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The Influence of Warning Label Presentation in Memory Recognition of Aging Adults

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THE INFLUENCE OF WARNING LABEL PRESENTATION IN
MEMORY RECOGNITION OF AGING ADULTS

by

Brian J. Call

A Thesis Submitted to the
Department of Human Factors & Systems
In Partial Fulfillment of the Requirements for the Degree of
Master of Science in Human Factors & Systems

Embry-Riddle Aeronautical University
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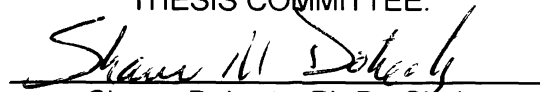
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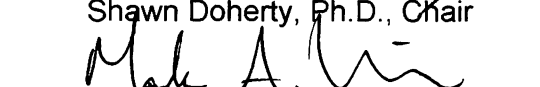
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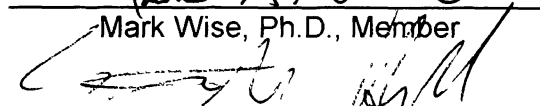
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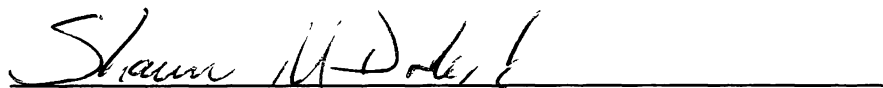
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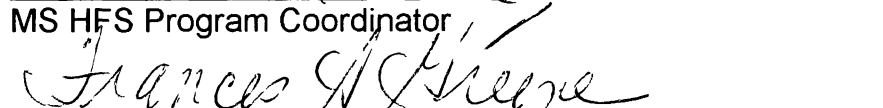
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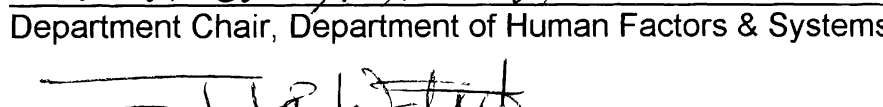

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ABSTRACT

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Research indicates that hundreds of thousands of people are injured each year as a result of poor communication between medical personnel, warning label information, and consumers when taking over the counter or prescription medication. Typically, as adult's age, they are increasingly responsible for remembering the hazards of taking medications. If inadequate information exists in memory in regards to side effects, dosage, and other warnings, the likelihood of improper usage will increase. Because aging adults typically have a reduction in cognitive resources, it was hypothesized that older adults would require the aid of additional warning information to assist in the retrieval process of this information. Therefore, it was predicted that aging adults will be able to retrieve information at a better performance level with a redundant set of text and pictorial information as it relates to warning labels than younger adults.

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LIST OF ABBREVIATIONS

ANOVA	Analysis of Variance
DCT	Dual Code Theory
USPC	United States Pharmacopoeia Conference

INTRODUCTION

Prescription and over the counter medications are an important part of outpatient treatment in the United States. They represent countless opportunities to cure illness or alleviate suffering. They also represent over 2 billion chances for patient error every year (Park, 1999). In order to maximize the benefits and minimize the dangers of using these products, users must comply with an often complex set of warning labels and instructions. A lack of understanding of these products or a lack of memorable experiences is often a cause of error (Smith, 1997). Recent reports by the U.S. Consumer Product Safety Commission state that hundreds of thousands of Americans are injured each year as a result of poorly designed and presented warning labels on products (Wogalter & Sojourner, 1999). According to Lehto and Miller (1986) product warnings are specific stimuli, which alert a user to the presence of a hazard, thereby triggering the processing of additional information regarding the nature, probability, and magnitude of the hazard. Typically, warning labels are intended to influence human behavior in ways that will improve safety. These labels are also intended to provide the human with information that enables them to not only understand the hazards and consequences, but also apply the appropriate behavior that will enable them to make conscious decisions towards the ultimate goal of preventing hazardous conditions before they occur. However, a warning can only be successful if it is transmitted and received in a manner in which the user sees the warning label, understands its purpose, and complies with it prior to entering a hazardous condition.

There are many environments in which consumers are exposed to warnings. For example, many pharmaceutical products may contain a printed statement on the medications container, a printed leaflet included with the medication, or images on the container as forms of exposing consumers to warning label information. Professional pharmacists are eager to provide information that will facilitate the safe and effective use of medications. Many pharmacists already provide information sheets and counseling with prescription and over the counter drugs,

most of which contain large amounts of written descriptions of medicine usage and effects. These informational sheets are typically one page in length, and include information on medication usage, dosage, side effects, warnings, and storage. However, to be effective with all users in our vast population this information must be read, understood, and rememberable by all. These medication users span the population, including older adults, non-native English speakers, and users with a range of cognitive abilities and medical knowledge. If these warnings are hard to remember, read or understand, then compliance may suffer, and the goal of preventing hazards before they occur will not be fulfilled (Park & Jones, 1997).

Currently, the emphasis on drug related warning labels can be attributed to several different factors, which include the increasing elderly population, competition between drug manufacturers, and the switching of prescription drugs to over the counter status. These factors place a greater responsibility for medication selection and dosage on the individual consumer. Research consistently demonstrates that people want to be informed of the benefits and risks associated with pharmaceutical drugs. As individuals get older the use of pharmaceutical products typically increases. As medical technology advances, the average life expectancy will tend to increase. However, despite the old adage that as people get older, they get wiser, there is evidence that suggests that when adults age the ability to recognize information declines (Schaie, 1988). Although the effects of age on information processing are progressive throughout adulthood, it is difficult to pinpoint exactly what age these effects will become apparent. According to Schaie and Willis (1986) who conducted a recall study with individuals ranging from an age of 25 to 81 years old, there is a steady gain in memory for recall until the late 30's or early 40's are reached. After that age, there is stability in recall and comprehension until the mid 50's to early 60's. However, beyond about age 60, Schaie and Willis (1986) suggested that there is a steady decrement of retention that occurs.

This gradual reduction in cognitive capacity is not really noticeable until the loss is substantial enough to affect everyday activities. For example, younger adults in their 20s and 30s

notice no losses at all, even though they are declining at the same rate as people in their 60s and 70s, because they have more capacity than they need. Furthermore, Chasteen, Park, and Schwarz (2001) stated that by the time people are in their mid-60s, the continuous decreases in cognitive abilities may become noticeable. Typically when most people are becoming more frequent consumers of medical services, they begin to notice that they are having more trouble remembering and learning new information. The process of learning or remembering new information and encoding it for storage requires more time to process in memory as individuals get older. In this context the term encoding refers to placing information in memory in a form that can be translated into working memory. Because of the reduced efficiency of neural transmissions in the brain and sensory deficits, one's ability to quickly and accurately perceive information during the encoding phase is declined. This may prevent individual experiences from receiving the attention needed for complete encoding into secondary memory. In addition, the extensive life experiences of older adults makes it more likely that new information will not adequately be distinguishable from previous learning's, which would make it difficult for the individual to make connections between the newly learned material, and the inference they make about this material (Salthouse, 1991).

The results of these studies suggest that individuals may be effected by a declining rate of retention beginning in early adulthood, because of their unique knowledge, and individual differences. However, they are more than likely to suffer from these capacity limitations more in elderly life. This data suggests that as adults get older, they require more assistance in recognizing and retrieving important information, such as medical information found on pharmaceutical products.

Statement of the problem

The purpose of this study was to determine if older adults would benefit, in terms of memory recognition, from additional or redundant information added to already existing warning labels on pharmaceutical medications. Presently, most medications include either text warning information or pictorial type information that reflects critical information about the dosage, and effects of over the counter and prescription medication. Pictorial images can be defined as any non-verbal graphical symbol or image that conveys ideas or information (Lodding, 1983). In this study the terms pictorial, image, or picture image, all referred to the same definition as listed above. This study specifically addressed how memory recognition was specifically effected by the presentation of a warning label within certain age groups, and whether or not consumer product warning labels that contained text would be more effective in changing human behavior if additional pictorial information were provided with the already existing textual content.

REVIEW OF THE LITERATURE

Human Information Processing and Memory

A human being who is presented with some specific fact, no matter what age, can often recognize that fact, or some representation of it, at a later point in time. Therefore, humans possess memory and process information. So, what is memory, and how is it processed? In its most general form, memory is a type of repository that retains information to later be retrieved. Humans not only have memory, but they also possess an elaborate memory system that allows them to process the information they have retained. One standard definition of memory is defined by Broadbent (1958) who stated that memory is the persistence of learning over time through the storage and retrieval of information. Within the memory system there are typically three processing stages. These stages are composed of a perception stage, which is concluded as the immediate initial recording of sensory information into the memory system, Short-term memory, or sometimes called Working memory, which is described as a storage facility that holds items for later processing, and retrieval, and Long-term memory, which is the infinite store of information. Working memory, the more contemporary term for short-term memory, is conceptualized as an active system for temporarily storing and manipulating information needed in the execution of cognitive tasks (e.g., learning, reasoning, and recognition), and will be focused on in this paper. These elements can be mapped onto a standard theory of human information processing (Kantowitz, 1987).

These stages are composed of perception, cognition, and action/response, (see figure 1).

