

DESIGN OF LABELS TO IMPROVE WARNING COMPREHENSION AND ACTION

Literature Selection

Banda, S. F. and K. Sichilongo (2006). "Analysis of the level of comprehension of chemical hazard labels: a case for Zambia." Sci Total Environ **363**(1-3): 22-7.

We have surveyed the impact of chemical hazard label elements on four target sectors, i.e. the agricultural, industrial, transport and the consumer (the general public) sectors, in order to assess the type of reactions the respondents perceive to a given chemical label element such as symbol, hazard phrase, color, and hazard signal word. The survey revealed that the level of education, gender and/or age did not influence the respondents' perception of the extent of hazard but rather familiarity or frequency of use of the chemicals and acquaintance with chemical label elements was significant in the assessment of the extent of perceived hazard posed by a given chemical. Symbols such as the St Andrews Cross--though common--is virtually not understood by more than 80% of the respondents in all the sectors. We noted that respondents appreciate symbols they can relate to, which are flame-like, ghost-like and exert immediate impacts to respondents. Color codes have found use in the agriculture sector because of their ease to be recalled especially by the majority of illiterate farm workers. The survey revealed that red in agricultural circles is well associated with high toxicity while other colors such as yellow and blue can not clearly be associated with hazard. The word "toxic" is not used in the industry and transport sectors where the most hazard signal word is "danger". The Globally Harmonized System (GHS) classification adopted "danger" and "warning" for use as signal words. The survey revealed that effective chemical hazard symbols must not be too abstract to the client but should contain features that are known or easily comprehended.

Basara, L. R. and J. P. Juergens (1994). "Patient package insert readability and design." Am Pharm **NS34**(8): 48-53.

As the popularity of self-medication and direct-to-consumer advertising of prescription drugs increases, the quality, availability, and utility of current patient information strategies become key concerns for pharmacists. It has been suggested that patient package inserts (PPIs) are a high-quality source of information for patients. To determine if this is true, 63 PPIs from three types of sources were assessed for readability and design. Suggested readability level is fifth-to-seventh grade. The PPIs studied had, on average, a 10th-grade reading level. Design characteristics, such as type size and paper quality--which affect patients' likelihood of using the PPI and keeping it for reference--were poorest in PPIs produced by pharmaceutical manufacturers. Overall, associations produce the best PPIs, with commercial vendors and pharmaceutical manufacturers following. However, both readability and design evaluations showed that all PPIs need improvement. Design and testing of new PPI formats and a reassessment of readability are recommended.

Braun, C. C., P. B. Mine, et al. (1995). "The influence of color on warning label perceptions." International Journal of Industrial Ergonomics **15**(3): 179-187.

Current standards and guidelines on warning design recommend pairing the colors red, orange, and yellow with the signal words DANGER, WARNING, and CAUTION, respectively. Much of the previous literature, however, has used achromatic stimuli to assess levels of hazard. Therefore, the major purpose of the present research was to determine whether consumer products presented in color differed in perceived hazard from those products presented achromatically. A sample of 33 participants rated 24 labels that varied across product class, signal word (DANGER, WARNING, and CAUTION), and chromaticity. A composite variable "perceived hazardousness" was formed from the averaged ratings from questions regarding likelihood of injury, hazardousness of the product, and carefulness in usage. Likewise, a composite variable "perceived readability" was formed from the averaged ratings concerning readability and saliency. Results showed that labels presented in color were perceived to be more hazardous and more readable than those presented in black-and-white. Adhesives were perceived to be more hazardous than general cleaners, bathroom cleaners, and automotive products. Differences in perceived readability may be explained by width-to-height ratios that varied across product

classes. Implications for warning design are discussed.

Braun, C. C. and N. C. Silver (1995). "Interaction of signal word and colour on warning labels: differences in perceived hazard and behavioural compliance." *Ergonomics* **38**(11): 2207-20.

Previous research has examined the connoted hazard of various colour and signal words separately. The purpose of the present research was to examine the interaction of signal words and colours. Two separate experiments examined the influence of colour on perceptions of hazard and on compliance to printed warnings. In experiment 1, a sample of 30 undergraduates rated the perceived hazard of signal words printed in specific hazard colours. Results indicated that the level of hazard varied as a function of the signal word and the colour in which it was presented. Of the colours used, red conveyed the highest level of perceived hazard followed by orange, black, green and blue. More importantly, it was noted that a signal word such as DEADLY connoted less hazard when printed in green than in red ink. Experiment 2 examined the effect of colour on compliance with printed warnings. Sixty-five undergraduates interacted with a pool-water test kit and a two-part adhesive. The warning on each product was factorial for colour (i.e. red, green and black). Behavioural compliance was assessed by indicating if subjects donned protective gloves as directed by the warning. The data indicated that warnings printed in red resulted in a higher proportion of compliant behaviour than green and black combined. Implications for warning design are discussed.

Daniel, K. L., K. D. Goldman, et al. (2001). "Interpretations of a teratogen warning symbol." *Teratology* **64**(3): 148-53.

BACKGROUND: Warning symbols are used on teratogenic medications to communicate the message that women should (1) not take that medication if they may already be pregnant, and (2) not get pregnant while taking that medication. Communications research indicates that people interpret symbols or pictures in different ways. Other studies have shown that patients do not always receive education materials that are part of prescription protocol. Researchers at the Centers for Disease Control and Prevention (CDC) tested the interpretation of the teratogen warning symbol and its ability to convey the correct information without accompanying education. **METHODS:** A teratogen warning symbol currently printed on some medication packaging uses graphics and text warning the user not to get pregnant. Researchers interviewed women of childbearing age about their interpretation of the warning symbol and its meaning. Ninety-seven women were interviewed in a variety of locations, including public health clinics, literacy and job training offices, health clubs, and malls. **RESULTS:** Only 21% of women interpreted correctly without prompting that they should either not take the medication if they are pregnant or not get pregnant while taking the medication. Twenty-seven percent of women first thought the symbol meant the package contained birth control medication, and 24% said it simply indicated the package contained drugs or medicine. An additional 7% said they did not know what the symbol was supposed to mean; 39% of respondents offered circumstances in which prescription medications might be shared. **CONCLUSIONS:** Misinterpretation of warning symbols can result in serious consequences. This research should serve as an urgent call for mandating education for all patients receiving drugs with teratogenic properties, and careful pretesting and modification of warning symbols before they are used on medications with teratogenic effects. Published 2001 Wiley-Liss, Inc.

Davis, T. C., M. S. Wolf, et al. (2006). "Low literacy impairs comprehension of prescription drug warning labels." *J Gen Intern Med* **21**(8): 847-51.

BACKGROUND: Adverse events resulting from medication error are a serious concern. Patients' literacy and their ability to understand medication information are increasingly seen as a safety issue. **OBJECTIVE:** To examine whether adult patients receiving primary care services at a public hospital clinic were able to correctly interpret commonly used prescription medication warning labels. **DESIGN:** In-person structured interviews with literacy assessment. **SETTING:** Public hospital, primary care clinic. **PARTICIPANTS:** A total of 251 adult patients waiting for an appointment at the Louisiana State University Health Sciences Center in Shreveport (LSUHSC-S) Primary Care Clinic. **MEASUREMENTS:** Correct interpretation, as determined by expert panel review of patients' verbatim responses, for each of 8 commonly used prescription medication warning labels.

RESULTS: Approximately one-third of patients (n=74) were reading at or below the 6th-grade level (low literacy). Patient comprehension of warning labels was associated with one's literacy level. Multistep instructions proved difficult for patients across all literacy levels. After controlling for relevant potential confounding variables, patients with low literacy were 3.4 times less likely to interpret prescription medication warning labels correctly (95% confidence interval: 2.3 to 4.9). CONCLUSIONS: Patients with low literacy had difficulty understanding prescription medication warning labels. Patients of all literacy levels had better understanding of warning labels that contained single-step versus multiple-step instructions. Warning labels should be developed with consumer participation, especially with lower literate populations, to ensure comprehension of short, concise messages created with familiar words and recognizable icons.

Davis, T. C., M. S. Wolf, et al. (2006). "Literacy and misunderstanding prescription drug labels." Ann Intern Med **145**(12): 887-94.

