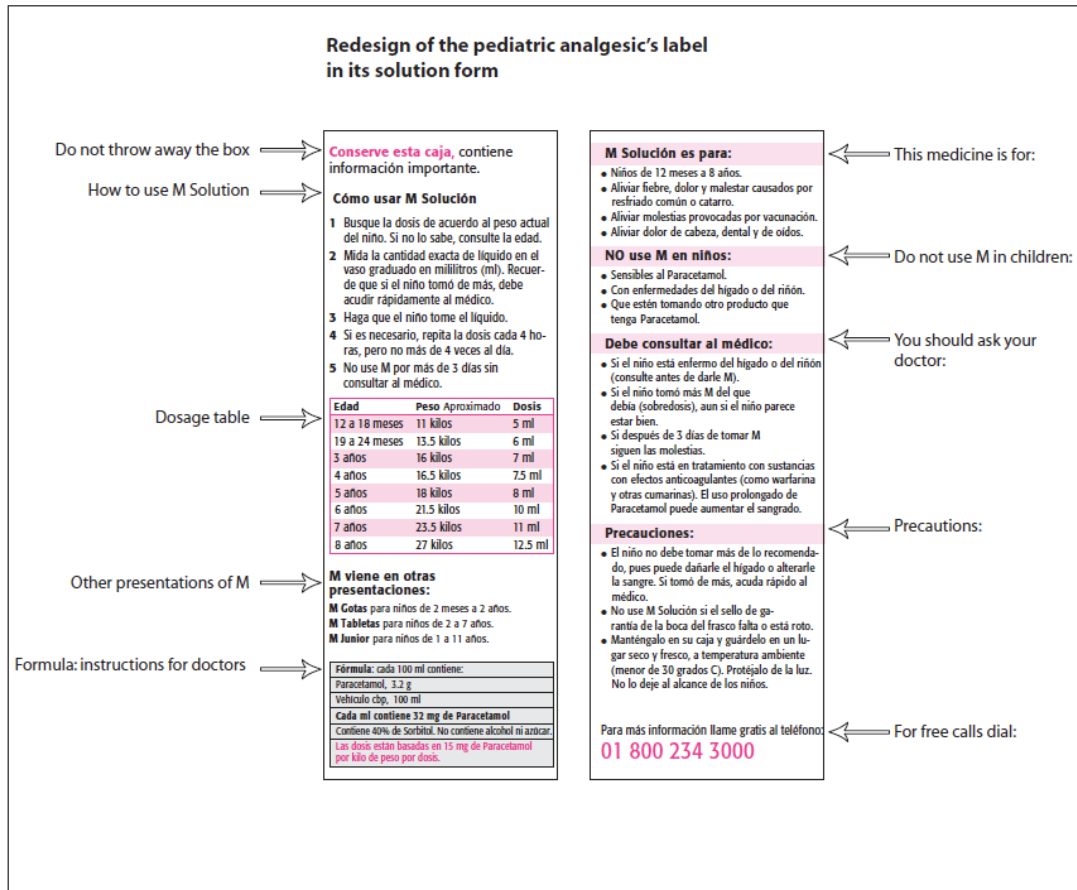
Use M when:  
Do not administer M to:  
How to use M:  
When to consult the doctor:

<sup>2</sup> Hereafter the paediatric analgesic will be addressed as 'M'.

5. Each heading was clearly differentiated by colour and bold type face

6. Formata was chosen as a legible type family that has various possibilities of weight, case and proportion. Formata is also economical and its condensed version does not lose its legibility. Text was aligned left to avoid wide spaces between words.

7. The coloured pink background was changed into white and the text in black, which helped legibility. See image 2.



**Image 2.** Redesign of the pediatric analgesic in its solution form. Some of the graphic changes are shown; the organization of the text can be appreciated through the headings, use of bulleted lists and the change of background colour.

*Outcome of M label redesigned*

CEAD's redesign of the label of the paediatric analgesic rose 145% the performance level, from 29.5% to 72.4%. It is interesting to mention that this rise can be due to two factors:

- 1) The layout of the label improved the localization of information —without difficulties— from 50% to 83.7%, and
- 2) The language used in the new label helped achieve a better comprehension of the text; the rate of understanding improved from 50.4% to 86.5%. The simpler/familiar language in the label is quite different from the baroque words and the medical terms typically used in medicine labels.