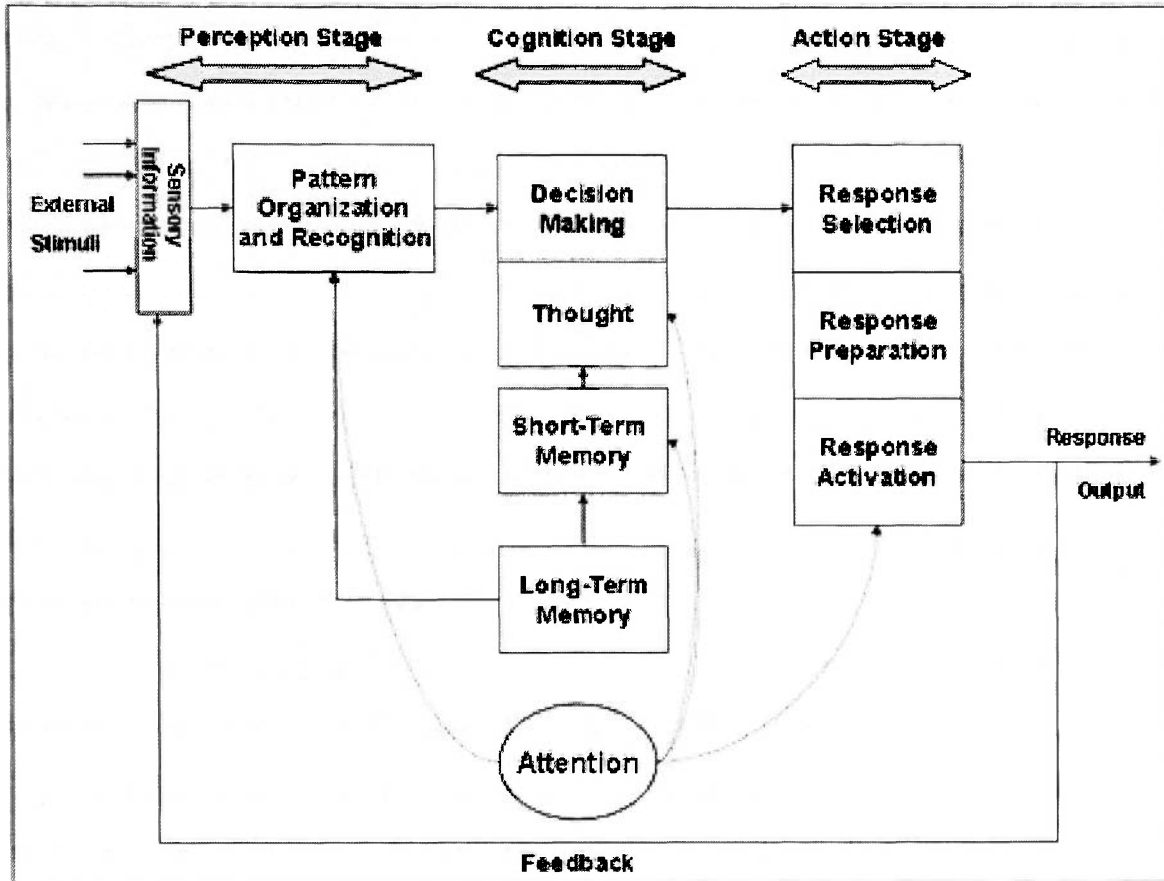


Figure 1: An elaborated model of Human Information Processing, (Kantowitz, 1987).

The perception stage is involved with the detection and identification of displayed information. The cognition stage assumes that information has been extracted from the displayed materials and allows the user to compare this information to something already in memory, other displayed items, logical comparisons, and decision-making to form a mental representation of what has been observed. Following the perceptual and cognitive stages of the processing model, an overt response, assuming one is required, needs to be executed (Kantowitz, 1987). This modeling approach categorizes people's mental activities into a coherent sequence of processing stages. The cognitive stage imposes constraints on human performance. For example, people may have limited abilities to attend to multiple sources of information, or they may have difficulty

retrieving information from memory. Sensory memory is designed to receive and hold visual stimulation from external sources. According to Mayer (2001), humans pass stimulus into their sensory system through receptors that acquire this information. Such receptors would include auditory information through the ears, or visual information through the eyes. This suggests that humans have separate information processing channels for processing auditory and visual information. During the time that information is being processed through channels into the sensory memory system, other cognitive processes, mostly associated with attention, must be performed in order to process this information further, so that it will be transferred into working memory. The capacity of attentional resources dictate the amount of separate processes that can occur simultaneously within working memory. This remains to be one of the limitations of working memory that prevents the passage of information into our long-term memory system.

The Components of Working Memory

Working memory can be thought of as a dynamic place where intermediate results of the memory processes are retained, and will be available for later processing. Within working memory, there are two basic types of components: storage and central executive functions (Baddeley, 1986). The storage system is composed of two components, which are known as the articulatory loop and the visuospatial sketchpad, and they are seen as relatively passive slave systems primarily responsible for the temporary storage of verbal and visual information respectively. One of the most important, but least understood, aspects of Working Memory is the central executive, which is conceptualized as very active and responsible for the selection, initiation, and termination of processing routines (e.g., encoding, storing, and retrieving).

The purpose of the central executive control, or sometimes termed limited capacity attentional system is to make decisions, facilitate reasoning, and direct attention to the triggering of the slave systems, termed articulatory loop, and visuo-spatial sketchpad. The visuo-spatial sketchpad takes care of visual imagery tasks, and visual search tasks, whereas the articulatory loop performs auditory tasks. These two slave systems are partially self-governing, in that they

can recirculate a small amount of information without interrupting the processing by the central executive, and can operate independently. When overloaded, however, these systems either begin to drain resources from the central executive, or simply perform the task poorly. If these systems drain resources from the central executive, it will degrade whatever performance the central executive is performing at that moment (Baddeley, 1986). For example, the central executive's resources may be drained if the articulatory loop or visual sketchpad become overloaded due to the task being too difficult for the person performing the particular task to accomplish. In other words, the working memory system is known as a closed memory system, with only some fixed resources to spread to the other slave systems. Once these resources are drained from the central executive, they are not replaced by any other components, instead the central executive functions merely suffers along with the insufficient resources for its own processing performance (Baddeley, 1986).

Limited Capacity of working memory

Mayer (2001) indicated that the human information processing system was composed of different channels for processing different types of information. This indicates that humans are limited in the amount of information that can be processed in each channel at one time. For example, when an illustration is presented, humans are able to hold only a few portions of that illustration in working memory at any given time. The constraints on a human's processing capacity forces people to make decisions about which pieces of incoming information to pay attention to, the degree to which one should build connections between selected pieces of information and one's existing knowledge. Working memory is the dynamic part of the memory system that is responsible for maintaining temporary information during mental operations. It has a limited capacity that constrains the performance of cognitive skills such as reading and arithmetic, reasoning and problem solving (Baddeley, 1986). The development of working memory is therefore of interest not only from the point of view of how memory develops, but also in the wider context of the development of cognitive skills. Our immediate memory cannot obtain

information into memory, hold, and retrieve vast quantities of information for long periods of time, and there is a severe limit on how much of this information can be acquired and retrieved from memory. The fundamental assumption is that human cognition is limited by quantitative constraints on processing, or limitations of capacity. This assumption is in addition to restrictions associated with quantity, quality, age, different types of knowledge, etc. Working memory has been pinpointed by different researchers as being responsible for capacity limitations during the processing of information and the recognition of information (Mayer and Moreno, 1999 and Mayer, 1999). One of the main methods of verifying specific assumptions about the way in which limited capacity affects cognitive functioning is to compare individuals or groups that are supposed to differ in working memory capacity (Hedden & Park, 2001). According to Plude and Hoyer (1985), older adults differ from younger adults primarily in terms of the efficiency of allocating limited resources. Hasher and Zacks (1988) have also proposed that the quantity of resources does not decline, but instead there is an age-related impairment in the selectivity or efficiency with which resources are allocated to processing components. They also propose that effective working memory capacity is reduced with increased age because a portion of the capacity is pre-occupied by an interruption or interference during the processing of new information. Hasher and Zacks (1988) believed that age-related cognitive slowing and reductions in attentional resources both reduced cognitive control. In other words, it was believed that the ability to manage one's thoughts, initiate recognition, and actions in unity with task relevant goals would suffer as a result of reduced cognitive control. This description of cognitive control shares characteristics with the supervisory attentional system, which takes control of processing in novel situations, when error detection is required, or when predominating thoughts or responses must be avoided. According to Salthouse (1996) cognitive slowing includes a fair amount of interference, that is, cognitive slowing reduces the amount of quality information simultaneously available in working memory, or the attentional resources of dynamic capacity in working memory. It is difficult to separate reduced working memory capacity from attentional capacity.

because most conceptualizations of working memory involve some notion of attentional resources

Aging Effects in the retrieval of information

Similar to the viewpoint that attentional resources are dynamically limited, the notion of reduced working memory capacity suggests that both the storage capacity and manipulation of information in working memory are limited with age. In support of this notion, Salthouse, Mitchell, Skovronek, and Babcock (1989) have concluded that the performance of older adults is declined as a function of the increasing complexity of mental operations involved in various tasks that are retained in working memory. This limitation in working memory capacity can result in poorer retention of integrated information, such as found in text comprehension, or memory recognition, where memory demands are relatively high. As people age, they go through physical, cognitive, and emotional changes. For some, the changes are gradual while others experience them more abruptly. Perhaps some of the most frustrating changes are those dealing with mental processes. Previous research claimed that one of these changes occur in working memory (Hedden & Park, 2001). It is now basically an accepted idea by many researchers that working memory does decrease in old age. However, it is not known what exactly is responsible for this decline.