BACKGROUND: Health literacy has increasingly been viewed as a patient safety issue and may contribute to medication errors. OBJECTIVE: To examine patients' abilities to understand and demonstrate instructions found on container labels of common prescription medications. DESIGN: Cross-sectional study using in-person, structured interviews. SETTING: 3 primary care clinics serving mostly indigent populations in Shreveport, Louisiana; Jackson, Michigan; and Chicago, Illinois. PATIENTS: 395 English-speaking adults waiting to see their providers. Measurement: Correct understanding of instructions on 5 container labels; demonstration of 1 label's dosage instructions. RESULTS: Correct understanding of the 5 labels ranged from 67.1% to 91.1%. Patients reading at or below the sixth-grade level (low literacy) were less able to understand all 5 label instructions. Although 70.7% of patients with low literacy correctly stated the instructions, "Take two tablets by mouth twice daily," only 34.7% could demonstrate the number of pills to be taken daily. After potential confounding variables were controlled for, low (adjusted relative risk, 2.32 [95% CI, 1.26 to 4.28]) and marginal (adjusted relative risk, 1.94 [CI, 1.14 to 3.27]) literacy were significantly associated with misunderstanding. Taking a greater number of prescription medications was also statistically significantly associated with misunderstanding (adjusted relative risk, 2.98 [CI, 1.40 to 6.34] for \geq or =5 medications). LIMITATIONS: The study sample was at high risk for poor health literacy and outcomes. Most participants were women, and all spoke English. The authors did not examine the association between misunderstanding and medication error or evaluate patients' actual prescription drug-taking behaviors. CONCLUSIONS: Lower literacy and a greater number of prescription medications were independently associated with misunderstanding the instructions on prescription medication labels.

Didonet, J. and S. S. Mengue (2008). "Drug labels: are they a readable material?" Patient Educ Couns **73**(1): 141-5.

OBJECTIVE: This study aims to evaluate cardiovascular drug labels from the perspective of how readable the text materials are. METHODS: Comparison of drug labels written in accordance with the 1997 Brazilian legislation with those written in accordance with the 2003 Brazilian legislation, with journalistic text and scientific essays using as tool the Flesch Index. RESULTS: The journalistic text had an average Flesch Index of 62.6%; the scientific essays, 23.5%; the drug labels written in accordance with the old legislation, 43.8%; and those written in accordance with the most recent legislation, 47.2%. CONCLUSION: Drug labels are more readable than scientific essays and less readable than journalistic texts; they were classified as difficult to read. PRACTICE IMPLICATIONS: Text readability formulas are an objective measure that may improve the search for better-written communication materials and thereby a greater understanding of drug labels by patients. However, a more detailed validation of an objective measure of text evaluation should be considered by the health authorities of each country, with their own language as basis.

Dowse, R. and M. Ehlers (2005). "Medicine labels incorporating pictograms: do they influence understanding and adherence?" Patient Educ Couns **58**(1): 63-70.

The objective was to determine the influence of medicine labels incorporating pictograms on the understanding of instructions and on adherence. Eighty-seven Xhosa participants attending an outpatient clinic who had been prescribed a short course of antibiotics were

randomly allocated to either a control group (41 participants given text-only labels), or an experimental group (46 participants given text + pictogram labels). All participants had a maximum of 10 years of formal schooling. Follow-up home visits were conducted after 3-5 days to assess understanding of instructions and to evaluate adherence. A high adherence of greater than 90% was found for 54% of the experimental group, compared with only 2% of the control group. Average percentages for understanding in the control and experimental groups were 70 and 95%, respectively, and average adherence was 72 and 90%, respectively. The presence of pictograms was found to contribute positively to both understanding of instructions and adherence.

Edworthy, J., E. Hellier, et al. (2004). "Linguistic and location effects in compliance with pesticide warning labels for amateur and professional users." *Hum Factors* **46**(1): 11-31.

Three studies explored amateur and professional users' compliance with pesticide warning labels. Professionals were classified as people working in a profession in which the use of pesticides is a necessary part of their job. Amateurs used pesticides only in their leisure time. The first study showed that the wording used affected perception of the appropriateness of hazard statements, one of the most effective variations being the use of the personal pronoun (statements beginning "You should..."). The location of warning information was also found to affect actual compliance: Compliance increased when warning information was presented in the directions for use section. A supplemental directive increased compliance only for professional users. In a final study, "best-case" and "worst-case" linguistic variations were combined with best-case and worst-case locations for safety information. Instruction statements using the personal pronoun and presented in the directions for use section resulted in the highest levels of compliance. The differences in compliance between amateur and professional users are interpreted within the framework of Rasmussen's (1986) distinction among skill-, rule-, and knowledge-based behavior. Actual or potential applications of this research include the design of warning labels and safety information.

Ferguson, J. M., R. Discenza, et al. (1987). "Increasing the odds of patient compliance through prescription warning labels." *J Health Care Mark* **7**(1): 37-46.

Ensuring patient compliance with instructions for medication continues to be a major problem. The authors report an experiment suggesting that warning labels promote compliance. In addition, other methods of improving compliance are discussed.

Goldsworthy, R. C., N. C. Schwartz, et al. (2008). "Interpretation of pharmaceutical warnings among adolescents." *J Adolesc Health* **42**(6): 617-25.

PURPOSE: Warnings are an important component of pharmaceutical risk mitigation efforts, yet very little research attention has been directed toward adolescent interpretation of such warnings. This study examined adolescents' interpretations of and preferences for warning symbols and statements related to pharmaceuticals with teratogenic properties. **METHODS:** A total of 200 adolescents interpreted one of four warning symbols and four warning statements. Responses were coded using an established three-tier coding system. Symbol preferences were elicited. Interpretation accuracy and symbol preferences were analyzed by symbol and statement. **RESULTS:** The symbol in use on medication labels at the time of the study elicited nearly goal levels of interpretation accuracy; however it exceeded allowable levels of critical confusion. An alternative symbol elicited more fully correct responses than the existing symbol and was preferred to the existing symbol by a margin of 2 to 1. Yet another symbol was most preferred despite eliciting fewer correct interpretations. The impact of warning statements on overall warning interpretation varied by statement and statement-symbol combinations. At least one statement appeared to lessen the overall message of caution, and few adolescents expressed an awareness of risk if one "may become pregnant" until explicitly informed of this risk. **CONCLUSIONS:** Comprehension of medical warning symbols and statements among adolescents is an important public health issue. Those involved in adolescent health education and research have considerable theoretical and practical tools for approaching the development and evaluation of such warning messages. Understanding how warnings are interpreted can lead to more effective communication efforts and reduce risk.

Gorn, G. J., A. M. Lavack, et al. (1996). "An experiment in designing effective warning labels." Health Mark Q **14**(2): 43-61.

This paper proposes a model for the design of effective warning labels concerning drinking and driving. One important aspect of the model is that producing a multiplicity of warning labels should result in a higher probability that at least a few of the warning labels will be of high quality and effectiveness. Secondly, greater similarity between the warning label designer and the intended target group should enhance the effectiveness of the warning label. In the present study, 49 warning labels were created by university undergraduates, and the effectiveness of these warning labels was assessed by a group of university students (target group members). A number of labels were judged as being effective, and more effective than the government warning label. Extending the notion of being close to the target group, warning labels designed by male and female university students for university students of the same sex were judged as more effective than warning labels designed for the opposite sex.

Gustafsson, J., S. Kalvemarm, et al. (2005). "Patient information leaflets--patients' comprehension of information about interactions and contraindications." Pharm World Sci **27**(1): 35-40.

OBJECTIVE: To determine how well patients could correctly recognize and comprehend the various information items on patient information leaflets, and to explore the reasons underlying poor comprehensibility. METHODS: Leaflets from 30 randomly selected, commonly prescribed medicines were examined by experts using protocols to evaluate leaflet layout, language and content. The same leaflets were also evaluated by patients who had their medicines dispensed at 24 randomly selected Swedish pharmacies. A questionnaire was used for the patients' examination. RESULTS: The results showed that most information on the leaflets is sound and is well comprehended by the patients. For two information items regarding 'risks of interactions' and 'contraindications' the patient scores were low, indicating poor comprehensibility. CONCLUSION: Leaflets with low scores on warnings of interactions and contraindications were found to deliver more complex messages to older patients as compared to leaflets with high scores for these items.

