

17

Research on Pharmaceutical Labeling: An Information Processing Approach

Michael S. Wogalter
Russell J. Sojourner
North Carolina State University

Various methods are employed to communicate pharmaceutical information to the general public. Information may be conveyed by a variety of sources including labeling on the product container itself, on enclosures such as patient product inserts (PPIs), on exterior packaging, through advertising, or via direct communication with medical professionals. In many instances, the printed material supplied with a pharmaceutical product may be the only medium used to educate consumers on information associated with the product. Using these printed materials to communicate pharmaceutical information to older adults is a practice that is receiving greater attention. Interest is due in large part to the fact that older adults tend to consume more medications than other population groups. This fact, combined with the onset of visual and cognitive difficulties that accompany the aging process, make the creation of effective methods of communicating medication information to adults in general, and older adults in particular, an important challenge.

Pharmaceutical labels are used to disseminate information about medication uses, indications, benefits, and potential hazards. Effective medication labels serve

as both a source of information and as a method used to influence behavior. Both purposes are important, and a growing body of research has revealed various factors that influence label effectiveness.

Information Processing Model

Many of the processes associated with pharmaceutical labeling can be organized using one of several models of human information processing. This modeling approach categorizes people's mental activities into a coherent sequence of processing stages. Figure 17.1 depicts a simplified human information-processing model that is useful in organizing the factors that influence the effectiveness (or ineffectiveness) of pharmaceutical labeling. For a label to be effective at communicating information and influencing behavior, it must first capture attention and then maintain attention long enough for a person to adequately extract information from the material. Next, the material must be understood and needs to concur with the person's existing attitudes and beliefs; if it is in disagreement, the information should be adequately persuasive to evoke a change toward agreement. Finally, the message must motivate the consumer to perform proper compliance behavior. Each stage of the model can produce a bottleneck preventing information from being processed further. Accordingly, the model predicts that a label that is not noticed will not be read, a label that is not read will have little or no influence on beliefs and attitudes, and a poorly understood label will probably not motivate the appropriate behavior.

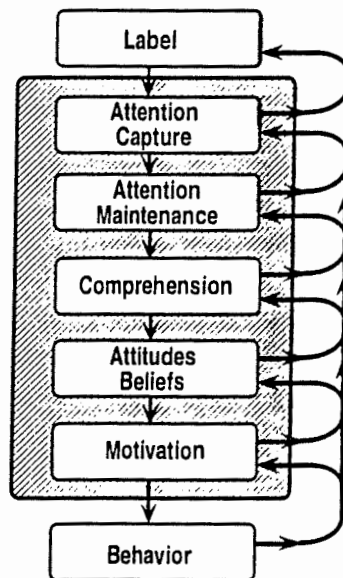


FIG. 17.1. An information processing model that describes a series of stages involved in successful communication and behavioral compliance.

This chapter is organized using this information-processing model. It is similar to the one described in Wogalter and Laughery (1996), except that in the earlier version Attention was described as a single stage. In the current model, Attention is separated into two stages, Attention Capture and Attention Maintenance. These stages delineate the process of noticing and then focusing attention to the warning.

In this chapter, each stage is described as it relates to warning labels in general, and next, research relating to pharmaceutical labels is emphasized. Research using adults of all ages will be cited, although studies involving older adults are mentioned where they exist.

ATTENTION CAPTURE

The first stage in the information-processing model concerns the capture of attention. An effective warning must initially attract the attention of persons at risk in the target audience. Because many environments are cluttered, the label must fight to grab attention in visual contexts. Thus, a label needs to be designed to adequately stand out from the background (i.e., be salient or conspicuous) in order to be noticed. This is particularly true when people are not actively seeking information concerning medication hazards and warnings. In situations like these, the “warnings have to look for people” (Laughery & Wogalter, 1997, p. 1181). Laughery and Wogalter (1997) proposed several basic human factors guidelines that can increase the saliency of displayed information:

Contrast. Printed information should have high contrast (light-dark difference) with the background; dark print on light background or vice versa increases its prominence or salience (Barlow & Wogalter, 1993). Certain color combinations (e.g., black and yellow) may facilitate adequate contrast.

Size. Within reasonable limits, bigger is generally better (Barlow & Wogalter, 1991, 1993). However, the absolute size of the label is not the only consideration. A label designer should also consider the relative size of the message components. For example, information on how to prevent injury should be allocated relatively more space than other, less important information (e.g., inert chemical composition).

Location. Because English-language users tend to scan left to right and top to bottom, important information should be located near the top or to the left if possible (Hartley, 1994). Warnings should not be buried within less important text (Strawbridge, 1986). Another consideration is sequencing of information. The preferred placement of warning statements is before rather than following usage instructions (Vigilante & Wogalter, 1997).

Signal words. Signal words can be used in labels to attract attention. The most common are CAUTION, WARNING, and DANGER, which are intended to denote increasing levels of hazard, respectively. In addition, fairly consistent perceptions of additional signal words have been found using diverse participant groups

including older adults, elementary, middle-school, and college students; and non-native English speakers (Wogalter & Silver, 1995).

Pictorials. Pictured concepts can make labels more noticeable (Young & Wogalter, 1990). Laughery, Young, Vaubel, and Brelsford (1993) found that pictorials reduce reaction time and enhance eye movement toward warnings.

Habituation. Repeated and long term exposure to a label may result in a loss of attention-capturing properties over time (Wogalter & Laughery, 1996). Even a well-designed label that incorporates the features that facilitate attention capture will eventually become habituated—although habituation may be slowed by these features.

Application of Attention Capture to Pharmaceutical Labels

Recent research has specifically addressed the attention-capturing properties of pharmaceutical labels. Generally, drug labels contain considerable information restricted to a very small space, resulting in printed information being compacted and reduced to very small sizes, which can negatively affect attention capture. Type size is particularly important for older adults because age-related vision problems may preclude them from reading the material on many pharmaceutical labels. Four point type (i.e., 4/72 inch in height) is commonly found on over-the-counter pharmaceutical products.