It is generally assumed that aging is associated with a reduction in processing resources (Salthouse, 1991). This is viewed in terms of limitations on speed (Cerella, 1985) working memory capacity and attentional resources (Hartley, 1992). Craik (1983) hypothesized that the amount of attentional resources available to fuel complex cognitive tasks were reduced by aging as a result of demanding cognitive processing such as, encoding or placing information into memory, and retrieval or recovering information from memory, which deplete a greater proportion of available resources in older adults compared to younger adults. The logic is that the more demanding encoding and retrieval are the more attentional resources they will consume. Rabinowitz, Craik, and Ackerman (1982) found that older adults are less likely to encode, or place

in memory specific related information about to be remembered items, than younger adults will. Instead older adults encode information in a more general, automatic manner that typically leads to poorer retrieval and subsequent performance. Thus, a reduction in attentional or working memory resources may lead to a more general encoding strategy and poorer memory performance. For example, a difficult cognitive task would require more attentional capacity than a simple cognitive task. Several components of memory tasks would therefore be expected to decline with increasing age as a result of reduced processing resources. Tulving (1983) described two major reasons for forgetfulness. First, either the relevant information in memory was no longer available, or second, it was inaccessible. Since it is difficult to prove that any information in memory is truly inaccessible, it may be that this information cannot be retrieved because there was not an appropriate retrieval mechanism available to reinstate the retrieval of this information. Tulving (1983) promoted the notion that memory is a joint product of stored memory traces, and that these memory traces can decay unless some type of environmental support is present to assist in the retrieval of information when it is needed. Tulving and Thomson (1973) stressed that any type of environmental support, or retrieval cue that is presented at the time of learning or at the time of encoding, will aid retrieval at the time of testing, or that is, at the time to remember this item or event. Tulving and Pearlstone (1966) observed that remembering a word list was considerably better when some type of environmental support, or retrieval cue was added at the time of encoding such as, the addition of images or pictorials to already existing text instructions. Craik (1983) presented reasonable evidence that adult age related memory declines were greatest in situations where environmental support or cues were least available.

According to Craik (1983), the notion that a supportive task environment that facilitates encoding or that guides retrieval can offset the effects of reduced attentional resources is of particular interest. For example, the degree of age related memory decrements depends on the quality of encoding during times of study, and of the retrieval cues provided at times of study,

which facilitate the recovering of this information from memory. When this type of support is absent, age related decrements are usually increased. When support is provided to guide the retrieval of information, as in a recognition task, age related decrements are much reduced (Schonfield & Robertson, 1966). This suggests that a supportive retrieval environment reduces memory decrements and makes retrieval less attention demanding, particularly for older adults. Craik and Jennings (1992) suggested that deficiencies in memory due to limited cognitive resources of older adults can be repaired by the provision of environmental supports that decrease the processing requirements of the memory task, so that age differences become less distinctive. According to a study by Craik and Jennings (1992) it was found that age differences are indeed smaller when subjects use environmental supports such as related cues to retrieve target items from memory compared to no support at all. This occurred, presumably, because the related support drew upon world knowledge and did not require resource or mental representations to link to the target item, thus acting as an environmental support. For example, if older adults participated in the act of taking medication, there would be much more benefit in retrieving information placed on warning labels if the standard information was accompanied by additional information, such as images or text, that assists the recognition process. This redundancy of information could decrease the amount of attentional resources that were tasked during encoding and retrieval, and provide relief from cognitive demands in older adults. For example, Booher (1975) had participants read instructions which explained the proper use of a piece of equipment. Booher then tested participants with instructions provided by text only and instructions provided by text and a redundant set of images to aid in the explanation of the instructions. Booher described that this provided a redundant coding of information during the encoding process, so that one illustration emphasized the instructions, and supplementary information to aid in the explanation of the items. In all conditions, the use of this method aided the retrieval of information.

Redundant Information and Aging Effects

Aging adults typically show a decline in attentional resources within working memory and when complexity is added to the intake of information, these adults consume more resources in working memory, which in turn decreases their chances of retrieving this information at a later point in time. This suggests that by using supplementary or additional information to aid in the retrieval of relevant information would increase the chances for older adults to retrieve the information they encoded. This notion is supported by Paivio's Dual Code Theory (DCT). Paivio's Dual Coding Theory (DCT) is similarly structured to working memory in that it details certain memory routines, such as, encoding, storage, and retrieval. The major difference between Baddeley's working memory model and Paivio's dual code theory is that the working memory model proposes a more generic coding process, whereas DCT assumes multiple memory codes or traces that are modality specific (Marcshark, 1992). According to Paivio, humans possess a verbal system specialized for processing textual information, and a nonverbal system specialized for processing mental imagery, or pictorial information, see figure 2 (Paivio,1971)

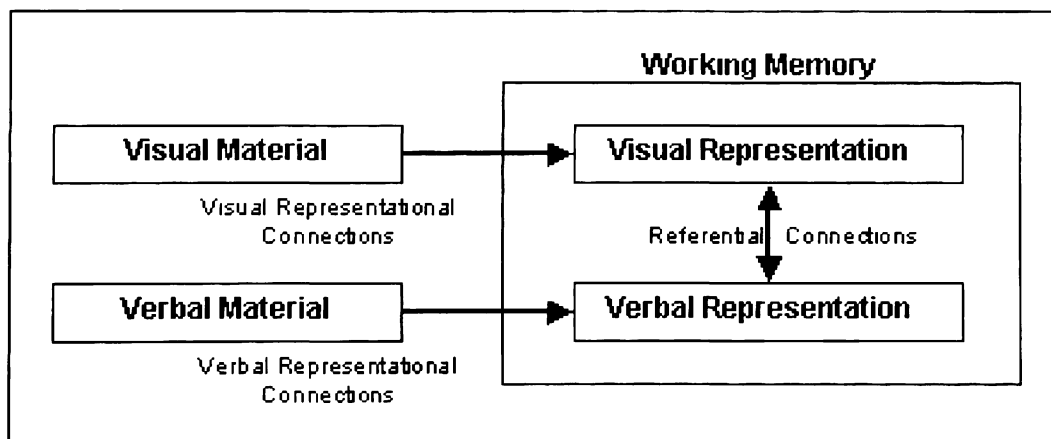


Figure 2 Dual Coding Theory of memory from visual and verbal materials (Meyer, 1989)

These two channels can function independently, but are also interconnected. Interconnectedness implies that stored imagery information can be transformed into verbal information, and vice versa. Although the concept of interconnectedness allows the transformation in either direction, Paivio (1971) admitted that nonverbal, or imagery (i.e., pictorial images) is better transformed into verbal or textual information, than is verbal information into imagery information. In fact, according to Paivio and Csapo (1973) there exists a 2:1 ratio in recognition in favor of pictures over words.

Paivio (1974) stated that in terms of recognition and recall, humans typically try to make inferences about what information they are viewing. Therefore, if they are only viewing textual information, for example, humans will have limited information to make an inference about. Paivio also stated that textual information decays faster in working memory, than pictures do, therefore not providing enough time for humans, especially older adults to make a decision about what they have seen.

Mayer (2001) began to build upon Paivio's Dual Code Theory by making the connection between separate information processing channels for visually represented material and auditorily represented material. When information is presented to the eyes, such as illustrations, pictures, or printed text, humans initially begin processing that information in their visual channel, and then make an interconnectedness with the other channel in question (see figure 3).

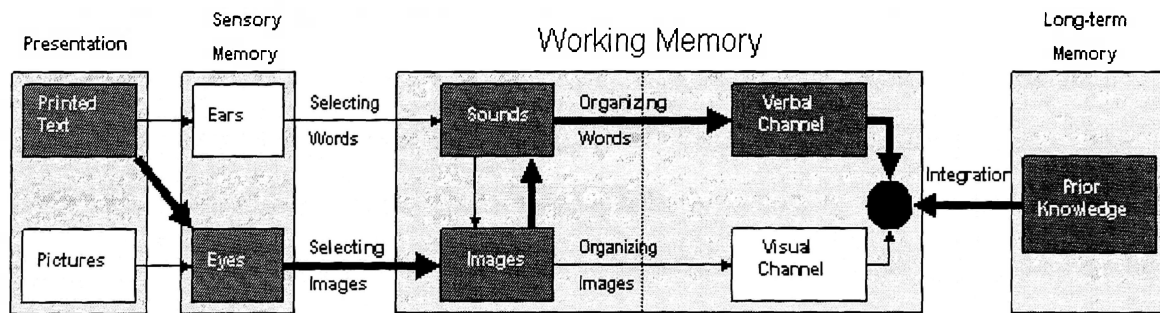


Figure 3: Interconnectedness of Printed Text in Working Memory, (Mayer, 2001).

On the other hand, when information is presented to the ears, such as nonverbal sounds, humans begin by processing this information in the auditory channel. This concept of separate information processing channels is currently most associated with Paivio's Dual Code Theory and Baddeley's Model of Working Memory.