### *Formal presentation to the regulatory authorities*

The presentation of the redesigned label to the regulatory officials had to be clear in such a way that the pharmaceutical laboratory could demonstrate officials that the new label followed the legal requirements, and that this new way of presenting instructions was clearer to citizens who could read and write. For that purpose, CEAD presented a table that stated how each element of the new label complied with each specification. The table included each text of the previous label, the proposal of the new text and the modifications applied. This presentation allowed the officials to analyse each change and to verify that requirements were fulfilled.

### **Some deviations from CRIA's process**

Some differences were found while applying this design process, rooted in the Australian context, into the Mexican reality:

This process is a good tool to redesign medicine labels. However the 81% performance level chosen for Australia was not applicable to the Mexican context. CEAD proposed reducing such percentage to 72% because of the different level of education in terms of literacy<sup>3</sup>, and also in terms of health literacy. A significant amount of the Mexican population is not used to reading in their every day life; reading requires understand the word, check whether it is in their lexicon, and make sense of the word within the text. Reading requires extra effort because it is not practiced often and implies cognitive overload to many people. If medicine instructions present difficult words in difficult layout, reading is quickly discouraged.

Another factor closely related to reading was the large number of functional literates<sup>4</sup> in Mexico. When interviewing, basically mothers, CEAD realised that many of them could read, but they could not understand what they were reading. Their interpretation of the text did not show full understanding.

When CEAD went through scoping and benchmarking, the first two stages of the process worked at the same time, realised that it was impossible to establish a level of performance without knowing and being in touch with the real educational situation of users and users at risk in Mexico.

CEAD also found that some myths of users, nurses and some doctors were interfering with medicine instructions. For example, nurses indicate mothers not to give an analgesic to their children when they had vaccination administered, because the analgesic reduces the vaccination's effect; or people have the tradition to give this medicine to their children by smashing half of the adult's tablet and dissolve it with water. The new label could emphasise in some of these issues, such as the ingestion of M when vaccinating the child. However, it was impossible to address beliefs that are installed in people's life and solve them through the redesign of a medicine label.

The 72% level of performance initially proposed by CEAD for this medicine, was later on applied to the Guidelines for OTC medicines in Mexico, due to the factors mentioned before.

## **II. Spreading the process. Second step**

Once CEAD acquired experience in information design process for medicine instructions, a seminar was taught to pharmaceutical specialists, for designers who worked in the laboratories and for government officials who worked in regulatory affairs. Three types of seminars in three different moments and time were offered. The first one consisted of one-week intensive workshop taught by David Sless and two members of CEAD. The workshop was divided into theoretical and practical issues of CRIA's method and the application to Mexican products. Different kinds of participants attended and reacted in various ways: from the sceptical person to those very interested in helping people understand medicine instructions. A particular exercise

<sup>3</sup> Health literacy means "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions" (Selden et al. 2000).

<sup>4</sup> Functional literates have been defined as those individuals who have had the chance to get the basic criteria when reading a text in a superficial level, but that they cannot traspas the deep level of the message behind the text.

severely. They became aware of the importance of legible and understandable instructions for good product use. It was important to bring people out of their own discipline and become a helped them realize how instructions are important when a consumer interacts with any kind of product. Participants had to face instructions of products such as cleaning liquids, insecticides, washing products, etc. Several of them could not follow the instructions and criticised them consumer like everybody else. This activity, among other exercises, showed them that 'perhaps consumers did not understand their products' labels.

Two months after the first seminar took place, a second seminar was organized that should have lasted four weeks. The purpose of the second seminar was to guide participants in developing their own medicine label. However, it did not work because it was difficult to gather the group again, since participants were very close to their place of work and easily distracted.

A third seminar was then implemented during eleven weeks. CEAD supervised the work of each group of participants who met once per week to show the progress of the design process. They worked for five different over-the-counter medicines that were specially chosen because of their different therapeutic properties: an antacid (Alka seltzer), a women's antifungus (Gyno-daktarin), a compound of vitamins (Stresstabs), a stomach ache reliever that changed from prescription medicine into over-the-counter product (Buscapina) and a skin cream with cortison (Vioformo-cort). The variety of products allowed exploring different kinds of problems; participants were grouped in interdisciplinary teams —because they came from different professional backgrounds, either government or private pharmaceutical laboratories—, and worked together during eleven weeks.

The seminar ended with their projects presentation to the highest regulatory officials and to pharmaceutical laboratories. The seminar helped to promote the new [voluntary] regulation because the two parties —government and laboratories— understood that clearer labels would assure responsible and correct self-medication.