Hancock, H. E., A. D. Fisk, et al. (2005). "Comprehending product warning information: age-related effects and the roles of memory, inferencing, and knowledge." Hum Factors **47**(2): 219-34.

Two experiments were conducted to determine if age affects comprehension for explicit and implied warning information and, if so, to reveal the nature of such effects. Experiment 1 measured younger (18-23 years) and older (65-75 years) adults' comprehension for real-world warnings via a verification test presented immediately after reading the warnings or after a delay. In Experiment 2, younger (18-22 years) and older (64-76 years) participants also read fabricated warnings that were inconsistent with real-world knowledge. In both experiments, older adults frequently failed to infer the correct hazard and safety information. The older adults also had trouble understanding warning information even when it was explicitly stated (when no inferences were required), especially when memory demands were high and product-specific knowledge could not be used. That many of the older adults did not understand commonly used product warnings indicates that the wording on many household products is not conducive to being understood by everyone who uses them. Actual or potential applications of this research include the recommendation that designers of product labels, warnings, and instructions should consider minimizing memory load and maximizing opportunities for knowledge application when designing consumer warnings.

Hancock, H. E., W. A. Rogers, et al. (2001). "An evaluation of warning habits and beliefs across the adult life span." Hum Factors **43**(3): 343-54.

Beliefs about warnings and habits associated with reading them were assessed for 863 individuals of various ages. Information gathered for various common household products included (a) how frequently people attend to warning information, (b) the degree of risk they believe is involved during product usage, and (c) how important they believe warnings are for different product types. Also assessed were perceived helpfulness and comprehension for symbols commonly found on product labels or on signs in the environment. Respondents 55 years and older reported reading product warnings more frequently than did younger adults, although they generally perceived warnings as less important. However,

no overall age-related differences were found for perceived level of risk involved in using different product types. Although older adults generally perceived symbols to be very helpful when using a particular product, their comprehension levels were poorer than those of younger adults for half of the symbols. Overall, these data suggest that adults of all ages do read warnings on a variety of product types and that they believe warning information is important. This research illustrates the importance of including older adults in usability studies during the development of warning systems, given age-related effects may be associated with some aspects of the warning processing but not others.

Hancock, H. E., W. A. Rogers, et al. (2004). "Safety symbol comprehension: effects of symbol type, familiarity, and age." Hum Factors **46**(2): 183-95.

A new procedure for evaluating symbol comprehension, the phrase generation procedure, was assessed with 52 younger and 52 older adults. Participants generated as many phrases as came to mind when viewing 40 different safety symbols (hazard alerting, mandatory action, prohibition, and information symbols). Symbol familiarity was also assessed. Comprehension rates for both groups were lower than the 85% level recommended by the American National Standards Institute. Moreover, older participants' comprehension was significantly worse than younger participants', and the older adults also generated significantly fewer phrases. Generally, prohibition symbols were comprehended best and hazard alerting symbols worst. In addition, symbol familiarity was positively correlated with symbol comprehension. These findings indicate that important safety information depicted on signs and household products may be misunderstood if presented in symbolic form. Furthermore, certain types of symbols may be better understood (e.g., prohibition symbols) than other types (e.g., hazard alerting symbols) by both younger and older individuals. These findings signify the utility of the phrase generation procedure as a method for evaluating symbol comprehension, particularly when it is not possible or desirable to provide contextual information. Actual or potential applications of this research include using the phrase generation approach to identify poorly comprehended symbols, including identification of critical confusions that may arise when processing symbolic information.

Hawley, S. T., B. Zikmund-Fisher, et al. (2008). "The impact of the format of graphical presentation on health-related knowledge and treatment choices." Patient Education and Counseling **73**(3): 448-455.

Objective To evaluate the ability of six graph formats to impart knowledge about treatment risks/benefits to low and high numeracy individuals. Methods Participants were randomized to receive numerical information about the risks and benefits of a hypothetical medical treatment in one of six graph formats. Each described the benefits of taking one of two drugs, as well as the risks of experiencing side effects. Main outcome variables were verbatim (specific numerical) and gist (general impression) knowledge. Participants were also asked to rate their perceptions of the graphical format and to choose a treatment. Results 2412 participants completed the survey. Viewing a pictograph was associated with adequate levels of both types of knowledge, especially for lower numeracy individuals. Viewing tables was associated with a higher likelihood of having adequate verbatim knowledge vs. other formats ($p < 0.001$) but lower likelihood of having adequate gist knowledge ($p < 0.05$). All formats were positively received, but pictograph was trusted by both high and low numeracy respondents. Verbatim and gist knowledge were significantly ($p < 0.01$) associated with making a medically superior treatment choice. Conclusion Pictographs are the best format for communicating probabilistic information to patients in shared decision making environments, particularly among lower numeracy individuals. Practice Implications Providers can consider using pictographs to communicate risk and benefit information to patients of different numeracy levels.

Houts, P. S., C. C. Doak, et al. (2006). "The role of pictures in improving health communication: a review of research on attention, comprehension, recall, and adherence." Patient Educ Couns **61**(2): 173-90.

OBJECTIVE: To assess the effects of pictures on health communications. METHOD: Peer reviewed studies in health education, psychology, education, and marketing journals were reviewed. There was no limit placed on the time periods searched. RESULTS: Pictures

closely linked to written or spoken text can, when compared to text alone, markedly increase attention to and recall of health education information. Pictures can also improve comprehension when they show relationships among ideas or when they show spatial relationships. Pictures can change adherence to health instructions, but emotional response to pictures affects whether they increase or decrease target behaviors. All patients can benefit, but patients with low literacy skills are especially likely to benefit. Patients with very low literacy skills can be helped by spoken directions plus pictures to take home as reminders or by pictures plus very simply worded captions. Practice implications: Educators should: (1) ask "how can I use pictures to support key points?", (2) minimize distracting details in pictures, (3) use simple language in conjunction with pictures, (4) closely link pictures to text and/or captions, (5) include people from the intended audience in designing pictures, (6) have health professionals plan the pictures, not artists, and (7) evaluate pictures' effects by comparing response to materials with and without pictures.

Howie, J. G., T. A. Jeffers, et al. (1977). "Prevention of adverse drug interactions." Br J Clin Pharmacol 4(5): 611-4.

1 The awareness and recognition of adverse interactions between drugs by prescribers is low. 2 A 6-month prospective study on patients on long-term outpatient anticoagulant therapy in the Grampian area has been carried out to evaluate a simple and cheap warning system. 3 The practitioners of patients in the test group were issued with warning labels which showed drugs known to interact. A reduction in the initiation of prescriptions for potentially interacting drugs was shown between the test and control groups (no warning labels). 4 The 140 practitioners who completed the study found the system to be convenient and useful. Extension to other high-risk drugs with the potential to interact with other drugs is planned. This system has the advantage of being drug and patient-orientated whereas lists of drug interactions or drug discs require more conscious effort by the prescriber.

Hurst, R. (1986). "Using federal standards to determine adequacy of consumer product's precautionary labeling." Vet Hum Toxicol 28(6): 557-62.

The results of the present investigation indicate that a majority of the more hazardous products provided some type of warning, although they may not necessarily contain the specific phrases required by the Act. In contrast, products that were deemed minimally hazardous were more likely to omit important precautionary information. In addition, our study also demonstrated that the primary labeling deficiency was the lack of comprehensive first aid information. For the health care professional, the importance of clear, correct, concise and complete first aid information for each potential route of exposure is well appreciated; however, it appears that the manufacturers are reluctant to provide complete first aid information on their product labels. Many manufacturers or sellers offer arguments against providing comprehensive precautionary and first aid information such as: the consumer never reads the label; if the warning label is "too busy", the warning's effect will be minimized; or a seller may lose a competitive edge if his/her product contains a panel of hazard warnings while his/her competitor's identical product provides no warning which may lead a consumer to believe that the competitor's product is safer. While the above arguments may be viable, they are significantly weakened when one considers the potential health risks or costly litigation that may ensue as a result of an inadequate label. Therefore, it is imperative that product manufacturers and sellers become aware of all of the potential hazards associated with their products, and disseminate all of this information through sufficient warning labels.

Hwang, S. W., C. Q. Tram, et al. (2005). "The effect of illustrations on patient comprehension of medication instruction labels." BMC Fam Pract 6(1): 26.