Recent research has focused on ways to counteract the small print, cluttered nature of labels. One remedy is to increase the available surface area on small containers. Barlow and Wogalter (1991) developed six alternative label designs (tag, wings, cap, box, disc, and wraparound) on very small (0.3 fluid ounce) product containers and compared them to a conventional control label design. Depictions are shown in Fig. 17.2. Undergraduates (mean age = 19 years) and older adults (mean age = 76 years) evaluated the container labels on various dimensions including one relevant to attention capture, the likelihood of noticing the warning.

Results indicated that alternative label designs compared to the conventional design were judged to be more noticeable by both participant groups. The students rated the tag label significantly higher than the other labels. The older adults judged the tag and wings labels most noticeable.

A later study by Wogalter, Forbes, and Barlow (1993) focused on the tag, wings, and control labels and introduced a type size manipulation in which the information was printed in three different sizes. Both undergraduates (mean age = 19 years) and older adults (mean age = 72 years) perceived the control inferior in warning noticeability compared to the alternative labels. In addition, both groups indicated that larger print size made the warnings more likely to be noticed.

The noticeability measures cited thus far only involved subjective evaluations. To evaluate effects on behavior, Wogalter and Young (1994) performed a compliance study that investigated whether the tags and wings labels would promote safer behavior when attached to a product that participants actually used. Undergraduates

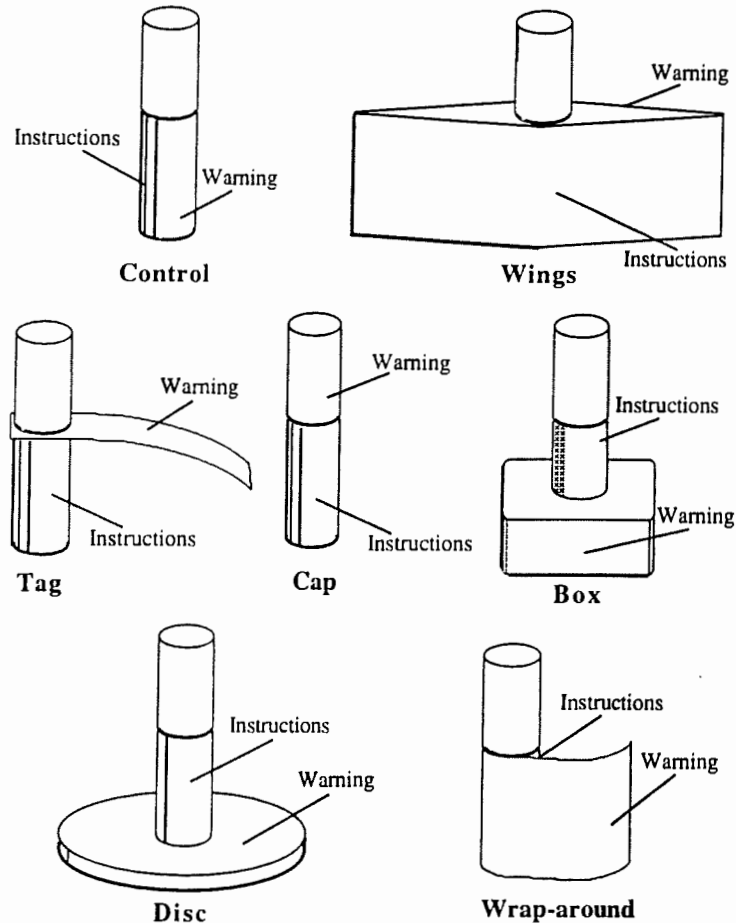


FIG. 17.2. Seven small container labeling methods. NOTE. From "Increasing the Surface Area on Small Product Containers to Facilitate Communication of Label Information and Warnings," by T. Barlow and M. S. Wogalter, 1991, in *Proceedings of Interface 91*, p. 90. Copyright 1991 by Human Factors Society. Reprinted with permission.

used a small glue bottle having either a control, wings, or tag label while performing a model airplane assembly task. Participants were not told that warnings design and compliance behavior were the main interests of the study (i.e., there was incidental exposure to the warning while doing the task). Although the content of the information printed on all labels was identical, the increased surface area of the tag and wings label enabled larger print (the font on the control label was 5-point type and, on both alternative labels, it was 9-point type). Whether or not participants wore protective gloves (as directed by a warning on the label) was measured. Participants complied significantly more often with the tag (80%) warning than with either the wings (36%) or control (13%) warning.

Kalsher, Wogalter, and Racicot (1996) continued to investigate the benefits of expanded surface area labels, but instead of using glue product labels, they used prescription medication containers. Undergraduates (mean age = 22 years) and older adults (mean age = 73 years) rated labels that varied by type (control, tag, fold-out), print size, and presence or absence of pictorials, on various dimensions including noticeability. A clear preference for the alternative labels was shown by both populations, and labels with pictorials were rated as more noticeable than labels without.

Wogalter and Dietrich (1995) also investigated the attention-getting aspects of medication labels. However, rather than using an alternative label design, they used an existing OTC easy open design. This type of OTC container, as shown in Fig. 17.3, has substantially more usable surface area than more conventional containers holding the same or similar medications. The easy open containers have space on the cap section for placing additional information.

In the Wogalter and Dietrich (1995) study, there were six label conditions, differing in color and placement of warning information. One control label was identical to a conventional OTC product commercially available at any pharmacy—having front, back, and side labels (but nothing of material relevance on the cap section). A second control label lacked the side, back, and cap labels (only the front label was used). The four experimental containers had the labels of the conventional control (with front, back, and side labels) but also included an additional label on the cap. All of the cap labels had the same information. It repeated some of the most important information from the back and side labels, plus it had larger print, a signal word (WARNING), and a signal icon (an exclamation point surrounded by a triangle). The four experimental cap conditions differed only by color (white, orange, both orange and white, and fluorescent green).