There are two ways of conceptualizing the differences between these two channels. One of these channels is based on sensory modality, which focuses on whether humans process the presented materials through their eyes or ears. According to the sensory modality approach, one channel processes visually represented material and the other channel processes auditorily represented material. This notion is most consistent with Baddeley's distinction between the visuospatial sketchpad and the articulatory loop. In contrast, the presentation mode approach focuses on whether the presented stimuli is verbal, such as spoken or printed words, or nonverbal, such as pictures. According to the presentation mode approach, one channel processes verbal material and the other channel processes nonverbal material. This concept is most consistent with Paivio's distinction between verbal and nonverbal systems. Mayer (1999) utilized the presentation mode approach to distinguish between the construction of pictorially based and verbally based models in working memory. Mayer (1999) suggested that when humans are able to devote adequate cognitive resources to the task at hand, it is possible for information originally encoded in one channel to also be encoded in the other channel. Such cross channel representations of the same stimulus play an important role in Paivio's dual coding theory. For example, since the presentation mode approach focuses on whether the presented information is verbal or nonverbal (i.e., text or pictures), if a word was presented as printed text, the processing would initially begin in the visual channel. This would occur because a human sees this printed text with their eyes, which would be considered nonverbal information at first, and later would be articulated into the auditory channel, this process further enforces Paivio's dual coding theory.

In terms of retrieval and recognition, Clark (1994) argued that presenting redundant information, such as pictures and printed text, may cause decreased performance in memory recognition for older adults. This argument suggests that if text is delivered into the visual channel initially, along with a pictorial image that is also delivered via the visual channel, that an overload of capacity resources within working memory may occur if the person viewing this information cannot adequately form an interconnectedness of the two forms of visual stimuli. However, this argument is inconsistent with Paivio's (1979) Dual Code Theory, which stated that pictures and text activate independent imaginal and verbal codes and that the availability of each code differs. In general, Paivio stated that pictures and other visual objects are coded dually, as an image and verbally, so that there are two ways to access the information. This would mean that, for example, a picture which would be coded using both an imaginal code and a verbal code would be more available than abstract text, which would be coded only using a verbal code (Paivio, 1979). Paivio updated his division of these two classes of phenomena in 1986, specifying that the verbal system refers primarily to language and the imagery system refers to nonverbal images, such as the analysis of scenes and generation of mental images. In addition, Paivio emphasized that while these two systems are functionally and structurally distinct, as well as functionally independent, they are interconnected so that they can act alone or in parallel. In this way, one system may trigger the other in a one-to-one or one-to-many bi-directional fashions. This ability to utilize two codes, would therefore, support the use of pictures and visually represented information. The basic assumption of Paivio's Dual Code Theory, and Mayer's presentation mode may suggest that two codes or forms of information are better than one. Many studies have supported Paivio's Dual Coding Theory (Clark, 1994; Mayer & Anderson, 1991; Mayer & Anderson, 1992; Mayer & Sims, 1994). Other studies point out the benefits of using pictures and text presented (Mayer & Anderson, 1991), rather than just text alone, and note how the visual mode enhances verbal text and can often describe information in a way that is not possible with text alone (Sternberg, 1990).

One question of interest is whether or not individual differences, such as age, would play a role into the effectiveness of remembering presented redundant information. Mayer and Moreno (1999) conducted a series of recall and retention tests across a broad range of age groups. Of the nine experiments performed, seven experiments indicated that the addition of pictures to text increased memory retrieval performance in age's ranging from 25 to 75. According to Wetzel, Radtke, and Stern (1994), the basic assumption in the redundant encoding approach is that the more information that is presented at the time of encoding would facilitate more information to be available at the time of retrieval (Paivio, 1974). Craik and Jennings (1992) summarized this assumption by stating that older adults benefit more than their younger counterparts from more supportive encoding conditions. Craik and Jennings also support evidence that older adults tend to remember fewer specific features than younger adults do, and therefore having more information available would increase their chances of retrieval. Kemper (1992) suggested that older adults may benefit from redundancy of information at the time of encoding, because age related declines are especially evident when inferences must be made from different meanings of textual information. This is supported by Kemper (1992) who claimed that textual processing relies heavily on working memory capacity, which as discussed earlier, declines with age.

One of the most useful means of examining the improvement of memory retrieval in older adults is related to the use of medication, to include over the counter drugs and prescription medication. Since the majority of older adults interact frequently with different types and amounts of medication, it is suggested that their ability to retrieve relevant information regarding medication would be imperative. Typically medical information is conveyed to users in the form of a warning label. In many cases, warning labels that appear on medication only contain textual information, or instructions, and in many cases are difficult for adults of all ages to understand. This is especially true for older adults who often have a degraded sense of attentional resources in their working memory capacity. Therefore, it is predicted that older adults would

benefit from additional information to support the already existing information that appears on products such as over-the-counter drugs or prescription medications

Warning Presentation and the Effects of Aging

Aging consumers face an array of products, medications, and tools that may be hazardous to their health or safety. One familiar related activity is taking over-the-counter and prescription medication. This tends to be quite common in the elderly who, because of the associations of physiological aging as well as disease, have health problems. In fact, aging often brings complicated medication regimens involving several drugs that need to be taken on different schedules throughout the day. Furthermore, people over 60 years old consume more prescription and over-the-counter drugs than any other age group (Rogers, Lamson, & Rousseau, 2000). Given the growing usage of medication in the elderly and the cognitive and information processing aspects of appropriate self-medication, an important literature on issues related to self-medication has developed (Morrow, Leirer, Adrassy, Tanke, & Stine-Morrow, 1996).

The costs of misunderstanding warning information may be particularly problematic for older adults. For example, 75% of older adults report using prescription drugs and 82% report using over-the-counter drugs. Approximately 15% of acute hospital admissions for patients over age 70 have been attributed to unfavorable drug reactions, indicating that warning labels may be ignored or not rememberable by this population (Kart, Dunkle, & Lockery, 1994). Understanding how best to present warning information is a complex undertaking. There are a large number of variables that can affect the extent to which a warning is ultimately complied with, which include presentation format of the warning label, design factors, and memory recognition (Park, Morrell, & Shifren, 1999).

Another medical domain in which cognitive functioning has been found to be important is in medication adherence. For instance, Morrell, Park, and Poon (1989), found that older adults' failure to comply with appropriate medication instructions was a consequence of inaccurate interpretation of dosage instructions on medicine labels. Additionally, Morrell, Park, and Poon

(1990) found that older adults were particularly disadvantaged when inferences were required to interpret medication instructions, which Morrell considered a particularly demanding cognitive task. In subsequent work, Park (1992) outlined a model proposing that successful adherence to a medication regimen involved understanding medication instructions, ability to integrate medication information across a number of prescribed medications, ability to recognize medication information, and remembering to take the prescribed medication. Taken together, these findings highlight the importance of cognitive functioning in appropriate recognition of medications, and facilitate the ultimate goal of medication compliance.

For example, when considering issues of text and pictorial design, researchers have typically focused on three main elements. These involve the appearance of the media, the language of the text, and the effectiveness of the media. Aside from key issues on page size, line length, typefaces, and allocating space to present these warnings there has been considerable literature on the language of text. For example, text appears to be easier to read and to understand when authors use simple wording and short varied sentence lengths (Albert & Chadwick, 1992).

The research literature on the effects of aging on learning and memory is even larger than the literature that has been described so far. According to Bond, Coleman, and Peace (1993), overlapping areas of research were discussed to determine the complexity of aging adults and the presentation of warning information. Those areas included physiological research, and cognitive research. Physiological research looks at the biology of aging and its physiological associates. Most people, for example, experience with age a decline in eyesight and other senses (Kosnik, Winslow, Kline, Rasinski, & Sekuler, 1988). Cognitive research on aging focuses on changes in memory, learning, and judgment (Salthouse, 1982). Such cognitive changes also have implications for text design. Studies of aging, for example, focus on how attitudes and beliefs about what older people should and should not do, and determine to a considerable extent what, in fact, they do accomplish (Hess, 1994). Such beliefs might affect how people use medical

information. In terms of cognitive research, Hess (1994), describes two main areas of research in the field of text design for older readers including that working memory capacity (i.e., information held and used in ongoing tasks) declines as people get older (Baddeley, 1986) and the more difficult the task and the older the person, then the more excessively difficult that task becomes (Salthouse, 1982). Meyer, Young, and Bartlett (1989) suggested that it is important to consider several overlapping variables in studies of older people learning from text, which included verbal ability, text structure, and tasking operations, such as remembering. One might not expect differences between older and younger readers when the verbal ability of the readers is high, when they have good prior knowledge, when the texts are well presented, and when the tasks are relatively straightforward. Differences, however, might be expected to emerge with less able readers, less familiar materials, poorly structured text, and more complex tasks. According to Salthouse (1992), older patients must be able to logically manipulate the medical information provided and reach conclusions that are consistent with the presented information in order to retrieve or recognize this information at a later time.

Changes in memory cognition with age may intensify the effects of particular variables on the use of warnings. For example, symbols are frequently used to convey information. However, although the results are somewhat mixed, the frequency of evidence suggests that symbol comprehension, and memory recognition is impaired for older adults. Generally speaking, studies on the effects of aging suggested that pictorial elements will be easier for older people to use, because pictures are more intuitive in how we react with objects in our every day lives. However, Salthouse (1991) suggested that older adults may also find text to be somewhat additionally intuitive, because during the younger portion of their lives, that involved the majority of learning, they were exposed to text more often than other forms of multimedia that have been placed in the learning environment over the last 30 years.