BACKGROUND: Labels with special instructions regarding how a prescription medication should be taken or its possible side effects are often applied to pill bottles. The goal of this study was to determine whether the addition of illustrations to these labels affects patient comprehension. METHODS: Study participants (N = 130) were enrolled by approaching patients at three family practice clinics in Toronto, Canada. Participants were asked to interpret two sets of medication instruction labels, the first with text only and the second

with the same text accompanied by illustrations. Two investigators coded participants' responses as incorrect, partially correct, or completely correct. Health literacy levels of participants were measured using a validated instrument, the REALM test. RESULTS: All participants gave a completely correct interpretation for three out of five instruction labels, regardless of whether illustrations were present or not. For the two most complex labels, only 34-55% of interpretations of the text-only version were completely correct. The addition of illustrations was associated with improved performance in 5-7% of subjects and worsened performance in 7-9% of subjects. CONCLUSION: The commonly-used illustrations on the medication labels used in this study were of little or no use in improving patients' comprehension of the accompanying written instructions.

Kalsher, M. J., M. S. Wogalter, et al. (1996). "Pharmaceutical container labels: enhancing preference perceptions with alternative designs and pictorials." International Journal of Industrial Ergonomics **18**(1): 83-90.

The appropriate use of pharmaceuticals, as well as their hazards, are not commonly known to most people. In fact, the only information available to consumers at the time of consumption is usually the material found on the product label. Unfortunately, people often have difficulty with the labels because the print on the label is too small for them to read. Two alternative (tag and fold-out) designs were developed to increase the available surface area on a fictitious prescription drug label. The alternative label designs, with and without pictorials depicting instructions and warnings, were compared to a standard control label. In Expt. 1, 84 undergraduates rated the labels on several preference dimensions, including: ease of reading the labels, likelihood of noticing the warnings, likelihood of reading the warnings, preference for each of the labels, and likelihood that they would recommend each label for use by a friend or family member. Across all dimensions, undergraduates preferred the alternative labels, especially the tag labels, and labels with pictorials. In Expt. 2, the ratings of 58 older adults (mean AGE = 73 years) showed a similar pattern of results. Implications of these results and recommendations for future research in this area are discussed.

Laughery, K. R., K. P. Vaubel, et al. (1993). "Explicitness of consequence information in warnings." Safety Science **16**(5-6): 597-613.

Four experiments were carried out to assess effects of product warning explicitness on purchase preferences and caution in use. Explicitness was defined as the specificity or detail with which potential injury consequences were described. All experiments employed a paradigm in which warnings varying in explicitness were described for familiar products. Subjects rated various perceptions of the products, purchase preferences, and intent to act cautiously in using the product. Results indicated that more explicit warnings were associated with greater levels of perceived dangerousness, hazard understanding, injury severity, and manufacturers' concern. While explicit warnings were also associated with an increased intent to act cautiously in using products, no clear relationship was found between explicitness and purchase preferences. It is recommended that product warnings should be explicit regarding injury consequences, especially where injuries may be severe. Given such information, product users, particularly those less familiar with a product, are more likely to exercise greater caution during use. Further, manufacturers' concern that explicit warnings may negatively impact sales appears to be unwarranted.

Lesch, M. F. (2003). "Comprehension and memory for warning symbols: Age-related differences and impact of training." Journal of Safety Research **34**(5): 495-505.

Problem: Prior research indicates that many warning symbols are poorly understood, particularly by the elderly. Method: The effectiveness of three different training conditions to improve comprehension and memory for warning symbols was assessed for younger (18-35 years of age) and older (50-67 years of age) participants. All three conditions paired the symbols with associated text during training; however they differed in the extent to which they further elaborated on the meanings of the symbols. Results: Training substantially improved accuracy and speed of responding on a comprehension test; however there was little difference among conditions. Additionally, while the magnitude of the training effect was similar for both age groups, older participants performed much more poorly than younger participants, both before (37% vs. 52% correct) and after training (68%

vs. 88% correct on the immediate post-test), and found it more difficult to reject incorrect meanings (55% vs. 68% correct). Conclusion: Relatively simple training conditions can dramatically improve accuracy and speed of responding to warning symbols. Impact on industry: Training should be used to improve warning symbol comprehension since failures to adequately understand warning information may lead to injury or death. Furthermore, attempts should be made to address individual differences in warning processing such as those related to changes in cognitive processing across the lifespan.

Lesch, M. F. (2008). "Warning symbols as reminders of hazards: Impact of training." Accident Analysis & Prevention **40**(3): 1005-1012.

Prior research indicates that many warning symbols are poorly understood. However Lesch [Lesch, M.F., 2003. Comprehension and memory for warning symbols: Age-related differences and impact of training. *J. Safety Res.* 34, 495-505] found that accident scenarios could be used to improve comprehension of warning symbols. The current study further investigated the potential benefits of accident scenario training. During training, warning symbols with verbal labels corresponding to the meaning of the symbol were paired with accident scenarios which expanded on the nature of the hazard, the required/prohibited actions, as well as the possible consequences of failing to comply. A number of measures were obtained prior to, and following (immediately and 2 weeks later), the accident scenario training: comprehension across three knowledge types (verbal label, required/prohibited actions, potential consequences of failure to comply), ratings of agreement with statements reflecting perceived control, and ratings of hazard and intent to comply. Benefits of training were observed on all dependent measures: Comprehension improved from 43 to 82% correct, reaction times were reduced by about 2 s, and level of confidence in correct responses increased by 23%. Ratings of perceived hazard, intent to comply, and perceived control over accident/injury involvement also increased. It is suggested that accident scenario training can be used to help prevent accidents and injuries by ensuring that responses to warnings are "sure and swift".

Morrow, D. G., V. O. Leirer, et al. (1996). "Using icons to convey medication schedule information." Appl Ergon **27**(4): 267-75.

We examined older adult comprehension and memory for medication schedules conveyed by different types of visual icons as well as text. Three icons were compared: a timeline, a pair of 12 h clocks (one for AM and one for PM hours) and a 24 h clock. In Experiment 1, older and younger participants paraphrased and then recalled schedules that were conveyed by the three icons or by text. Text and timeline schedules were paraphrased more accurately than either clock icon. Paraphrase errors suggested that subjects had trouble integrating schedule information across the two 12 h clocks. Analysis of paraphrase times showed that the text schedule was paraphrased most quickly, followed by the timeline, the 24 h clock and the 12 h clock. No differences were found for the accuracy of recalling the icon and text schedules. Experiment 2 examined free and cued recall after limited study time by older adults. Because text superiority in Experiment 1 may have reflected greater familiarity with text than with icons, recall was examined across four trials in Experiment 2. Text was recalled most accurately, followed by the timeline, the 24 h clock and the 12 h clock. Study-test trials did not influence recall. Text schedules may have been generally more effective than the icons because of their greater familiarity. The timeline may have been the most effective icon because it was more compact and familiar than the clock icons used in the study. The findings suggest that including such icons in medication instructions requires training.

Murray, L. A., A. B. Magurno, et al. (1998). "Prohibitive pictorials: Evaluations of different circle-slash negation symbols." International Journal of Industrial Ergonomics **22**(6): 473-482.

To indicate a prohibited activity, pictorials are frequently overlaid with a red circle and 45° left-to-right slash. Previous research suggests that the combination of the slash and symbol may affect the overall identifiability of the warning. The purpose of the present research was to determine whether people's judgments of four types of the circle-slash (a slash over the symbol, a slash under the symbol, a partial slash, and a translucent slash) would differ in perceived effectiveness. Sixteen pictorials with semantically different message content (e.g., NO TRUCKS, DO NOT CLIMB TOWER), in both left-facing and right-facing

orientations were viewed by 60 participants. The results revealed that the over and under slashes were preferred to the translucent or partial slashes. Both orientation and slash type influenced preference for a subset of nonsymmetrical symbols. Some of the pictorials with the over slash were given lower evaluations when critical features were concealed. The general preference for the over and under slashes may be due to familiarity and its concordance with Gestalt principles of good figures. Implications for the development of prohibitive pictorials are discussed. Relevance to industry Pictorials are increasingly being used to communicate safety information in cases where the target audience may use different languages. The present research examines different versions of the circle-slash negation symbol for the purpose of determining when critical pictorial elements may be obscured. Implications for pictorial recognition are discussed.