The results showed that participants (mean age 75 years) judged the containers with the added label on the cap more positively than the currently sold design without the cap information. Furthermore, participants preferred the colored cap

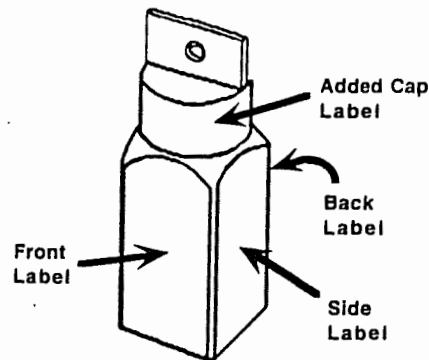


FIG. 17.3. OTC easy open cap container.

labels, ranking them higher than the white label. Thus it appears making use of existing surface space together with various conspicuity-enhancing features improves judged noticeability.

As we have seen, various methods derived from human factors principles can be used to increase the salience of printed information. However, the unique nature of pharmaceutical labels (e.g., a large amount of printed information on a small amount of space) make application of the principles difficult. Nevertheless, research indicates that using expanded surface area and conspicuity-enhancing features such as larger print, color, signal words, and pictorials can promote attention capture.

Attention capture is the initial requirement to get information processing underway, and thus it is the first hurdle. With the capture of attention, the information flow is allowed to continue to subsequent stages. Nevertheless, over time and repeated exposure, all labels, even ones with numerous attention-getting properties, will lose their ability to attract attention. Although there are no easy solutions to the problem of habituation, one approach is to intermittently vary the label appearance, structure, and content, making it look less familiar. This will retard habituation for a time, until the appearance must be altered again.

ATTENTION MAINTENANCE

Individuals might notice the presence of warnings and instructions on a label but not stop to examine them. If they do not examine it further, the effectiveness of the label will be limited only to knowing that a label is present, and there will be nothing conveyed regarding the content. Thus to proceed further with information processing, after the information on a label is noticed, attention must be maintained and focused on the material. At this stage, individuals decide to examine the information printed on a label. Many of the same design features that capture attention also appear to help maintain attention (Barlow & Wogalter, 1991; Wogalter, Forbes, et al., 1993). For example, large print not only attracts attention but also increases legibility, which lets users focus on the characters forming the message. Legible print and pictorials make reading less effortful and can make the material more desirable to read.

Factors that also influence attention maintenance include formatting and brevity. A label that is aesthetically pleasing in the way it is formatted will likely attract and hold attention during which the material is examined and information extracted (Hartley, 1994). Formatting can be based on many factors including the amount of "white space," information groupings, line spacing, and so forth. Material that is in an outline/list format is generally preferred to that in paragraph/prose style (Desaulniers, 1987). Furthermore, if the label contains large amounts of text, individuals may decide that it takes too much effort to read. Thus, brevity is desirable (Wogalter et al., 1987). See Hartley (1994) and his chapter in this volume (chap. 14) for more detail on formatting.

Application of Attention Maintenance to Pharmaceutical Labels

Older adults tend to consume more medications and have reduced vision capabilities relative to other population groups. Thus, the persons who most need the information may not be able to obtain it as they have difficulty reading the small print (Wogalter, Magurno, Scott, & Dietrich, 1996). As described earlier in the attention capture section, Barlow and Wogalter (1991) and Wogalter, Forbes, et al. (1993) found that alternative label designs with larger print increased noticeability ratings. They also found that these designs also increased participant's willingness to read the labels. Enhancements designed to attract attention (expanded surface area, etc.) also frequently promote attention maintenance such as reading behavior (Kalsher et al., 1996; Sojourner & Wogalter, 1997; Young & Wogalter, 1990).

Morris and Kanouse (1980) found that a moderate amount of information on drug leaflets is preferred. Too little and too much are negative features. This result reveals the conflict between brevity and completeness. Brief messages are more likely to be read but they may be incomplete. Messages that are highly comprehensive in content may address all of the questions that individuals may have, yet reduce the likelihood that people will make the effort to read the material.

Labeling and communication of drug information more generally require systems consideration. The packaging, the on-product label, and the insert all have different roles. A more complete insert will allow health care professionals or interested consumers to acquire more detailed information. The exterior packaging serves to convey the drug's appropriateness during purchase decisions, whereas the on-product label conveys information on use, and so forth. Allocating different information components to different parts of the label system may permit brevity and larger print on the container label, thereby increasing people's willingness to read what is there.

COMPREHENSION

A person may notice a label and examine it, but if he or she does not understand the words and pictures, the information goes no further, and processing stops. This creates a bottleneck that fails to inform and, down the line, negatively affects compliance. In the comprehension stage, information coming in makes connections with existing knowledge related to the label's message. The incoming information acts as a cue, activating memory structure and elaborating on the label information; this information is relatively easily assimilated into memory. If the message contains information that is not known, then with sufficient time and effort, the new information may be accommodated into memory where new structure and connections are created (i.e., learning may take place).

As necessary as it is, research on the factors that make label wording comprehensible is surprisingly limited. There is research on signal words that shows that certain terms may be useful in producing understanding of the level of hazard

involved. Some signal word studies (e.g., Wogalter & Silver, 1995) have examined understanding using subjective ratings, frequency of occurrence in the language, and readability indexes. Two novel approaches have used measures of variability (e.g., standard deviations) and missing (blank) evaluations as indications of understandability. The assumption is that if people's subjective evaluations are highly variable it indicates that people have different conceptions of what the word means (suggesting its use may not be appropriate if the intention is to communicate a particular level of hazard). When participants fail to evaluate the words (i.e., leave them blank), it is an indication that the terms are not well known (once again suggesting lack of viability as signal words). The tabled data in Wogalter and Silver (1995) could be used to select understandable terms spanning the entire hazard-level dimension as evaluated by older adults, young children, and recent U.S. immigrants.

Other than signals words, research on label wording is virtually nonexistent. Although there is considerable research testing label comprehension, this research does not necessarily test comprehension factors. For example, although Wogalter et al. (1996) found that knowledge acquired (using a comprehension test) differed depending on cap label conditions, this does not mean that the differences among conditions is a result of a direct impact on the comprehension factor. Instead, the difference between cap conditions was probably due to effects on the attention capture or attention maintenance phases. In other words, the earlier stages in the information-processing model may cause a bottleneck that shows up when a higher level stage is measured. Thus, although comprehension may be measured (i.e., the dependent variable), it does not mean that the manipulation (i.e., the independent variable) directly affects the comprehension stage.