Age-related differences favoring young adults have been found for information on prescription medication labels, (Morrell, Park, & Poon, 1989), such as, fire safety symbols (Collins

& Lerner, 1982), traffic signs, mine safety symbols (Collins, 1983), and hazard symbols for household products (Easterby & Hakiel, 1981)

Additional information about the effects of aging on the processing of warnings may come from the cognitive aging literature. Hartley (1992) reported the encouraging finding that older adults are able to benefit from additional information added to the relevant information. Thus, supportive information to warnings, such as color highlighting, or signal words, or pictorial information might prove especially beneficial for older adults.

Summary

Human Factors is particularly relevant to the study of warnings, and aging adults. One of the goals of human factors professionals is to ensure the safety of individuals as they interact with different systems and products. Another important concern in this field is the importance with the hazard's associated with many kinds of drugs, which are not commonly known to the general public.

There has been remarkably little research conducted on the importance of memory recognition in aging adults as it applies to processing of warning label information. However, it would seem to be of tremendous importance for warnings containing information about medications. For example, individuals might read the warnings associated with a particular medicine the first time they take it. Every time thereafter, however, they would have to remember the instructions and warning-related information, such as, not to consume alcohol while taking the product or to take with food or water. Therefore, younger adults appear to have an advantage over their older counterparts regarding memory recognition and less reduction of resources when performing tasks that require encoding and retrieval of information.

Statement of Hypothesis

Because aging adults typically have a reduction in cognitive resources, it was hypothesized that they would require the aid of additional information to assist in the retrieval process of information. Therefore, it was predicted that aging adults would be able to retrieve information at a better performance level than without the assistance of additional redundant

information. Performing next highest should be those participants exposed to the pictorial images alone condition. The single coded format should provide more intuitiveness than the text alone condition due to the fact that Paivio suggested that pictures do not decay in memory as fast as text would, and thus performance should be higher than the other conditions, though not as high as the fully redundant, dual coded text and pictorials condition.

It is expected that older participants exposed to the text alone format will perform worse than the other conditions. Actual pharmaceutical pictorials are used to reiterate the same information that would be written in the form of text, however, pictorial images appear to be more intuitive with the way humans view everyday objects and interact with society. Although pictorials normally aid in the acquisition of information, a consistent recommendation in the literature (e.g., Collins, 1983) is the requirement not to use pictorials as a sole means of communication, but rather to combine pictorials with text in order to provide as much information as possible at the time of encoding information. In this experiment, it was believed that participants in the text alone condition would not receive enough intuitive information to make a connection between the observed information and their own knowledge of the information displayed. It was predicted that adults who have redundant information would benefit in terms of memory recognition, because they would be provided with the same information in two different formats, which should provide these adults with a greater chance of connecting these multiple forms of information and retrieve them at a later time.

METHOD

Participants

Participants for this study were obtained from the local community in Raleigh, NC. A total of 20 females, and 16 males participated in this study. The participants were categorized into one of 3 age groups with 12 participants per age group for a total of 36 participants. These age groups consisted of group 1 (18-37 years of age), group 2 (38-57 years of age), and group 3 (58 years of age or older). The mean age of participants in group 1 was 26.6 years old, the mean age of participants in group 2, was 49.0 years old, and the mean age of participants in group 3 was 72.9 years old. Each participant was required to have at least a high school education. In addition, each participant was required to have at least 20/40 vision acuity, which was verified by a valid driver's license, and also required an English speaking background.

Apparatus

Three study sheets were created that contained different presentation formats of warning labels that might be seen on prescription or over the counter medication. These warning labels formats included; text only labels, pictorials only labels, and a combination of these two formats with text and pictorial labels combined together, and were shown to the participants. Each study sheet contained pictorial related information that was developed by the United States Pharmacopoeia Conference (USPC), and given to the experimenter accompanied by a research license agreement. A total of 75 pictorial images were used in this study, all of which were provided by the USPC. Only 30 of these pictorial images were used for the initial study testing of the participants. That is, 10 warning labels were used in each of the 3 warning label conditions, and the additional 45 were entered into the testing phase as distracters by having 15 distracters in each of the 3 warning label conditions.

Design

The purpose of this study was to investigate whether recognition memory would be affected by warning label presentation type, and whether older adults would benefit by having

additional information added to a pharmaceutical warning label. A memory recognition test was distributed to 36 participants such that each participant would receive a study phase and a testing phase. The experiment was analyzed using a 3x3 factorial mixed ANOVA model. Refer to table 1.

		Warning Condition		
		Text Only	Pics Only	Pics & Text
Age Group	1	12	12	12
	2	12	12	12
	3	12	12	12

Table 1: 3 x 3 Factorial ANOVA Design of Age and Warning Condition

Two independent variables are presented in this study. The first variable was participant's age, categorized into three levels or age groups, and was assessed as a between-subjects variable. The levels of age group included 18-37 (group 1), 38-57 (group 2), and 58 years old or older (group 3). The second variable was a within-subjects variable, known as warning condition that contained three levels of warning label formats, which included text only, pictures only, and a combination of text and pictures. In each of the three age groups, all levels of the warning condition were tested.

The dependant measure in this study was memory recognition of warning label information assessed through a composite scored metric that defined the overall memory

recognition performance of hits, correct rejections, misses, and false alarms, which were assessed from the testing phase of the experiment. In the experiment a hit was represented by the participant correctly choosing a warning label that they had previously seen during the study phase of the experiment. A correct rejection was represented by the participant correctly rejecting a warning label that did not appear during the study phase of the experiment. On the other hand, a miss was represented by the participants failure to choose a warning label that did appear during the study phase, and a false alarm was represented by the participant who incorrectly chose a warning label, thinking that it appeared during the study phase of the experiment, when it actually did not appear.

Procedures

After appropriate screening, each participant was randomly assigned to begin the experiment with one of the three possible conditions. Participants were asked to read and sign an informed consent form (see appendix A) prior to beginning the experiment. Potential participants were then asked to fill out a brief pre-test questionnaire (see appendix B) that consisted of personal information, which contained age, gender, education level, ethnicity, and occupation, with age, and education level being the qualifying factors. Once participants were accepted as viable subjects, they were asked to validate their ability to read and speak English, and to validate that they had at least 20/40 vision. This was accomplished by viewing the participant's valid driver's license.

Before the start of the experiment, each participant was asked to answer questions that dealt with their opinions on the use and understanding of warning labels placed on prescription and over-the-counter medication (see appendix B). To provide realism, each participant was given a scenario that indicated they had just received a series of prescriptions from their doctor. Participants were then informed that they would have only a sixty-second period to review the information presented to them, and then would be asked questions about the information they had just viewed. The sixty-second time period to view the information was implemented based

on previous research, and given to prevent the possibility of rehearsal. To further provide realism that would occur in everyday life, each participant was given a distracter task between each the study phase, and the test phase of each presentation format. For example, after a participant viewed the text only warning labels, they would then complete a distracter task, consisting of a word search game that lasted for 3 minutes, and then were asked to recognize the original 10 warning labels from a total set of 25. The purpose of the distracter task was to simulate events that may occur in everyday life that would distract someone's memory from the warning information they viewed regarding their medication usage, such as events or occurrences that occur in between the time they initially viewed this warning information and the time they actually need to take this medication. The distracter task was also used to disallow this information from being retained in short-term memory (see appendix C).

The three warning label conditions were represented by A, B, or C:

Sheet A contained 10 separate text instructions only, with no pictorial images present as the study phase (see appendix D).

Sheet A also contained a test phase for text only, (see appendix E).

Sheet B contained 10 separate pictorial images only, with no textual instructions present as the study phase (see appendix F).

Sheet B also contained a test phase for pictorial images only, (see appendix G).

Sheet C contained 10 separate text instructions that were combined with a corresponding pictorial image placed above the respective text instruction as the study phase (see appendix H).

Sheet C also contained a test phase for the combined pictorial image and text, (see appendix I).

With Sheet A, B, C, there were 6 possible combinations in which these warning label sheets could be viewed by a participant. Those were: ABC, ACB, BAC, BCA, CAB, and CBA. For redundancy and counterbalancing, those 6 combinations were reviewed twice in each age group, which consisted of 12 participants per age group, for a total of 36 participants to view this information.