Rother, H.-A. (2008). "South African farm workers' interpretation of risk assessment data expressed as pictograms on pesticide labels." *Environmental Research* **108**(3): 419-427.

Pesticide companies and regulators in developing countries use the United Nations Food and Agricultural Organization (FAO) recommended pictograms on pesticide labels to communicate risk information based on toxicological and environmental risk assessment data. The pesticide label not only is often the only access people have to pesticide risk information, but also in many countries is a legally binding document. As a result of the crucial role pesticide labels play in protecting health and the environment and as a legal instrument, pictograms are used to overcome literacy challenges in transmitting pesticide risk information. Yet, this risk communication tool is often prone to misinterpretations of the risk information which results in hazardous exposures to pesticides for farm workers and end-users generally. In this paper, results are presented from a study with 115 farm workers on commercial vineyards in the Western Cape, South Africa, assessing their interpretations of 10 commonly used pictograms. A standardized questionnaire based on four commonly used pesticide labels was administered. Overall, 50% or more of the study farm workers had misleading, incorrect and critically confused interpretations of the label pictograms. Interpretations often reflected farm workers' social and cultural frames of reference rather than the technically intended risk information. For example, the pictogram indicating a pesticide's toxicity requires boots must be worn, evoked interpretations of "dangerous to pedestrians" and "don't walk through pesticides". Furthermore, there was a gender variation in pictogram comprehension whereby males generally had more correct interpretations than females. This is a result both of a lack of training for women who are assumed to not work with pesticides, as well as a lack of pictograms relevant for female exposures. These findings challenge the viability of the United Nations current initiative to globally harmonize pictograms used on all chemical labels under the new Globally Harmonized System for the Classification and Labelling of Chemicals (GHS). Particularly as the GHS pictograms were not piloted prior to adoption of the system and represent complex risk assessment data such as chronic hazards. Public health and pesticide policy, backed by relevant research, need to address developing applicable and effective pesticide risk communication tools, particularly for developing country populations. **Merely providing risk assessment derived information in a pictogram does not ensure that an end-user will interpret the message as intended and be able to make risk decisions which mitigate risks from exposures to pesticides or chemicals in general.**

Roumie, C. L. and M. R. Griffin (2004). "Over-the-counter analgesics in older adults: a call for improved labelling and consumer education." *Drugs Aging* **21**(8): 485-98.

The use of analgesics increases with age and on any given day 20-30% of older adults take an analgesic medication. Over-the-counter (OTC) analgesics are generally well tolerated and effective when taken for brief periods of time and at recommended dosages. However, their long-term use, use at inappropriately high doses, or use by persons with contraindications may result in adverse effects, including gastrointestinal haemorrhage, cardiovascular toxicity, renal toxicity and hepatotoxicity. Many OTC drugs are also available through a prescription, for a broader range of indications and for longer durations of use and wider dose ranges, under the assumption that healthcare providers will help patients make safe choices about analgesics. Safe and effective use of medications is one of the greatest challenges faced by healthcare providers in medicine. More than 60% of people cannot identify the active ingredient in their brand of pain reliever. Additionally, about 40%

of Americans believe that OTC drugs are too weak to cause any real harm. As a result of a recent US FDA policy, the conversion of prescription to OTC medications will result in a 50% increase of OTC medications. To reduce the risks of potential adverse effects from OTC drug therapy in older adults, we propose that the use of analgesics will be enhanced through the use of patient and healthcare provider education, as well as improved labelling of OTC analgesics. Improved labelling of OTC analgesics may help consumers distinguish common analgesic ingredients in a wide variety of preparations and facilitate informed decisions concerning the use of OTC drugs.

Sansgiry, S. S. and P. S. Cady (1997). "An investigative model evaluating how consumers process pictorial information on nonprescription medication labels." Health Mark Q **14**(4): 71-90.

Currently, marketed over-the-counter (OTC) medication labels were simulated and tested in a controlled environment to understand consumer evaluation of OTC label information. Two factors, consumers' age (younger and older adults) and label designs (picture-only, verbal-only, congruent picture-verbal, and noncongruent picture-verbal) were controlled and tested to evaluate consumer information processing. The effects exerted by the independent variables, namely, comprehension of label information (understanding) and product evaluations (satisfaction, certainty, and perceived confusion) were evaluated on the dependent variable purchase intention. Intention measured as purchase recommendation was significantly related to product evaluations and affected by the factor label design. Participants' level of perceived confusion was more important than actual understanding of information on OTC medication labels. A Label Evaluation Process Model was developed which could be used for future testing of OTC medication labels.

Sansgiry, S. S., P. S. Cady, et al. (1997). "Readability of over-the-counter medication labels." J Am Pharm Assoc (Wash) **NS37**(5): 522-8.

OBJECTIVE: This study evaluated information on over-the-counter (OTC) medication labels. Brand-name OTC products were examined to determine compliance with the Label Readability Guidelines recommended by the Nonprescription Drug Manufacturers Association (NDMA). Additionally, the use of pictures on OTC medication labels was assessed. The effect of pictures on other aspects of label design that may affect comprehension was also evaluated. **DESIGN:** We evaluated 100 OTC medication labels (20 analgesics and 80 cold/cough products). Assessment of label content was based on certain aspects of label design, such as package size, font size of written information, format of information on warnings and indications, use of pictures, and use of advertising claims on product labels. **RESULTS:** Many products evaluated did not meet NDMA guidelines. Even when font size of product name increased with increase in package size, font size on warnings and indications remained constant at 6 points. Lack of boldface (63%), use of all uppercase font (30%), use of hyphenation (49%), lack of paragraph breaks (19%), and the small font size of 6 points or less (98%) could reduce readability. Packages containing pictures were significantly larger than packages without pictures. Several packages (30%) contained pictures in the indications section. Many products contained advertising claims that were classified as "green" or "quality" (41%) and "free" (38%). Additionally, 43 different advertising claims were identified; some of these may be difficult for patients to interpret. **CONCLUSIONS:** The findings may help FDA develop specific regulations to improve label readability. Pharmacists who recommend OTC products to consumers should be aware of these issues and evaluate requests by consumers regarding OTC drugs accordingly.

Shrank, W., J. Avorn, et al. (2007). "Effect of content and format of prescription drug labels on readability, understanding, and medication use: a systematic review." Ann Pharmacother **41**(5): 783-801.

OBJECTIVE: To evaluate the evidence regarding the optimal content and format of prescription labels that might improve readability, understanding, and medication use. **DATA SOURCES:** We performed a systematic review of randomized controlled trials, observational studies, and systematic reviews from MEDLINE and the Cochrane Database (1990-June 2005), supplemented by reference mining and reference lists from a technical expert panel. **STUDY SELECTION:** We selected studies that focused on the content of physician-patient communication about medications and the content and format of

prescription drug labels. DATA EXTRACTION: Two reviewers extracted and synthesized information about study design, populations, and outcomes. DATA SYNTHESIS: Of 2009 articles screened, 36 that addressed the content of physician-patient communication about medications and 69 that were related to the content or format of medication labels met review criteria. Findings showed that patients request information about a drug's indication, expected benefits, duration of therapy, and a thorough list of potential adverse effects. The evidence about label format supports the use of larger fonts, lists, headers, and white space, using simple language and logical organization to improve readability and comprehension. Evidence was not sufficient to support the use of pictographic icons. Little evidence linked label design or content to measurable health outcomes, adherence, or safety. CONCLUSIONS: Evidence suggests that specific content and format of prescription drug labels facilitate communication with and comprehension by patients. Efforts to improve the labels should be guided by such evidence, although additional study assessing the influence of label design on medication-taking behavior and health outcomes is needed. Several policy options exist to require minimal standards to optimize medical therapy, particularly in light of the new Medicare prescription drug benefit.

Shrank, W. H., J. Agnew-Blais, et al. (2007). "The variability and quality of medication container labels." *Arch Intern Med* **167**(16): 1760-5.