A common (and sometimes unfortunate) misconception held by subject-matter experts is that certain kinds of hazards and the information conveyed on labels will be as well understood by less expert people as by themselves (Laughery, 1993). The knowledge held by experts is sometimes so ingrained that they may not realize that others may not understand it. Therefore, the resulting label may not do its job with respect to conveying clearly the needed information. In some cases, the target audience is well trained, for example, physicians and other professionals to whom the product may be restricted in its use and application (e.g., prescription medications), and therefore some assumptions can be made concerning the extent of their knowledge. Frequently, however, the lay public is the intended target of the message. Thus the main concern are individuals who have lower (or different) reading skills and education about the particular hazards of concern. Reading comprehension in older adults with lower education levels tends to decline with age (Meyer, 1987). To have a better chance of reaching these groups, the label should be made understandable by the lowest practical level of readers. Consider the statement "low birth weight" found on the label of some cigarette warnings. This statement is intended to convey the warning that smoking is harmful to the baby. However, there is some anecdotal evidence that some women have interpreted the statement to be a benefit of continuing to smoke, such as making labor

easier because the baby will be smaller, whereas others have interpreted it as a way to keep their own weight down. Had this warning been tested with a representative sample of the target population, in this case women of childbearing age, the wording could have been changed to avoid ambiguity.

Although there is not much research specifically on label language, other literatures (e.g., basic grammar, technical writing) point to factors that are likely to affect word comprehension. Some of these characteristics include the use of short, high-frequency words in the form of brief statements. In fact, computer-based readability indexes exist that are based on these criteria (e.g., the Flesch and Dale-Chall formulae) and that can automatically measure the grade level or percentage of the population that will understand the text. The readability indexes and the simplified language criteria are only starting points, however. Numerous research studies (e.g., Davison & Green, 1987; Klare, 1984) have shown that these criteria can provide misleading measures of comprehension and probably should be used only as a rough guide in the preliminary writing stages.

Other factors can also influence the understandability of text messages. A label that has headings and is logically organized (e.g., by content matter, ordered temporally or procedurally) and physically formatted (e.g., small chunks of text in a bulleted list format separated by white space) is likely to promote better comprehension than a single large chunk of disorganized prose. Guidelines on these characteristics can be found in the technical writing literature and are likely to benefit the construction of preliminary label prototypes (Hartley, 1994). However, to really assure label understandability, variants of the warning message should undergo usability evaluations using a representative sample of the target population. Iterative label redesign may be necessary if the tested message does not meet adequate comprehension (Hartley, 1995).

Although there is not much research on the specific factors influencing the word understandability of label text, there is a larger literature on pictorials. Pictorials are a potentially useful way to facilitate understanding. Well-designed pictorials can be worth a thousand words (more or less) and potentially communicate large amounts of information in a glance (Dewar, in press). Also there are benefits for people who have difficulty reading text because of low literacy levels, lack of familiarity with the language, or vision problems that make reading very small print difficult. However, although standards organizations like the American National Standards Institute (1991) and the International Standards Organization (1984) have specific testing methods to assure understanding is at adequate levels, most pictorials in common use today probably have not been tested and many may not be understood by the intended targets.

Application of Comprehension to Pharmaceutical Labels

The purpose of having understandable medication labels is to provide individuals with use, benefit, and risk information. Understandable labels enable informed decisions and promote safe actions by users of pharmaceutical products. As

mentioned earlier, the text needs to be sufficiently salient and large to get people to notice and read it. We have reviewed a number of studies that have tested alternative label designs that appear to reduce the print size problem. Enlarging the label surface area allows one to increase text size, to reprint the most important textual material in a salient manner, and to provide space for pictorials.

The general characteristics of word and statement simplification are likely to benefit text comprehension. Comprehensibility can also be enhanced by organizing the information on labels. In a study on label organization, Vigilante and Wogalter (1997) had students, community volunteers, and older adults arrange component text sections of four actual OTC medications. They found that participants arranged the four labels in a consistent order, preferring that, after the medication brand name, that labels have information in the following order:

1. Drug indications.
2. Warnings (cautions and precautions) and use (directions).
3. Active ingredients.
4. Inactive ingredients.
5. Safety-sealed designation.
6. Storage instructions.
7. Manufacturer information.
8. Bar code.

All three groups had similar orderings, although the older adults' assignments were somewhat more variable. These results are similar to those found by Morrow, Leirer, Altieri, and Tanke (1991) who had seniors arrange sections of a prescription drug label. See chap. 15 by Morrow and Leirer in this volume for a more extensive discussion of this topic.

Recent research has shown that some kinds of pictorials are successful at communicating important pharmaceutical-related information and warnings effectively. For example, Magurno, Wogalter, Kohake, and Wolff (1994) tested a diverse population group on the meanings of 30 pharmaceutical pictorials developed by the U.S. Pharmacopoeia Convention (USPC) and found that 18 of the pictorials met or exceeded the ANSI (1991) standard comprehension criterion of 85%. Furthermore, upon redesign, six more pictorials met the 85% correct comprehension criterion. Wolff and Wogalter (1993) performed similar testing using 28 of the 30 USPC pictorials and found that all but five of the pictorials surpassed the ANSI criterion. Ringseis and Caird (1995) tested comprehension for a set of pharmaceutical pictorials developed by the Pharmex Company and found that 9 of 10 pictorials tested (either original or redesigned pictorials) surpassed the ISO (1984) criteria of 67% correct comprehension.

Morrell, Park, and Poon (1990) developed and tested a unique pharmaceutical dosing pictorial. Medication label instructions were presented in either a traditional text format or in a format which combined text and pictorials. After studying a medication bottle label, participants were asked to recall the instructions. The

results showed that for younger adults, the mixed text and pictorials instructions were comprehended and remembered better than the plain text instructions, but older adults did worse when pictorials were present compared to text instructions alone.