RESULTS

Data Analysis

The data collected from the dependant measure of memory recognition consisted of the analysis of hits, misses, false alarms, and correct rejections that occurred during the testing phase of the experiment. These metrics were then combined into a one composite score by incorporating the sum of hits and correct rejections, with the sum of misses and false alarms. The sum of misses and false alarms was then subtracted from the sum of hits and correct rejections to render one composite score for each participant that was rated on a scale of +25 to -25. The highest possible outcome of the summed hits and correct rejections would render a total score of +25, which would indicate that the participant correctly hit the original 10 warning labels, and correctly rejected the 15 distracter warning labels. The lowest possible outcome of the summed misses and false alarms would render a total score of -25, which would indicate that the participant missed all 10 of the original studied warning labels, and chose the 15 distracter warning labels as false alarms. These data groups were summarized with mean scores and standard deviation, as they ranked on the scale of -25 to +25, for all three age groups and their applicable warning conditions (see Table 2)

Descriptive Statistics				
	AGE_GRP	Mean	Std. Deviation	N
TEXTONLY	1.00	18.6667	4.1633	12
	2.00	21.0000	2.2563	12
	3.00	17.8333	3.5633	12
	Total	19.1667	3.5897	36
PICONLY	1.00	22.8333	1.5859	12
	2.00	21.8333	2.1672	12
	3.00	20.6667	3.2845	12
	Total	21.7778	2.5423	36
PICSTEXT	1.00	22.7500	2.4168	12
	2.00	21.0000	2.5584	12
	3.00	17.8333	4.6286	12
	Total	20.5278	3.8581	36

Table 2: Mean Scores of Age Group and Presentation Type

These data were tested for significance using a Factorial Mixed Analysis of Variance Model for Repeated Measures, which was encompassed by tests of within subjects effects (see Table 3), and between subjects effects (see Table 4).

Tests of Within-Subjects Effects							
Measure: Warning Condition							
Source		Type III Sum of Squares	df	Mean Square	F	Sig.	Eta Squared
WARN	Sphericity Assumed	122.796	2	61.398	9.153	.000	.217
	Greenhouse- Geisser	122.796	1.952	62.897	9.153	.000	.217
	Huynh-Feldt	122.796	2.000	61.398	9.153	.000	.217
	Lower- bound	122.796	1.000	122.796	9.153	.005	.217
WARN * AGE_GRP	Sphericity Assumed	83.148	4	20.787	3.099	.021	.158
	Greenhouse- Geisser	83.148	3.905	21.294	3.099	.022	.158
	Huynh-Feldt	83.148	4.000	20.787	3.099	.021	.158
	Lower- bound	83.148	2.000	41.574	3.099	.058	.158
Error(WARN)	Sphericity Assumed	442.722	66	6.708			
	Greenhouse- Geisser	442.722	64.427	6.872			
	Huynh-Feldt	442.722	66.000	6.708			
	Lower- bound	442.722	33.000	13.416			

Table 3: Tests of Within-Subjects Effects

Tests of Between-Subjects Effects						
Measure: Warning Condition						
Transformed Variable: Average						
Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Eta Squared
Intercept	45346.009	1	45346.009	2913.997	.000	.989
AGE_GRP	158.796	2	79.398	5.102	.012	.236
Error	513.528	33	15.561			

Table 4: Tests of Between-Subjects Effects

This analysis consisted of a main effect for age. Age groups yielded $F(2,33) = 5.1, p < .05$.

Warning Condition, which yielded $F(2,33) = 9.153, p < .001$.

Effects For Age

According to post hoc analysis there was a main effect for age, which indicated differences between age group 1 and age group 3, with a significance of .023. The post hoc analysis also rendered differences between age group 2 and age group 3 with a significance of .033, and an effect size of .236. Age group 1 rendered a mean score of 21.42, on the scale of -25 to +25, which had better performance than group 2, which rendered a mean score of 21.28, and group 3 which rendered a mean score of 18.78 on the same scale of -25 to +25. See figure 4 below:

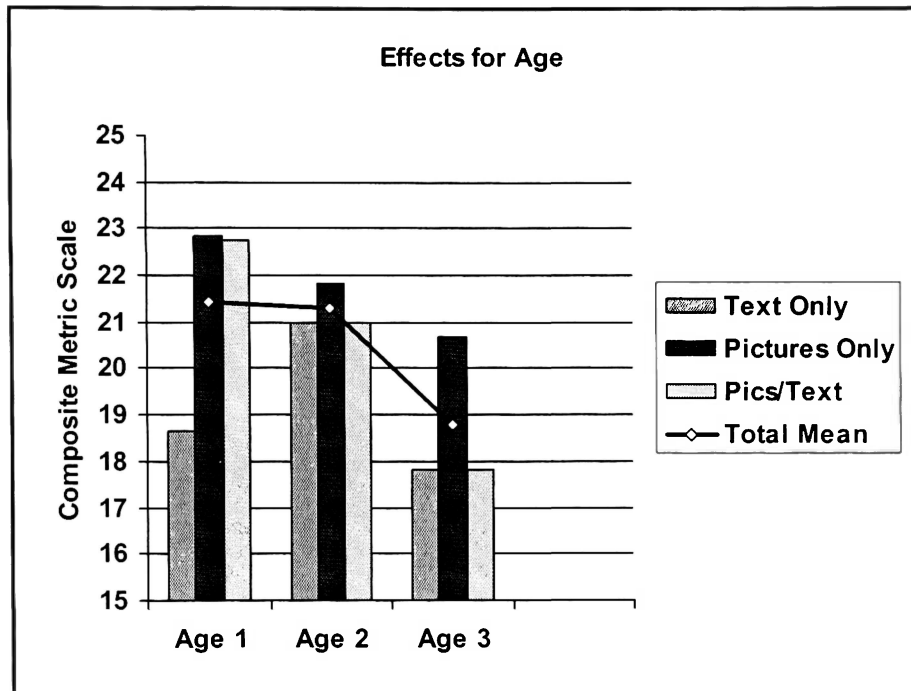


Figure 4: Mean Composite Scores for Age Effects

Effects For Presentation Type

According to post hoc analysis there was a main effect for presentation type, which occurred between text only and picture only, with a significance of .0001, and an effect size of .217. In general, the picture only condition rendered the highest performance by a composite score of 21.78. See figure 5 below:

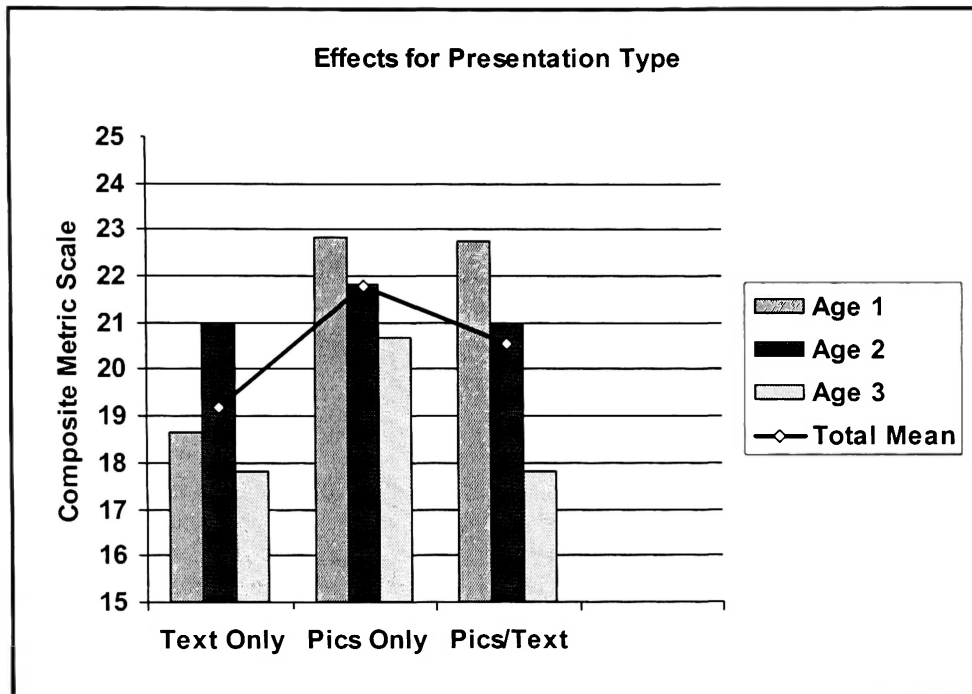


Figure 5: Mean Composite Score of Presentation Type

Interaction Effects

Statistically significant ($p < .05$) interaction included Warning Condition x Age Group, $F(4,66) = 3.099, p < .05$. Post hoc analyses of these interactions were conducted using the Bonferroni post hoc analysis, which indicated that there were significant interactions in age groups 1 and 3, with an effect size of .158. In fact, in age group 1, there was a statistically significant difference between text only and pictures only, with a difference in mean of -4.167. Also, in age group 1, there was a statistically significant difference between text only and pictures & text combination, with a difference in mean of -4.100, see figure 6. In age group 3 there was also a statistically significant difference between text only and pictures only, with a difference in mean of -2.833, and a difference in mean between picture only and the picture and text combination, with a difference in mean of 2.833. However, age group 2 had no significant interactions to report. These data also indicate that the redundant picture & text condition also gradually decreased as age progressed compared to the picture only condition.