BACKGROUND: Medication errors occur frequently, and poor medication labeling is cited as a potential cause. We assessed the format, content, and variability of prescription drug container labels dispensed in the community. METHODS: Identically written prescriptions for 4 commonly used medications (atorvastatin calcium [Lipitor], alendronate sodium [Fosamax], trimethoprim-sulfamethoxazole [Bactrim], and ibuprofen) were filled in 6 pharmacies (the 2 largest chains, 2 grocery stores, and 2 independent pharmacies) in 4 cities (Boston, Chicago, Los Angeles, and Austin [Texas]). Characteristics of the format and content of the main container label and auxiliary stickers were evaluated. Labels were coded independently by 2 abstractors, and differences were reconciled by consensus. RESULTS: We evaluated 85 labels after excluding 11 ibuprofen prescriptions that were filled with over-the-counter containers that lacked labels printed at the pharmacy. The pharmacy name or logo was the most prominent item on 71 (84%) of the labels, with a mean font size of 13.6 point. Font sizes were smaller for medication instructions (9.3 point), medication name (8.9 point), and warning and instruction stickers (6.5 point). Color, boldfacing, and highlighting were most often used to identify the pharmacy and items most useful to pharmacists. While the content of the main label was generally consistent, there was substantial variability in the content of instruction and warning stickers from different pharmacies, and independent pharmacies were less likely to use such stickers ($P < .001$). None of the ibuprofen containers were delivered with Food and Drug Administration-approved medication guides, as required by law. CONCLUSIONS: The format of most container labels emphasizes pharmacy characteristics and items frequently used by pharmacists rather than use instructions or medication warnings. The content of warning and instruction stickers is highly variable depending on the pharmacy selected.

Silver, N. C. and C. C. Braun (1993). "Perceived readability of warning labels with varied font sizes and styles." *Safety Science* **16**(5-6): 615-625.

Warning readability is a major issue in the labeling of various consumer products. The purpose of the present research was to examine several variables that are associated with readability: font type, font weight, point size, and point size contrast between the signal word and the main body of the warning (signal word-text size difference). A sample of 40 undergraduate students and 22 elderly persons rated 24 Ultra Tide detergent labels that contained a warning which varied across all levels of the type form variables. A composite variable "perceived readability" was formed from the averaged ratings from questions regarding how likely they would read the warning, its salience, and readability. Results showed that Helvetica type was perceived to be more readable than Times or Goudy. Moreover, Times was perceived to be more readable than Goudy. Bold type was perceived to be more readable than roman type. There was greater perceived readability of the warning when the main body was printed in 10-point size when compared to 8-point size. Results also showed that a signal word-text size difference of 2 points was perceived as more readable than a difference of 4 points. Implications for warning design are discussed.

Trommelen, M. (1997). "Effectiveness of explicit warnings." Safety Science **25**(1-3): 79-88.

In the present study the effectiveness of explicitness in warnings provided with children's products was investigated. Unsafe use of children's products leads to many accidents. One way to reduce the number of accidents is to provide products with adequate warnings. A consistent finding in the literature is that a consumer's responsiveness to warnings is affected by perceived hazardousness, which in turn is affected by explicit warnings. A warning is explicit when it informs a consumer on 1. (1) what to do/avoid 2. (2) the product-related hazards 3. (3) the consequences of unsafe behaviour in terms of injuries. Subjects were randomly assigned to one of three conditions. They were presented with a product manual of a child-care product, either a baby carrier or a feeding bottle, in which 1. (i) no warnings 2. (ii) non-explicit warnings 3. (iii) explicit warnings were provided. The effect of warning condition on perceived hazardousness, perceived severity of injury, intended compliance, comprehension, and recall of the warning was measured. The results indicate that with explicit warnings, subjects perceived the products investigated as more hazardous and the possible injuries as more severe. Results also show that explicit warnings were better understood and remembered. However no significant offer of explicitness was found on intended compliance.

Waichman, A. V., E. Eve, et al. (2007). "Do farmers understand the information displayed on pesticide product labels? A key question to reduce pesticides exposure and risk of poisoning in the Brazilian Amazon." Crop Protection **26**(4): 576-583.

Brazil is the world's fourth largest consumer of pesticides, and the largest in Latin America. In the Brazilian Amazon, the use of pesticides in varzeas (seasonally flooded land, where fresh vegetables are produced for regional urban markets) is intensive and is perceived by local farmers as necessary for the feasibility of vegetable production in the region. Usage of pesticides in Brazilian agriculture is regulated by Federal Law No. 7.802. However, law enforcement is almost absent in some remote areas. Given the limited or poor literacy skills of Amazon farmers and widespread use of pesticides, it is expected that occupational exposure to pesticides is likely to be high, increasing the vulnerability to acute and chronic poisoning. This paper investigates levels of understanding of pesticide handling among farmers by focusing on their ability to understand the information displayed on product labels, which might affect risk reduction. We found that the information displayed on product labels was not effective in promoting protective and safety measures. Farmers, in the main, do not read the labels, reporting that the fonts are too small, and that the instructions are too long and in overly technical Portuguese. They also understood few of the pictograms, which are directed at the illiterate. In many cases, the inability to understand the information displayed led to the adoption of practices which actually increased exposure, risks to human health and environmental contamination. This is alarming considering that 42% of farmers use methyl-parathion which is considered extremely hazardous by the WHO classification and whose use has been banned in the European Union. Farmers' adopted practices and understanding of product labels is presented and possible alternatives discussed, including changes to the Federal law on pesticide product labeling.

Wallace, L. S., A. J. Keenum, et al. (2008). "Suitability and readability of consumer medical information accompanying prescription medication samples." Patient Educ Couns **70**(3): 420-5.

OBJECTIVE: To examine readability and formatting characteristics of consumer medication information (CMI) accompanying prescription medication samples. METHODS: We collected the most commonly used prescription medication samples (n=100) from four out-patient clinics at a large teaching hospital in the Southeastern US. Seventeen percent of samples were not pills/tablets and of such diverse nature (e.g., injections, drops, and creams) that there were not enough in any category to draw conclusions. Therefore, our analyses were limited to 83pill/tablet samples, belonging to 11 drug classes (e.g., cardiovascular, and psychiatric). We noted if CMI was present, and if so we assessed it for how instructions were presented, reading level, text size, format/layout, and comprehensibility. RESULTS: No CMI was present in 39 (46.9%) samples. In 19 (22.9%), CMI was contained in a package insert and in 25 (30.2%) it was printed on the medication package. Average reading difficulty of CMI was at the 10th grade level (range=6-15) using

the Fry formula, and text point size was small (mean 9.9+/-2.2 on package inserts and 9.4+/-2.6 when printed on packages). CONCLUSIONS: Almost half of samples did not include any type of CMI. For those that had CMI, it was often written at a reading difficulty level higher than the average reading skills of American adults, and the format of most CMI was not optimal for comprehensibility. It is likely that many patients do not understand the instructions accompanying medication samples they receive from clinicians. PRACTICE IMPLICATIONS: Clinicians should be cognizant of the shortcomings of CMI accompanying medication samples and thereby, distribute them to patients with caution. Manufacturers too should consider revising CMI to comply with low-literacy guidelines.

Weatherby, L. B., B. L. Nordstrom, et al. (2002). "The impact of wording in "Dear doctor" letters and in black box labels." Clin Pharmacol Ther **72**(6): 735-42.

OBJECTIVES: The Food and Drug Administration and pharmaceutical manufacturers use "Dear doctor" letters to alert physicians about drug safety. To determine how such warnings may be improved, we retrospectively examined how variations in the wording of one series of "Dear doctor" letters affected their impact on concomitant dispensing of cisapride (Propulsid; Janssen Pharmaceutica, Titusville, NJ) and several medications contraindicated for concomitant use. METHODS: Concomitant dispensing was defined as dispensing cisapride and a contraindicated medication on dates when the intended duration of the two dispensings overlapped on at least 1 day. Using outpatient pharmacy claims from a New England health insurer, we calculated a concomitant dispensing rate for each calendar month as the number of concomitant cisapride dispensings divided by the total number of cisapride dispensings. We grouped drugs contraindicated for concomitant use with cisapride as (1) explicitly named in the warnings, (2) only mentioned as examples of a drug class, or (3) only implied as drug class members. We used multivariate analysis to relate temporal changes in concomitant dispensing rates to type of warning (explicit, example, or implied), patient demographic characteristics, season, calendar year, and temporal relationship to the "Dear doctor" warnings. RESULTS: A highly publicized letter sent in June 1998 was associated with a notable decline (58%) in the concomitant dispensing rate with explicitly contraindicated drugs but not in the concomitant dispensing of cisapride with the example or implied drugs. An earlier letter, which had been explicit but was accompanied by less publicity, had no measurable effect on this study's measure of coprescription, nor did a later letter that emphasized comorbidities. CONCLUSIONS: Explicit, well-publicized drug warnings can change prescriber behavior.