Wogalter, Sojourner, and Brelsford (1997) found that even when some pharmaceutical pictorials were not well understood, brief exposure to the verbal referent (its name in words) can significantly raise and then maintain comprehension over an extended period. In this study, participants were exposed to 20 pharmaceutical and 20 industrial safety pictorials. Participants were initially tested on the meaning of each pictorial. Later, a verbal description (either its simple verbal referent or a more detailed explanation) of each pictorial was given. Later, comprehension tests were given at different points in time. Results showed that brief exposure to the verbal referent substantially increased comprehension and that high levels were retained over time.

Pharmaceutical pictorials are also preferred by consumers. For example, Kalsher et al. (1996) demonstrated that consumers believe pharmaceutical pictorials are helpful and should be included on medication labels. Ratings showed that consumers strongly preferred drug labels with pictorials over those labels without pictorials.

Unfortunately, depicting pharmaceutical information by pictorials can be difficult. As described earlier, several commercially available pharmaceutical pictorials fail to meet the ANSI or ISO acceptability criteria (Magurno et al., 1994; Ringseis & Card, 1995; Wolff & Wogalter, 1993). The difficulty is partly due to the concepts being depicted. Abstract, less visible concepts (e.g., the passage of time for the concept "Take until gone") tend to be more difficult to design. Concrete, visible concepts (e.g., "Take with water") are much easier to design and generally perform well on comprehension tests.

Moreover, by their very nature, many medication instructions are often highly complex, comprising multiple ideas. Consider the seemingly simple instruction "Take two hours after meals." This instruction is actually an abstract, multiple-component concept that relates to the consumption of medication after the passage of a specific time duration relative to food intake. As might be expected, representing this concept with a highly understandable pictorial (without any text) would be difficult. In fact, various pictorials depicting this concept have been found to be poorly understood (Magurno et al., 1994)

In extreme cases, poor comprehension can lead to "critical confusions," resulting in people understanding the opposite of what they should, and possibly prompting people to perform the wrong behaviors. These confusions are of particular concern when dealing with potentially hazardous medicines. ANSI (1991) allows no more than 5% critical confusions in pictorial comprehension tests.

In recognition of the need to avoid using pictorials that inadequately or incorrectly convey the intended message, printed material accompanying prescription medications is likely to contain only an incomplete set of pictorials. That is, each and every textual instruction item may not be supplemented by an accompanying pictorial. Concrete concepts may be represented by pictorials, whereas the complex and abstract instructions may be represented by text alone.

The effect of using an incomplete set of pharmaceutical pictorials was recently examined by Sojourner and Wogalter (1997). Five prescription medication information sheets (similar to commercially available Drug Information Leaflets) were created containing medication instructions that specified the directions and warnings for drug use. There were five instruction sheet conditions: (a) text only, (b) pictorials only, (c) simultaneous text and redundant pictorials, (d) text with one half of the statements being accompanied by a redundant pictorial (incomplete pictorials), and (e) a no instruction control. On one of the evaluated dimensions, undergraduates rated how easy it was to understand the instructions on the drug information sheet. The results showed that text with a full set of pictorials was rated as easiest to understand, followed by the partial pictorials condition. Apparently, pharmaceutical instructions with both text and pictorials allows people to process information in the form they prefer—as a verbal (text) code or a nonverbal (pictorial) code.

However, pictorials should probably not be used as a sole source of pharmaceutical information. In the Sojourner and Wogalter study, the drug information sheets that contained only pictorials were rated lowest in both comprehension dimensions compared to any of the information sheets with text. Apparently, pictorials are considered beneficial in augmenting text, not replacing it.

Morrow, Leirer, and Andrassy (1996) performed two experiments that showed the detrimental effect of not using highly understandable pictorials and accompanying text. Three medication schedule pictorials were developed: a time line, a pair of 12-hour clocks (one each for AM and for PM hours), and a 24-hour clock. The pictorials were compared with text instructions using younger (mean age = 26 years) and older (mean age = 70 years) adult participants. In the first experiment, participants paraphrased and then recalled schedules that were conveyed by the different instructional methods. Text was paraphrased more quickly than any of the pictorials, and text and time line schedules were paraphrased more accurately than the two clock pictorials. In the second experiment, free and cued recall after limited study time was assessed. Again, text instructions were associated with highest performance and were recalled more accurately than any pictorial. Morrow and his colleagues explained that the superior performance associated with text is due to people's greater familiarity with textual instructions. Another reason may be the quality of the pictorials used. See Morrow and Leirer's chapter (chap. 15) in this volume for a more extensive review of this topic.

BELIEFS AND ATTITUDES

Given that a warning captures attention, is read, and is understood, then the next stage in the information-processing model concerns beliefs and attitudes. *Beliefs* refer to an individual's knowledge of a topic that is accepted as true (regardless of actual truth) and which is used to form opinions, expectations, and judgments. *Attitudes* are similar to beliefs but have more emotional involvement. Because of their similarity, beliefs and attitudes are grouped together in the model.

Although beliefs and attitudes follow comprehension in the model, their effect on human information processing could occur at earlier stages. For example, individuals who believe a product is safe may not look for a warning, and even when a warning is noticed, the individual may elect not to examine it further. The fact that later stages influence decisions at earlier stages points to the fact that there are backward or feedback effects among the stages of the information-processing model.

When people are familiar with a product, the probability of looking at, reading, and complying to the label is lower than if the product is unfamiliar (e.g., Godfrey, Allender, Laughery, & Smith, 1983; Wogalter, Brelsford, Desaulniers, & Laughery, 1991). Repeated use generally increases product knowledge, which can reduce the propensity to seek additional information about the product. Also, it could produce overconfidence about how to use a product, or lead to erroneously low levels of perceived risk, and, as a consequence, unsafe behavior may be produced. However, this does not necessarily mean that familiarity breeds unsafe behavior. When going from being unfamiliar to familiar, the information gained could include knowledge of how a product is used as well as possible side effects and warnings, which in turn, could result in safer behavior. Familiarity beliefs are detrimental when they cause people to not read labels for similar-appearing, but more hazardous, products.