### **III. Guidelines translation and adjustment. Third step**

Once government officials became sensitive enough to this problem, CEAD translated CRIA's guidelines and added the differences between Australia and Mexico so as to adapt and transform the guidelines as best as possible to the country. CEAD also proposed an additional new element, not used by CRIA, which the pharmaceutical laboratories were eager to use and apply. CEAD proposed a table that summoned up the different alternatives proposed at the seminar and that showed the different ways to express the same legal issue. The table is divided into 5 sections and faces of the package:

1. How to identify and choose
2. How to use
3. How to keep
4. How to dispose
5. General considerations of text organization such as organization of information and layout, and legibility and comprehension of language.

The table included examples taken from the projects worked by each seminar group and by CEAD. This table is now used by the Association of over-the-counter medicines, Afamela. See image 3.



### Principles of Effective Labelling

To identify and choose			
Mexican Regulation	Indications	Possible headings	Examples
1 Generic name	1 The medicine label should indicate the generic name of the product		Calcium   Paracetamol   Vitamin D
	2 The medicine label should indicate for which symptoms can be used.	[Name of product] is for: Use [name of product] to relief pain:	For relieving from pain and flu
To use			
Mexican Regulation	Indications	Possible headings	Examples
Information on warnings and precautions	The label should indicate which precautions should have the patient when using the medicine.	Do not use [name of product] if When NO to use [name of product]	Do not use this product if you are taking anticoagulants like warfarin Do NOT use [name of product] if you have had:
To keep and store			
Mexican Regulation	Indications	Possible headings	Examples
Information on safe places	The label should indicate how to keep the medicine.	How you should keep [name of product] Keep [name of product] in	Keep the medicine in a dry and fresh place, not more than 30 degrees C and out of the reach of children.
To dispose			
Mexican Regulation	Indications	Possible headings	Examples
Expiration date	The label should indicate the expiration date in a printed form.	Due date:	Due date: 3 December
General considerations of text organisation			
Topic	Indications	Examples	
Organization of information	Information should be organised in sections, with distinguishable headings that direct the user's reading.	How it should be taken Take one tablet per day with half glass of water after the main meal. Do not use it for more than 30 days.	

**Image 3.** This table shows the official regulations, the indications suggested to provide easier instructions, and examples of each one. Only one example of each section is presented for either the front face or the lateral face of the box.

On October 3rd, 2006, the Code of Ethics and the New Guidelines, were signed in Mexico City in a voluntary basis. This was the first step towards new regulation centred in helping consumers become responsible in self-medication; it meant that pharmaceutical laboratories and government officials were supporting a significant change in the use of over-the-counter medicines.

## Conclusion

CRIA's methodology applied by CEAD to the Mexican context was a good tool to redesign medicine labels. The significant improvement of the level of performance of the paediatric analgesic (145%) yielded an efficiency level a little higher than the 72% established. This is remarkable, because of the low socio-economic level that uses this medicine, without reading habits or health culture, with myths coming from families, nurses or physicians and the alarming amount of functional literate people. It is interesting to observe that this improvement is due to the layout modification as well as the change to comprehensible language from 29.5% to 72.4%. This was an important step towards responsible self-medication. However, this is only the beginning. The *Guidelines for Effectively Useful Labels for OTC Medicines in Mexico*<sup>5</sup>, approved on 3 October 2006 should be completed with the various experiences of each new label designed with a user centred method like CRIA's. Clear labelling, legible and understandable can offer information, but it does not solve self-medication among users who do not read labels. However, health education might be supported by means of advertising campaigns that insist users on 'reading instructions of how to use a medicine before administering it'. These actions, plus redesigning (and testing) medicine labels would be important steps to support correct use of OTC medicines in México.

<sup>5</sup> Official name given by the pharmaceutical and government authorities to the guidelines for information design medicine labels.

## Critical analysis and on-going project

A great deal of research is dedicated to health functional literacy, particularly because of economic reasons<sup>6</sup>; if a patient does not understand when reading medical instructions, his/her medical treatment might not be successful. This has economic implications because the treatment may last longer or it may affect his/her health, or a more complicated treatment might be necessary. Some specialists (Chez, 1999) rather programme an instructions session so the patient with literacy problems can understand fully the medical indications.

There are two issues that the author thinks that have to be carefully studied when applying information design to medicine labels, and that CRIA's method does not consider.

The first one deals with the question of how to know that a user is at risk, or that a user is functional illiterate. Most patients deny having this problem because they are embarrassed or feel guilty about this situation (Scudder, 2006; Wilson, F.J., 2003; Chez, 1999). When working with the children's analgesic, those people who were users at risk were detected when interacting with the medicine, not before. This changed the statistics because in the first diagnose testing or benchmark, a larger number of functional illiterate people were interviewed, whereas in testing the redesigned label, fewer people were users at risk or were functional literate. CEAD could not recognise before testing because it is a situation that an interviewer finds out while asking questions. Therefore, the author thinks it is important to develop a procedure to find out about users at risk or functional illiteracy before testing or before the quantifiable part of the test.