Webb, J., T. C. Davis, et al. (2008). "Patient-centered approach for improving prescription drug warning labels." Patient Educ Couns **72**(3): 443-9.

OBJECTIVE: To use a patient-centered approach to refine warning labels promoting the safe use of prescription drugs among patients, regardless of literacy level. METHODS: Ten discussion groups were conducted among adults recruited from a general internal medicine clinic and four adult education classes. Participants completed face-to-face cognitive interviews with literacy assessment to determine comprehension of the 10 most commonly used drug warning labels, followed by a discussion group that solicited feedback for revising text and icons. RESULTS: In all, 85 adults participated; 56% had limited literacy skills. Feedback from discussion groups indicated that the majority of icons were confusing, used difficult language, and text and icons were often discordant. Participants sought actionable language in the most simple and concise manner. In comprehension testing, five of the warning labels reached a set standard of >80% comprehension; the remaining labels were revised and three others modified on patients' request. A universal icon that conveyed 'Caution' was used for one label ("use only on your skin") as patients were unable to agree on an acceptable visual representation. CONCLUSION: A patient-centered approach to designing consumer medication information could improve the comprehensibility of existing warning labels. PRACTICE IMPLICATIONS: Pharmacies should review existing drug warnings to assess adequacy among patients, particularly those with limited literacy. Pharmacists should confirm patients understand auxiliary warnings to support safe and effective use.

Wogalter, M. S., J. W. Brelsford, et al. (1991). "Consumer product warnings: The role of hazard perception." Journal of Safety Research **22**(2): 71-82.

Three studies examined factors associated with people's hazard perceptions of consumer products. A specific interest was how these perceptions relate to willingness to read product warnings. In Study 1, 72 generically-named products were rated on perceived hazard, familiarity, and several expectations associated with warnings, including willingness to read them. Willingness to read warnings was found to have a strong positive relationship with perceived hazard. Though familiarity was negatively related to willingness to read warnings, it provided little predictive value beyond perceived hazard. In addition, products judged as more hazardous were expected to have warnings, to have them in close proximity to the product, and to be less aesthetically impaired by prominent warnings. Since hazard perception was found to be an important determinant of willingness to read warnings, potential components of hazard perception were examined in Studies 2 and 3. Study 2 showed that perceived severity of injury related more strongly to perceptions of hazard than likelihood of injury. In Study 3, participants generated accident scenarios and rated the severity and likelihood of each scenario. For each product, they also judged overall hazard and their intent to behave cautiously. Results supported the two earlier studies and showed that severity of the first generated scenario was most predictive of hazard perception. Theoretical implications and applications for warning design are discussed.

Wogalter, M. S., V. C. Conzola, et al. (2002). "Research-based guidelines for warning design and evaluation." Appl Ergon **33**(3): 219-30.

During the past two decades, the body of empirical research on warning design and evaluation has grown. Consequently, there are now basic principles and guidelines addressing warning design (e.g., signal words, color, symbols, and text/content), placement (e.g., location within product instructions), and how to enhance the usability of designs by considering factors internal to the user (e.g., beliefs, perceptions of risk, stress). Similarly, evaluation methods have been developed that can be used to measure the effectiveness of warnings such as the degree to which warnings are communicated to recipients and the degree to which they encourage or influence behavioral compliance. An overview of the empirical literature on warning guidelines and evaluation approaches is provided. Researchers, practitioners, and manufacturers can use these guidelines in various contexts to reduce the likelihood that injury and product damage from exposure to a hazard will occur.

Wogalter, M. S., S. W. Jarrard, et al. (1994). "Influencing of warning label signal words on perceived hazard level." Hum Factors **36**(3): 547-56.

This experiment investigated the influence of warnings, signal words, and a signal icon on perceived hazard of consumer products. Under the guise of a marketing research study, 135 people (high school students, college students, and participants from a shopping mall) rated product labels on six dimensions, including how hazardous they perceived the products to be. A total of 16 labels from actual household products were used: 9 carried the experimental conditions, and 7 were filler product labels that never carried a warning. Five conditions presented the signal words NOTE, CAUTION, WARNING, DANGER, and LETHAL together with a brief warning message. In another two conditions, a signal icon (exclamation point surrounded by a triangle) was presented together with the terms DANGER and LETHAL. In the final two conditions, one lacked a signal word but retained the warning message, and the other lacked both the warning message and the signal word. Results showed that the presence of a signal word increased perceived product hazard compared with its absence. Significant differences were noted between extreme terms (e.g., NOTE and DANGER) but not between terms usually recommended in warning design guidelines (e.g., CAUTION and WARNING). The signal icon showed no significant effect on hazard perception. Implications of the results and the value of the methodology for future warnings investigations are discussed.

Wogalter, M. S., M. J. Kalsher, et al. (1999). "Effect of signal word and source attribution on judgments of warning credibility and compliance likelihood." International Journal of Industrial Ergonomics **24**(2): 185-192.

Social-communication models frequently include message source as an important factor in persuasion. However, research on the contribution of source characteristics to warning

effectiveness is virtually non-existent. The present research involved two experiments. Experiment 1 examined the effects of the presence (vs. absence) of the signal word WARNING, supplementing it with the source-related term GOVERNMENT to the signal word, and the addition of more specific terms (i.e., US and FEDERAL) on ratings of credibility and compliance likelihood for alcohol, cigarette, and iron supplement warnings. Higher ratings were produced with the signal word's presence than its absence and adding more specificity (and length) to the source. The highest ratings accompanied the longest, most specific prefix: US FEDERAL GOVERNMENT WARNING. Experiment 2 investigated three types of sources on credibility and compliance likelihood: (1) specific regulatory governmental agencies (e.g., US FOOD AND DRUG ADMINISTRATION), (2) specific scientific professional groups (e.g., AMERICAN MEDICAL ASSOCIATION), and (3) general statements in which an explicit source is not mentioned (e.g., Important Health Warning). The inclusion of specific sources produced higher ratings compared to a signal word (WARNING) alone. Implications for warning design and further research are discussed. Relevance to industry Warning messages are used to communicate information about potential hazards and how to avoid injury and property damage. This research shows that the presence of a signal word and adding specific source information (telling who is giving the message) was found to increase credibility judgments and compliance intentions. Implications for enhancing warning effectiveness are discussed.

Wogalter, M. S., A. B. Magurno, et al. (1999). "Enhancing information acquisition for over-the-counter medications by making better use of container surface space." Exp Aging Res 25(1): 27-48.

Most over-the-counter (OTC) pharmaceutical container labels are printed in very small type. Consequently, people with visual impairments (e.g., presbyopia in older adults) have difficulty reading the material. Some OTC drugs are packaged in containers with easy-open caps. This design increases the surface area that could be used to enhance the labeling. In Experiment 1, older adults ($M = 75.1$ years, $SD = 8.1$) evaluated six container label variants for an actual OTC product. Besides having a multipanel main label, four containers had labels attached to the cap that displayed the most important information in large print but differed in color. Two control containers lacked a cap label; one had only a four-panel main label, and the other had only the front label. Participants ranked the containers on six dimensions (e.g., label noticeability, willingness to read). Results showed greater preference for containers with the cap labels. Experiment 2 again examined preferences but also measured information-acquisition performance after participants ($M = 79$ years, $SD = 5.8$) were briefly exposed to a realistic-appearing, but fictitious, OTC medication. Results showed greater knowledge and preference for containers with the cap labels. Experiment 2 showed that one of the cap colors (yellow) that was different from the main label was preferred over the white and orange (the same colors as on the main label), but color distinctiveness as an explanation was not fully supported because the green cap was not significantly different from the other cap labels. Implications for communicating information about OTC drugs using expanded labels are discussed.

Wogalter, M. S. and N. C. Silver (1995). "Warning signal words: connoted strength and understandability by children, elders, and non-native English speakers." Ergonomics 38(11): 2188-206.