Related to familiarity, an important factor associated with people's beliefs and attitudes is hazard perception. Familiar products tend to be less hazardous. Persons who do not perceive a product as hazardous will be less likely to notice or read an associated label (Wogalter et al., 1991; Wogalter, Brems, & Martin, 1993). And even if they do read the label, people may not comply with the directives on a product if they believe the hazard is low.

Another related factor is injury severity or the extent to which people think they may be hurt. People are more likely to consider injury severity than injury likelihood when forming their hazard perceptions (Wogalter et al., 1991; Wogalter, Forbes, et al., 1993).

Assuming that individuals do read the information on a label, if it does not conform to, or is discrepant with, an individual's existing beliefs and attitudes, then the information will likely be disregarded. The information conveyed must then be sufficiently persuasive to change the person's beliefs and attitudes to concur with the appropriate ones to assure safety. Although bringing about change to someone's belief structure is not an easy task, it is facilitated by first presenting information in a form that will be noticed, read, and understood using the facilitating characteristics discussed earlier—so it has a chance to affect beliefs and attitudes by giving a persuasive presentation of the critical information. In some cases, it might need to be strong enough to override people's preexisting knowledge and experience.

Application of Beliefs and Attitudes to Pharmaceutical Labels

Some people are under the misconception that if a drug store can sell a medication over the counter, or if a physician is willing to prescribe a medication, then it must

be safe. This "safety complacency" creates problems when people do not believe there are any risks and ignore the labeling.

Moreover, when individuals become familiar with a medication, they are less likely to look at or read the label information. Repeated use can produce overconfidence and may lead to incorrect administration of the drug. Familiarity can also cause a problem when people do not read labels of similar-appearing pharmaceutical products or of new (possibly more hazardous) versions of older products. However, as mentioned earlier, familiarity is not always detrimental; over time, the individual may learn why and how the medication is used as well as possible side effects and, as a consequence, produce safer behavior.

Clearly, then, when people have certain beliefs and attitudes that are discrepant with realities of medication consumption and risks, it creates a problem. The label must correct those beliefs and attitudes, but at the same time people may not look for or read the label. In such cases, the label design must ensure attention capture and maintenance and the vital importance of heeding the label. This can be accomplished in part by changing or altering the characteristics of the product label packaging so that it appears substantially different.

Recently, there have been proposals calling for standardized pharmaceutical label formats. Standardization could increase label usability, allowing consumers quickly to locate and extract important information from consistently organized pharmaceutical labels. Research has begun to examine characteristics of standardized labels. Morrow et al. (1991) and Vigilante and Wogalter (1997) found that people tended to consistently order components of labels for prescription and OTC medications, respectively. However, with standardization, labels will look very similar and may falsely promote familiarity beliefs and habituation across different kinds of drugs. Because standardization of medication labels will have both positive and negative outcomes, there still needs to be some flexibility so that critically important information can be conveyed in a salient fashion, particularly in cases where the medication has greater risks than consumers assume.

MOTIVATION

If pharmaceutical instructions are noticed, read, understood, and agree with a person's beliefs and attitudes (or are sufficiently strong to change beliefs and attitudes), the process moves to the motivation stage of the information processing model. To be effective at this stage, the instructions must motivate or "energize" the desired behavior. In this context, motivation takes two primary forms. First, individuals must be sufficiently motivated to read the label. Here, motivation feeds back to the attention maintenance stage in the information processing model. Motivation may derive from the person desiring to maintain safety (internally generated) or from the information on the product label, which, if designed well, should grab and hold attention (externally generated).

Second, individuals must be motivated to perform the correct behavior. One factor affecting compliance motivation is the message wording. In particular,

information on injury severity can motivate people because few want to get hurt. A warning that says "Consuming alcohol within 2–3 hours of taking this drug can cause liver failure, which can produce death" is more likely to motivate compliance than a simple "Ask your doctor before using this drug if you consume alcohol." The former is also more explicit than the latter. Explicit statements clearly state the dangers of noncompliance. For example, Laughery, Vaubel, Young, Brelsford, and Rowe (1993) showed that the more explicit statement "Do not exceed recommended dosages because nervousness, dizziness, or sleeplessness may occur" raised hazard perceptions more than the less explicit statement "Do not exceed recommended dosages because undesirable effects may occur." Similarly, other wording characteristics may motivate behavior, including statements from a more authoritative source (e.g., U.S. Food and Drug Administration) than a less authoritative source (e.g., a sports figure or an actor) (Wogalter, Kalsher, & Rashid, in press).

Another factor affecting motivation is the cost (any expenditure of effort, time, or money) of complying and not complying. When people perceive the cost of compliance to be greater than the benefits, they are less likely to take proper actions. The requirement to expend even a minimal amount of extra time or effort can dramatically reduce motivation to comply (Wogalter, Allison, & McKenna, 1989; Wogalter et al., 1987). One way of reducing the cost of compliance is to make the directed behavior easy to perform (Wogalter et al., 1987, 1989).

The costs of noncompliance can also have a powerful influence on compliance motivation. These costs include injury, reprimands, and fines. Information on these aspects need to be known or communicated. Explicit consequence statements (e.g., the extent of potential injury) provides such information. Such statements have the power to motivate because they express outcomes that people wish to avoid.

Other variables also affect motivation. Time pressure reduces compliance likelihood (Wogalter, Magumo, Rashid, & Klein, 1998). Also, social influence influences motivation. If people see others comply, they are more likely to comply, and, if they see others not comply, they are less likely to comply (Wogalter et al., 1989).

Application of Motivation to Pharmaceutical Labels

One factor playing a critical role for eliciting motivation is the message content. Labels should have direct, explicit statements that communicate the consequences of not complying so that users can appreciate the costs of noncompliance (usually in terms of warnings/cautions and contraindications). To reduce compliance costs, the label should contain step-by-step instructions and if possible should include all the materials necessary for safe use of the product. For example, if a bulb syringe, rubber gloves, or measuring instrument is to be used with some kinds of medications, they might be included with the product. Likewise, providing a 24-hour toll-free number to address medication-related questions might also decrease compliance costs. See chap. 13 by Bogner in this volume for more information on these issues.