Pairwise Comparisons							
Measure: Warning Condition							
			Mean Difference (I-J)	Std. Error	Sig.(a)	95% Confidence Interval for Difference(a)	
AGE_GRP	(I) WARN	(J) WARN					
1	1	2	-4.167(*)	1.038	.001	-6.786	-1.548
		3	-4.083(*)	1.134	.003	-6.943	-1.224
	2	1	4.167(*)	1.038	.001	1.548	6.786
		3	.083	.995	1.000	-2.427	2.594
	3	1	4.083(*)	1.134	.003	1.224	6.943
		2	.083	.995	1.000	-2.594	2.427
2	1	2	-.833	1.038	1.000	-3.452	1.786
		3	.000	1.134	1.000	-2.859	2.859
	2	1	.833	1.038	1.000	-1.786	3.452
		3	.833	.995	1.000	-1.677	3.344
	3	1	.000	1.134	1.000	-2.859	2.859
		2	-.833	.995	1.000	-3.344	1.677
3	1	2	-2.833(*)	1.038	.030	-5.452	-.214
		3	.000	1.134	1.000	-2.859	2.859
	2	1	2.833(*)	1.038	.030	.214	5.452
		3	2.833(*)	.995	.023	.323	5.344
	3	1	.000	1.134	1.000	-2.859	2.859
		2	-2.833(*)	.995	.023	-5.344	.323

Figure 6: Pairwise Comparisons of Warning Condition and Age

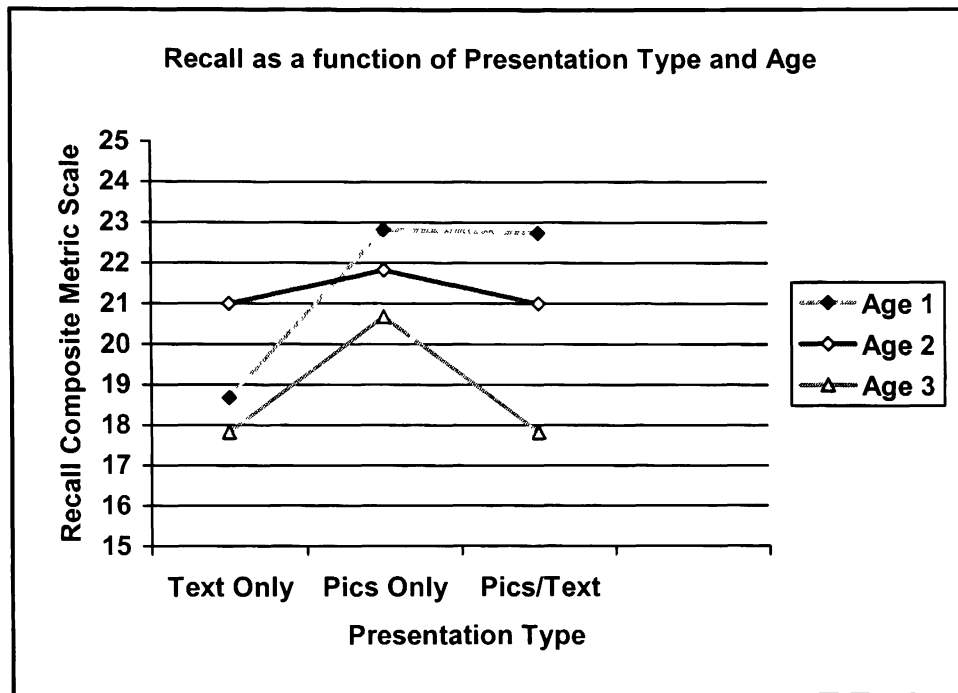


Figure 7: Data Plot of Recognition as a function of Presentation Type and Age

Figure 7 above indicates that each age group rendered better performance on pictures only. However, although the younger group (age group 1) only showed a slight decrease in the pictures & text condition as compared to the other age groups and it is apparent that in older age groups participants gradually decreased in performance during the testing phase of the pictures & text condition. Although age groups 2 & 3 indicated a similar reduction in the text only condition as compared to the pictures & text condition, age group 1 indicated a significant reduction in memory recognition performance for the text only condition.

DISCUSSION

The results of this study indicated that the experimental hypothesis of adding additional redundant information to already existing textual or picture information was not supported. Furthermore, memory recognition among older adults did not increase as a result of adding additional redundant information to warning labels, but rather gradually decreased over the course of the aging groups. It is believed that this gradual decrease is attributed to the dual processing theory of working memory, and the available resources to accommodate these materials. As stated earlier, the capacity of working memory decreases with age. According to (Baddeley, 1986) the central executive is in charge of allocating attentional resources for processing of information. It is suggested that aging adults decrease recognition performance of the combination of pictures and text because their working memory or attentional resource capacity becomes increasingly limited as they get older. In support of this notion, Paivio (1971) stated that Dual Coding Theory represents two methods of coding information. According to Paivio, humans possess a verbal system specialized for processing textual information, and a nonverbal system specialized for processing mental imagery, or pictorial information. As stated earlier, these two systems can function independently, but are also interconnected. This interconnectedness implies that stored imagery information can be transformed into verbal information, and stored verbal information, or text, can be transformed into a visual image, or a mental picture. Although the concept of interconnectedness allows the transformation in either direction, Paivio (1971) admitted that nonverbal, or imagery, (i.e., pictorial images) is better transformed into verbal or textual information, than is verbal information into imagery information. According to Paivio and Csapo (1973) there exists a 2:1 ratio in recognition in favor of pictures over text. The results of this study indicate that pictures were recognized with better performance across all age groups than that of text alone, or pictures and text. Although pictures were not quite recognized at a ratio of 2:1, they were recognized with better performance. Paivio (1971)

argued that pictures are better remembered than corresponding word lists because humans store the picture name as well as a visual representation in their memories. For text, on the other hand, they are less likely to store the visual code as well as the verbal code. Therefore, two of the same codes are better than one, hence the better memory for pictures. Mayer, 2001 built upon Paivio's Dual Code Theory by making the connection between separate information processing channels for visually represented material and auditorily represented material. When information is presented to the eyes, such as illustrations, pictures, or printed text, humans initially begin processing that information in their visual channel, and then make an interconnectedness with the other channel in question. In terms of retrieval and recall, Clark (1994) argued that presenting redundant information, such as pictures and printed text, may cause decreased performance in memory recognition for older adults. This argument suggests that if text is delivered into the visual channel initially, along with a pictorial image that is also delivered via the visual channel that an overload of capacity resources within working memory may occur if the person viewing this information cannot adequately form an interconnectedness of the two forms of visual stimuli. The result of Clark's theory may have been the result of the decreased performance in the picture & text combination condition, because there were too much information in the visual channel that entered working memory, therefore overloading the memory capacity available for the visual channel and allowing an unused verbal channel. This may suggest that the visual channel which received both text and pictures had to compete for resources that normally would not have happened if the text material were being processed in the verbal channel. Although age group 1, that is, the younger group did not have as much of a decrease in memory recognition on pictures & text as the other two age groups, this may suggest that as individuals get older, their limited capacity hinders them from making an interconnectedness of the information that enters the visual channel initially. In terms of the text only interaction, memory recognition indicated a greater decreased performance with age group 1, than the other aging groups. It is unclear what mechanism underlies this interaction. It was

anticipated that the younger participants would be better for all presentation conditions given the prior literature and while a main effect for age was shown that supports this statement, there is something in the nature of the textual presentation that reduced performance specifically for the younger participants. Paivio (1974), stated that in terms of recall and recognition, humans typically try to make inferences about what information they are viewing. Therefore, if they are only viewing textual information, for example, humans will have limited information to make an inference about this textual material. Paivio also stated that textual information decays faster in working memory, than pictures do, which indicates that the combination of pictures and text may overload the working memory capacity of aging adults. Therefore, these limited attentional resources may hold text and pictures in working memory, but not have enough resources left over to build connections, or make inferences between these pictorial images and text during the encoding phase, and therefore limiting the recognition of these encoded materials later (Mayer, 1994).

Although the effects of age on information processing are progressive throughout adulthood, it is difficult to pinpoint exactly what age these effects will become apparent. Perhaps different types of warning labels should be presented to different age groups as a means of improving memory recognition as aging occurs. However, the data suggested that pictures only rendered the best performance across all age groups in terms of memory recognition, and may suggest that pictorial images should appear on warning label presentations at a minimum. Previous research suggested that redundant information would improve retrieval in older adults due to their limited capacity. However, the results of this experiment indicated that redundant information did not necessarily improve memory recognition within the age groups of this study. Further research should be performed in order to indicate the underlying mechanisms behind the performance of text only warnings with younger age groups, and the older groups performance with redundant information. This exploration of aging and warning label presentation will help to better define the benefits of over the counter and prescription medication for the future.

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Appendix A Participant's Informed Consent Form

Title of Project

Human factors performance measures
The primary researcher Mr Brian Call, graduate student

Purpose of the Research Project

You are invited to participate in a study where you will be tasked to complete a task in the pursuit of human factors performance in medicine

Procedures

You will be given an instructional scenario and asked to review it prior to beginning the experiment. There is a time limit to complete the tasks. Upon completion of the tasks you will be asked to fill out a series of questionnaires.

Benefits of this Project

Your participation will be helpful in determining the relative effectiveness of the instructional materials. While you may find the experiment interesting and/or informative, there are no direct benefits to you as a participant. No guarantee of benefits has been made to encourage you to participate. You may receive a synopsis or summary of this research when completed. If you so desire, leave a current email address or contact information. Email address _____

Anonymity and Confidentiality

The results of this study will be kept strictly confidential. The information you provide will have your name removed and only a subject number will identify you during analyses and any written reports of the research.

Freedom to Withdraw

You are free to withdraw from this study at any time without penalty. If you choose to withdraw, you will not be penalized, nor will your data be analyzed as part of this study. If the investigator determines from the pre-study questionnaire that you are not suitable as a subject for this experiment, you will not be asked to complete the study.

Subject's Responsibilities

I know of no reason I cannot participate in this study. I voluntarily agree to participate in this study.