Signal words, such as DANGER, WARNING and CAUTION, are commonly used in sign and product label warnings for the purpose of conveying different levels of hazard. Previous research has focused on whether people's perceptions of connoted hazard are consistent with the levels suggested by design standards and guidelines. Most investigations have used college students to evaluate the terms; other populations who may be at greater risk have not been adequately studied. One purpose of the present research was to determine whether young children, the elderly, and non-native English speakers perceive similar connoted hazard levels from the terms as undergraduates and published guidelines. A second purpose was to assess the terms' comprehensibility using various metrics such as missing values (i.e. ratings left blank) and understandability ratings. A third purpose was to develop a list of potential signal words that probably would be understandable to members of special populations. In the first experiment, 298 fourth- to eighth-grade students and 70 undergraduates rated 43 potential signal words on how careful they would be after seeing

each term. The undergraduates also rated the terms on strength and understandability. In the second experiment, 98 elders and 135 non-native English speakers rated the same set of terms. The rank ordering of the words was found to be consistent across the participant groups. In general, the younger students gave higher carefulness ratings than the undergraduates. The words that the younger children and the non-native English speakers frequently left blank were given lower understandability ratings. Finally, a short list of terms was derived that 95% or 99% of the youngest students (fourth- and fifth-graders) and 80% of the non-native English speakers understood. Implications of hazard communication are discussed.

Wogalter, M. S. and W. J. Vigilante, Jr. (2003). "Effects of label format on knowledge acquisition and perceived readability by younger and older adults." *Ergonomics* **46**(4): 327-44.

This research examines consumers' information acquisition and preference for labels of a simulated over-the-counter (OTC) medication. Twelve otherwise identical OTC drug bottles were compared with different back labels varying in (a) print size, (b) amount of white space between text, and (c) label design (standard vs extended/pull-out). A no back label condition served as a control. Older (mean age=77.7 years) and younger (mean age=21 years) adults were given one of the 12 bottles and asked to perform one of two information acquisition tasks: (a) they examined the bottle for 3 minutes and then completed a questionnaire with the bottle absent, or (b) they answered the same questionnaire while the bottle was present. Afterwards, participants were given all of the bottles and asked to rank them according to perceived readability. The younger adults' information acquisition performance was significantly better than the older adults' for all label conditions except the control condition where both groups' low performance did not differ. Specifically, the older adults' performance was significantly better in the medium and large print conditions than in the small print conditions--with the latter conditions not differing from the control condition. Younger adults showed no performance differences among the different print-size conditions. No substantial effects on knowledge acquisition performance from the white space manipulations were found. However, the perceived readability ranks showed that both groups preferred larger print size and white space. The white space effect was smaller than for print size, particularly for older adults. The extended/pull-out label design was facilitative for older adults in that it allowed the use of larger print. The results suggest that older consumers may be unable to acquire information in the 'fine' print frequently found in various kinds of product literature.

Wogalter, M. S. and S. L. Young (1994). "The effect of alternative product-label design on warning compliance." *Appl Ergon* **25**(1): 53-7.

Many potentially hazardous products are packaged in small containers. Because of the limited amount of space available on these containers for warnings and other information, manufacturers often reduce the size and amount of printed material on the labels. This frequently impairs the message's legibility, noticeability and comprehensibility. Recently, several alternative label designs have been investigated using preference ratings, but whether the designs facilitate safer behaviour has not been determined. In the present experiment, two alternative designs (tag and wings) were compared with a conventional (control) design for their effect on behavioural compliance with a warning on a very small container of glue. Participants performed a parts-assembly task using the glue without being informed of the study's real purpose. Whether participants wore protective gloves as directed by the warning was measured. Results showed that the tag design produced significantly greater compliance than the other two designs. Measures of noticing, reading and recall of the warning mirrored the compliance results. While participants generally preferred the control label, they most preferred the tag warning. Overall, the results suggest that alternative designs like the tag can enhance warning communication and compliance in cases where surface area is limited.

Wolf, M. S., T. C. Davis, et al. (2007). "To err is human: patient misinterpretations of prescription drug label instructions." *Patient Educ Couns* **67**(3): 293-300.

OBJECTIVE: To examine the nature and cause of patients' misunderstanding common dosage instructions on prescription drug container labels. METHODS: In-person cognitive interviews including a literacy assessment were conducted among 395 patients at one of

three primary care clinics in Shreveport, Louisiana, Jackson, Michigan and Chicago, Illinois. Patients were asked to read and demonstrate understanding of dosage instructions for five common prescription medications. Correct understanding was determined by a panel of blinded physician raters reviewing patient verbatim responses. Qualitative methods were employed to code incorrect responses and generate themes regarding causes for misunderstanding. RESULTS: Rates of misunderstanding for the five dosage instructions ranged from 8 to 33%. Patients with low literacy had higher rates of misunderstanding compared to those with marginal or adequate literacy (63% versus 51% versus 38%, $p < 0.001$). The 374 (19%) incorrect responses were qualitatively reviewed. Six themes were derived to describe the common causes for misunderstanding: label language, complexity of instructions, implicit versus explicit dosage intervals, presence of distractors, label familiarity, and attentiveness to label instructions. CONCLUSION: Misunderstanding dosage instructions on prescription drug labels is common. While limited literacy is associated with misunderstanding, the instructions themselves are awkwardly phrased, vague, and unnecessarily difficult. PRACTICE IMPLICATIONS: Prescription drug labels should use explicit dosing intervals, clear and simple language, within a patient-friendly label format. Health literacy and cognitive factors research should be consulted.

Wolf, M. S., T. C. Davis, et al. (2006). "A critical review of FDA-approved Medication Guides." Patient Educ Couns 62(3): 316-22.

OBJECTIVE: To investigate whether consumer-directed, FDA-approved Medication Guides issued for potentially harmful medications are likely to be useful to patients with limited literacy. METHODS: Lexile analysis and the suitability assessment of materials (SAM) were conducted on the 40 currently issued Medication Guides to evaluate reading difficulty, content, and format. Structured interviews with a literacy assessment were also conducted among 251 primary care patients at a public hospital clinic in Louisiana to determine if patients directed attention to Medication Guides and other accompanying patient information materials. RESULTS: The average Lexile score estimated an 11th-12th grade reading level for the guides (M=1223, S.D.=200). None of the 40 Medication Guides met federal recommendations (6th-8th grade level). Most Medication Guides were deemed unsuitable because they did not provide a summary of content (90.0%) or limit the scope of information (77.5%). Only 23.0% of patients reported having looked at Medication Guides or accompanying patient information materials; patients with low literacy were less likely to have looked at them (16.7% versus 32.9%, $p=0.03$). CONCLUSION: Medication Guides in their current form are not likely to be useful to patients with limited literacy skills. PRACTICE IMPLICATIONS: Reading level of text in Medication Guides should be reduced, summaries or "highlights" provided, and the scope of information limited to increase the likelihood of use among individuals with limited literacy. Consumers should be involved in their development.

Wolf, M. S., T. C. Davis, et al. (2006). "Misunderstanding of prescription drug warning labels among patients with low literacy." Am J Health Syst Pharm 63(11): 1048-55.

PURPOSE: The common causes for misunderstanding prescription drug warning labels (PWLs) among adults with low literacy were studied. METHODS: A total of 74 patients reading at or below the sixth-grade level and receiving care at the primary care clinic at the Louisiana State University Health Sciences Center in Shreveport were recruited to participate in structured interviews. Patients were asked to interpret and comment on eight commonly used warning labels found on prescription medications. Correct interpretation was determined by expert panel review of patients' verbatim responses. Qualitative methods were employed to code responses and generate themes regarding the misunderstanding of these PWLs. RESULTS: Among this sample of patients with low literacy skills, rates of correct interpretation for the eight warning labels ranged from 0% to 78.7%. With the exception of the most basic label, less than half of all patients were able to provide adequate interpretations of the warning label messages. Five themes were derived to describe the common causes for misunderstanding the labels: single-step versus multiple-step instructions, reading difficulty of text, use of icons, use of color, and message clarity. Labels were at greater risk for being misunderstood if they included multiple instructions, had a greater reading difficulty, included unfamiliar terms, or used confusing icons that were discordant with text messages. Participants also frequently imposed an

incorrect meaning on label colors, which led to further confusion. **CONCLUSION:** Patients with low literacy skills demonstrated a lower rate of correct interpretation of the eight most commonly used PWLs than did those with higher literacy skills. Multiple-step instructions, reading difficulty of text, the use of icons, the use of color, and message clarity were the common causes of label misinterpretation.