SUMMARY AND FINAL COMMENTS

There are numerous issues involved in the design of pharmaceutical label information. An information processing approach has served as a framework to analyze the steps involved in attention capture, attention maintenance, comprehension, beliefs and attitudes, and motivation. Furthermore, this approach has been used to highlight the factors influencing label effectiveness. Several recommendations can be made:

1. Pharmaceutical labels should be designed so that they will be noticed and examined. Enhancing salience and visual interest will benefit attention capture and maintenance. The small size of most pharmaceutical containers makes application of good design principles a challenge, but as we have seen, there are ways to increase the surface area of labels which allow the use of attention-enhancing features such as pictorials and legible print. Particular consideration should be given to older adults who tend to take more medications than other age groups and who may have age-related vision problems.

2. Pharmaceutical information should be understandable by as large a portion of the intended audience as possible. Factors that would benefit understanding of the label material includes simplified wording, organization of the material using headings, and pictorials.

3. Pharmaceutical information should contain persuasive, assertive statements to ensure that readers have or form the correct beliefs and attitudes. Changing the appearance of labels may be useful in countering familiarity beliefs that might prevent a person from reading the persuasion attempt.

4. Information contained in pharmaceutical labels should motivate people to comply. Cost of compliance needs to be low, and the consequences of noncompliance should be communicated explicitly.

How does the designer of a pharmaceutical label know whether the pharmaceutical label has the correct combination of desirable features? Inevitably, trade-offs have to be made. For example, explicit warnings are recommended, yet they also require more space than less explicit warnings—space that could be used for larger print or the inclusion of a signal word. Consider also the case regarding label standardization, where consistency across drugs will enable quick and easy location of desired information, but may also promote habituation. How to make decisions on the importance of trade-off principles in pharmaceutical label applications will require further research. In the mean time, answers to questions on adequacy of particular pharmaceutical labels require testing using a representative sample of the target population.

Testing may use many methods including subjective ratings, legibility assessments, comprehension tests, and actual behavioral compliance. There are also techniques using initial label prototypes in usability and market testing. Compliance testing is best, but sometimes can not be employed because of ethical and time constraints. Unfortunately, most pharmaceutical labels probably have not been

tested at all, which is probably the main reason for their low quality. We believe that some testing is better than none at all, even if the tests do not use compliance measures or large numbers of test participants. Quite a number of improvements can be made with limited testing. Ideally, this testing should be an iterative process, requiring multiple label redesigns in order to find the right mix of adequate design factors. These data will help to confirm (or disconfirm) whether appropriate tradeoffs are successful.

Finally, testing can be directed at specific stages in the human information-processing model and may identify potential bottlenecks in the intermediate stages leading up to behavior. For example, if it is noted that people do not have the correct beliefs regarding a medication, enhancing label noticeability may not have any effect. Thus, the model also serves as a means of performing detective work when a warning is less effective than desired. By using the model as a basis for investigation, bottlenecks in the processing can be identified and appropriate steps taken to eliminate the barriers leading to safe behavior. This will be especially relevant to older adults who will surely benefit the most from advances in pharmaceutical label design.

REFERENCES

- American National Standards Institute. (1991). *American National Standard for Safety Warnings, Z535.1 to .5*. Arlington, VA: National Electrical Manufacturers Association.
- Barlow, T., & Wogalter, M. S. (1991). Increasing the surface area on small product containers to facilitate communication of label information and warnings. In *Proceedings of Interface 91* (pp. 88-93). Santa Monica, CA: Human Factors Society.
- Barlow, T., & Wogalter, M. S. (1993). Alcoholic beverage warnings in magazine and television advertisements. *Journal of Consumer Research*, 20, 147-155.
- Davison, A., & Green, G. (Eds.). (1987). *Linguistic complexity and text comprehension: A re-examination of readability with alternative views*. Hillsdale, NJ: Lawrence Erlbaum Associates.
- Desaulniers, D. R. (1987). Layout, organization, and the effectiveness of consumer product warnings. In *Proceedings of the Human Factors Society 31st Annual Meeting* (pp. 56-60). Santa Monica, CA: Human Factors Society.
- Dewar, R. (in press). Design and evaluation of graphic symbols. In H. J. G. Zwaga, T. Boersema, & H. C. M. Hoonhout (Eds.), *Visual information for everyday use: Design and research perspectives*. London: Taylor & Francis.
- Godfrey, S. S., Allender, L., Laughery, K. R., & Smith, V. L. (1983). Warning messages: Will the consumer bother to look? In *Proceedings of the Human Factors Society 27th Annual Meeting* (pp. 950-954). Santa Monica, CA: Human Factors Society.
- Hartley, J. (1995). Is this chapter any use? Methods for evaluating text. In J. R. Wilson & E. N. Corlett (Eds.), *Evaluation of human work* (pp. 285-309). London: Taylor & Francis.
- Hartley, J. (1994). *Designing instructional text* (3rd ed.). London: Kogan Page.
- International Standards Organization. (1984). *International Standard for Safety Colours and Safety Signs: ISO 3864*. Geneva, Switzerland: Author.
- Kalsher, M. J., Wogalter, M. S., & Racicot, B. M. (1996). Pharmaceutical container labels: Enhancing preference perceptions with alternative designs and pictorials. *International Journal of Industrial Ergonomics*, 18, 83-90.