A second issue found by the author is the need to study thoroughly the so called reading strategies. If one analyses the six different labels that were produced under this process, developed or guided by CEAD, all of them have similar characteristics in terms of language and layout. Most labels depend on the fact that readers follow a heading and a list. If users miss reading the heading, they may lose important information that can even have health repercussions. For example, if a heading is a negative statement, such as 'Do not give this medicine to' and a reader misses reading it, they might make an incorrect decision. This is an important issue that has to be addressed, not only for labels designed in Mexico, but labels designed in other countries as well, regardless of their cultural context. The amount of literature written on this issue reflects the existence of the problem. Most literature is not related to medicine instructions, but this is an application where health and perhaps life depends on. See Hartley & Trueman, 1985; Kirsch & Mosenthal, 1990; Lorch & Lorch, 1996; Klusewitz & Lorch, 2000.

These two issues are questioned and under study; results will be reported soon.

## References

- Bolaños, H, 2008. Press conference: Aumenta venta de medicina sin receta. [www.tabascohoy.com.mx/nota.php?id\\_nota=156768](http://www.tabascohoy.com.mx/nota.php?id_nota=156768). Accessed June, 2008
- Chez, A.R., 1999 Identifying Low-Literacy patients. *Prim Care Update Ob/Gyns*;6,(2) 72-74.
- Clarke A. Evaluation research. Londres: Sage Publications, 1999.
- González de Cossío, M., 2008 Nuevas etiquetas de medicamentos para apoyar la automedicación en México. El caso de un analgésico pediátrico (New medicine label to support self-medication in Mexico. The case of a children's analgesic) *Salud Pública de México* (forthcoming)
- Hartley, J., & Trueman, M. (1985). A Research Strategy for Text Designers - the Role of Headings. *Instructional Science*, 14(2), 99-155.
- Kerlegand de la Fuente, V. 2003 Alternativas en la fabricación, comercialización y uso de medicamentos La Insignia. México: [www.lainsignia.org/2003/abril/cyt\\_001.html](http://www.lainsignia.org/2003/abril/cyt_001.html).
- Kirsch, I. S., & Mosenthal, P. B. (1990). Exploring Document Literacy - Variables Underlying the Performance of Young-Adults. *Reading Research Quarterly*, 25(1), 5-30.
- Klusewitz, M. A., & Lorch, R. F. (2000). Effects of headings and familiarity with a text on strategies for searching a text. *Memory & Cognition*, 28(4), 667-676.

<sup>†</sup> \* In the U.S. inadequate health literacy may reduce health status, and possibly threaten health care quality and increase the use of unnecessary high-cost services. 'Analyses have suggested that low health literacy may threaten care quality and cause unnecessary hospital costs' (Lee, S.D., Bender, D.E., Ruiz, R.E. and Cho, Y.I., 2006).

- Lee, S.D., Bender, D.E., Ruiz, R.E. and Cho, Y.I., 2006. Development of an Easy-to-Use Spanish Health Literacy Test. *Health Services Research* 41 (4), 1392-1412.
- Lorch, R. F., & Lorch, E. P. (1996). Effects of headings on text recall and summarization. *Contemporary Educational Psychology*, 21(3).
- Scudder, L 2006 Words and Well-being. How literacy affects patient health. *Journal of Nurse Practitioners*. Elsevier.
- Selden, C. R., M. Zorn, S. Ratzan, and R. M. Parker (Eds). 2000. *Health Literacy*. Current Bibliographies in Medicine. No 2000–1. Bethesda, MD: National Library of Medicine at <http://www.nlm.gov/pubs/cbm/hliteracy.html>. Accessed June, 2008.
- Sless D & Shrensky R. *Designing medicine information for people*. Melbourne: Communication Research Institute of Australia, 2005.
- Sless D. & Wiseman R. *Writing about medicines for people: usability guidelines for consumer medicine information*. 2nd edition. Melbourne: Communication Research Institute of Australia, 1998.
- Villegas y Covarrubias. *Auditoría de imagen. Investigación cualitativa y cuantitativa*. En: Gordo, V, (ed) *Imagología*. México, DF: Grijalbo, 2003.
- Wilson, F. J. 2003 American College of Physicians. The crucial link between literacy and health. *Annals of Internal Medicine* Volume 139 • Number 10 pp 875-878.

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