- Klare, G. R. (1984). Readability and comprehension. In R. S. Easterby & H. J. G. Zwaga (Eds.), *Information design: The design and evaluation of signs and printed material* (pp. 479-495). New York: Wiley.
- Laughery, K. R. (1993) Everybody knows: or do they? *Ergonomics in Design*, 1, 8-13.
- Laughery, K. R., Vaubel, K. P., Young, S. L., Brelsford, J. W., & Rowe, A. L. (1993). Explicitness of consequence information in warnings. *Safety Science*, 16, 597-613.
- Laughery, K. R., & Wogalter, M. S. (1997). Warnings and risk perception. In G. Salvendy (Ed.), *The handbook of human factors* (2nd ed., pp. 1174-1197). New York: Wiley.
- Laughery, K. R., Young, S. L., Vaubel, K. P., & Brelsford, J. W. (1993). The noticeability of warnings on alcoholic beverage containers. *Journal of Public Policy and Marketing*, 12, 38-56.
- Magurno, A. B., Wogalter, M. S., Kohake, J. R., & Wolff, J. S. (1994). Iterative test and development of pharmaceutical pictorials. In *Proceedings of the 12th Triennial Congress of the International Ergonomics Association*, 4, 360-362.
- Meyer, B. (1987). Reading comprehension and aging. In W. Schaie (Ed.), *Annual review of gerontology and geriatrics* (pp. 93-115). New York: Springer.
- Morrell, R. W., Park, D. C., & Poon, L. W. (1990). Effects of labeling techniques on memory and comprehension of prescription information in young and old adults. *Journal of Gerontology*, 45, 166-172.
- Morris, L. A., & Kanouse, D. E. (1980). Consumer reactions to differing amounts of written drug information. *Drug Intelligence and Clinical Pharmacy*, 14, 531-536.
- Morrow, D., Leirer, V., Altieri, P., & Tanke, E. (1991). Elder's schema for taking medication: Implications for instruction design. *Journal of Gerontology: Psychological Sciences*, 46, P378-P385.
- Morrow, D. G., Leirer, V. O., & Andrassy, J. M. (1996). Using icons to convey medication schedule information. *Applied Ergonomics*, 27, 267-275.
- Ringseis, E. L., & Caird, J. K. (1995). The comprehensibility and legibility of twenty pharmaceutical warning pictograms. In *Proceedings of the Human Factors Society 39th Annual Meeting* (pp. 974-978). Santa Monica, CA: Human Factors Society.
- Sojourner, R. J., & Wogalter, M. S. (1997). The influence of pictorials on evaluations of prescription medication instructions. *Drug Information Journal*, 31, 963-972.
- Strawbridge, J. A. (1986). The influence of position, highlighting, and imbedding on warning effectiveness. In *Proceedings of the Human Factors Society 30th Annual Meeting* (pp. 716-720). Santa Monica, CA: Human Factors Society.
- Vigilante, W. J., & Wogalter, M. S. (1997). The preferred order of over-the-counter (OTC) pharmaceutical label components. *Drug Information Journal*, 21, 973-988.
- Wogalter, M. S., Allison, S. T., & McKenna, N. A. (1989). The effects of cost and social influence on warning compliance. *Human Factors*, 31, 133-140.
- Wogalter, M. S., Brelsford, J. W., Desaulniers, D. R., & Laughery, K. R. (1991). Consumer product warnings: The role of hazard perception. *Journal of Safety Research*, 22, 71-82.
- Wogalter, M. S., Brems, D. J., & Martin, E. G. (1993). Risk perception of common consumer products: Judgments of accident frequency and precautionary intent. *Journal of Safety Research*, 24, 97-106.
- Wogalter, M. S., & Dietrich, D. A. (1995). Enhancing label readability for over-the-counter pharmaceuticals by elderly consumers. In *Proceedings of the Human Factors and Ergonomics Society 39th Annual Meeting* (pp. 143-147). Santa Monica, CA: Human Factors and Ergonomics Society.
- Wogalter, M. S., Forbes, R. M., & Barlow, T. (1993). Alternative product label designs: Increasing the surface area and print size. In *Proceedings of Interface 93* (pp. 181-186). Santa Monica, CA: Human Factors Society.
- Wogalter, M. S., Godfrey, S. S., Fontenelle, G. A., Desaulniers, D. R., Rothstein, P. R., & Laughery, K. R. (1987). Effectiveness of warnings. *Human Factors*, 29, 599-612.
- Wogalter, M. S., Kalsher, M. J., & Rashid, R. (in press). Effect of signal word and source attribution on judgments of warning credibility and compliance likelihood. *International Journal of Industrial Ergonomics*.

- Wogalter, M. S., & Laughery, K. R. (1996). WARNING: Sign and label effectiveness. *Current Directions in Psychology, 5*, 33-37.
- Wogalter, M. S., Magurno, A. B., Rashid, R., & Klein, K. W. (1998). The influence of time stress and location on behavioral compliance with warnings. *Safety Science, 29*, 143-158.
- Wogalter, M. S., Magurno, A. M., Scott, K. L., & Dietrich, D. A. (1996). Facilitating information acquisition for over-the-counter drugs using supplemental labels. In *Proceedings of the Human Factors and Ergonomics Society 40th Annual Meeting* (pp. 732-736). Santa Monica, CA: Human Factors and Ergonomics Society.
- Wogalter, M. S., & Silver, N. C. (1995). Warning signal words: Connoted strength and understandability by children, elders, and non-native English speakers. *Ergonomics, 11*, 2188-2206.
- Wogalter, M. S., Sojourner, R. J., & Brelsford. (1997). Comprehension and retention of safety pictorials. *Ergonomics, 40*, 531-542.
- Wogalter, M. S., & Young, S. L. (1994). The effect of alternative product-label design on warning compliance. *Applied Ergonomics, 25*, 53-57.
- Wolff, J. S., & Wogalter, M. S. (1993). Test and development of pharmaceutical pictorials. In *Proceedings of Interface 93* (pp. 187-192) Santa Monica, CA: Human Factors Society.
- Young, S. L., & Wogalter, M. S. (1990). Comprehension and memory of instruction manual warnings: Conspicuous print and pictorial icons. *Human Factors, 32*, 637-649.

Processing of Medical Information in Aging Patients



Cognitive and Human Factors
Perspectives

Edited by

Denise C. Park
University of Michigan

Roger W. Morrell
University of Georgia

Kim Shifren
University of Michigan



LAWRENCE ERLBAUM ASSOCIATES, PUBLISHERS
1999 Mahwah, New Jersey London