Subject's Permission

I have read and understand the informed consent and conditions of this task. I have had all my questions answered. I hereby acknowledge the above and give my voluntary consent for participation in this experiment. If I participate, I may withdraw at any time without penalty. I agree to abide by the rules of this experiment.

Signature

Date

Should I have any questions about this research or its conduct, I will contact

Dr Shawn Doherty, from the Human Factors graduate department at Embry Riddle Aeronautical University (904) 226-6249 A copy of this consent form will be provided to you upon your request
Appendix B Pre-Test Questionnaire

1) What is your gender? ___M ___F

2) What is your age? ___ years

3) What is your occupation?

4) What is the highest level of education you have completed?

- ___ Elementary school
- ___ Middle school
- ___ High school graduate
- ___ Some college
- ___ College graduate
- ___ Masters degree
- ___ Doctorate degree

5) What is your ethnic background?

- ___ African-American
- ___ Asian
- ___ Caucasian
- ___ Hispanic
- ___ European
- ___ Middle Eastern
- ___ Native American
- ___ Multi-racial (please specify) _____
- ___ Other (please specify) _____

6) Have you ever had any problems reading or understanding the information presented on a prescription drug label? If so, explain

7) If you could have any information presented with a prescription drug, what would it be?

8) Have you ever forgotten important information about a particular prescription drug? If so, explain

9) When obtaining a prescribed drug, has a pharmacist ever provided you with additional information beyond what was printed on the label? If so, explain

10) How frequently has a pharmacist volunteered to provide you with additional information?
(Check one)

- ___ Never
- ___ Seldom
- ___ Occasionally
- ___ Frequently
- ___ Always

11) Have you ever had problems reading or understanding the additional information that was presented to you? If so, explain.

12) Have you ever held a job that involved the production or sale of medications? If so, explain.

Appendix C Instructions to Participants

Introduction:

Today you will be asked to evaluate a number of different methods of presenting medication information. This information will be used to determine an effective way of presenting medical instructions to consumers. We are collecting data on each individual's impression and understanding of different instructional formats. We appreciate your participation, and your opinion of these products. Do you have any questions at this time?

At this point the participant will also read and sign the consent form

Demographics Questionnaire:

Now we will begin the evaluation portion of the study. To aid the evaluation, I would like for you to answer some questions about yourself and your opinions regarding prescription medication. I have a short questionnaire for you to complete. Take as much time as you need, for there is no time limit.

Here the participant will receive a demographics questionnaire to fill out, then once they are finished I will collect the questionnaire.

Introduction to the study:

To set the stage for this study, I would like you to pretend that you've just left your physician's office where you received your annual physical. Although this procedure was routine, certain other tests revealed that you have a condition that needs immediate care. You will probably have to take a variety of medications to arrest this illness. You are now at your local pharmacy to get your prescription filled. You will be receiving several filled medications, and be advised by your pharmacist on the proper methods of taking this medication by receiving an information sheet with applicable warning labels for each of the medications. Each will contain various instructions regarding proper use of the medications you will be taking. After reviewing the warning

information labels on drug information sheet, you will be asked various questions about the information presented to you. Do you have any questions at this time?

Procedures

Here are the instructions regarding the dosage requirements for your medications. I am now going to give you a drug information sheet that provides you with additional information and instructions about the drugs you have been prescribed. You will have 1 minute to examine the information on the sheet. Due to the limited amount of time, you must quickly examine and familiarize yourself with the information on the sheet.

Here I will hand them the drug information sheet testing phase for warning condition 1, keep the time, then collect the sheet

Information Task #1

At this time I would like for you to relax, and complete a series of word related reasoning tasks. *(Here the participants will complete a 3 minute word search game, called boggle, provided by Parker Brothers)*

Medication Questionnaire

You will now receive the review portion the experiment, and have 2 minutes to circle those labels that you previously saw on the study sheet. *(I will now give the participant the test condition of the experiment, and time them for 2 minutes)*

Divider Task

(Here each participant was asked to sort a deck of regular playing cards, which was implemented to give a feeling of division between each study and test phase of each condition) You will now perform a card sorting exercise that will encompass sorting cards by suit, color, or numerical assignment.

Note After the divider task was complete, the participant began the study phase of the next condition in question.

Debriefing the participant

Your participation in this study is greatly appreciated and was extremely helpful in the investigation of human factors and performance indicators for the consumer. Thank you. Finally, do you have any further questions regarding the experiment?

(Here the participant was given a chance to ask questions about the purpose of the study, or give contact information in regards to receiving a copy of the final study.)

Appendix D Study Phase of Text Only Warning Labels

Text Only Condition

Part 1

Take 2 times a day with meals

Take 2 hours after meals

Do not store medicine where children can get it

Do not take with milk
or other dairy products

Place drops in lower eyelid

Are you pregnant or do you
plan to become pregnant?

Take with a glass of water

Shake well

Do not drink alcohol
While taking this medicine

Read the label

Appendix E Test Phase of Text Only Warning Labels

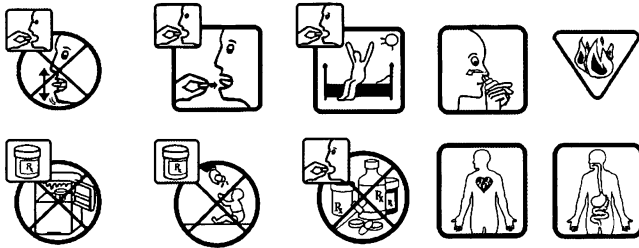
Text Only Condition
Part 2

Are you pregnant or do you plan to become pregnant?	Take 4 times a day with meals and at bedtime	Do not take with meals	Do not take with milk or other dairy products
Take 4 times a day	Take 2 times a day with meals	Wash hands/ Insert into vagina/ Wash hands again	Insert into rectum
Take 2 hours after meals	Dilute in water	For hypertension or high blood pressure	Get emergency help
Do not use additional salt	For lung/respiratory problems	Wear medical alert	Insert into vagina
Call your doctor	Do not store medicine where children can get it	Store in refrigerator	Take with glass of water
Place drops in lower eyelid	Take by mouth	Shake well	Read the label
Do not drink alcohol while taking this medicine			

Pictorials Only Condition

Part 1

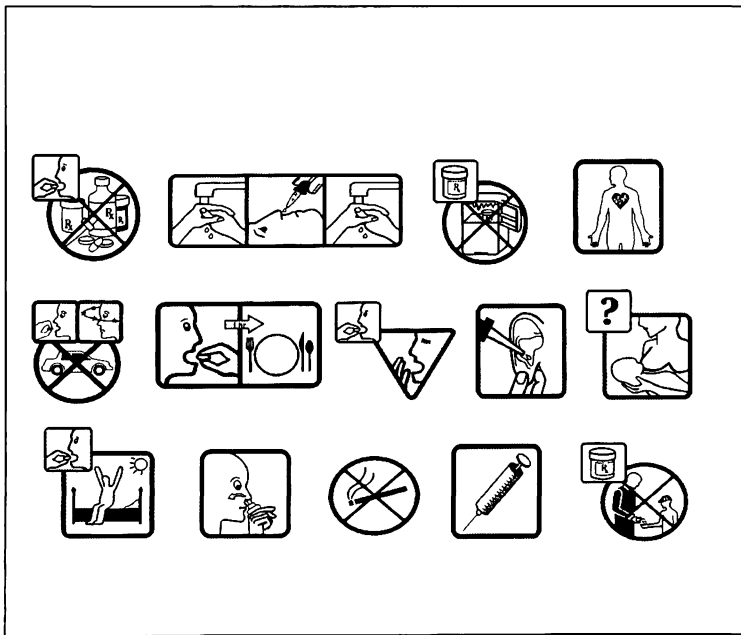
Pictorials Only Condition

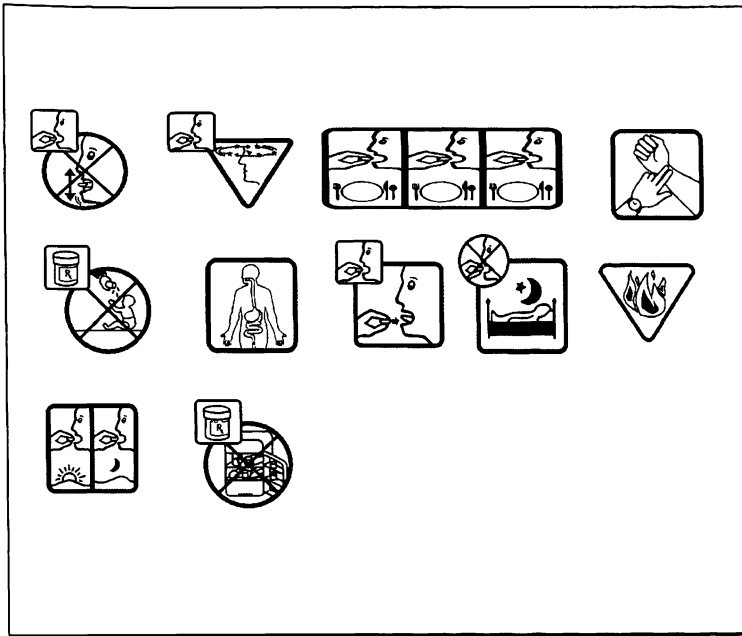


Appendix G Test Phase of Pictorial Only Warning Labels

Pictorials Only Condition

Part 2

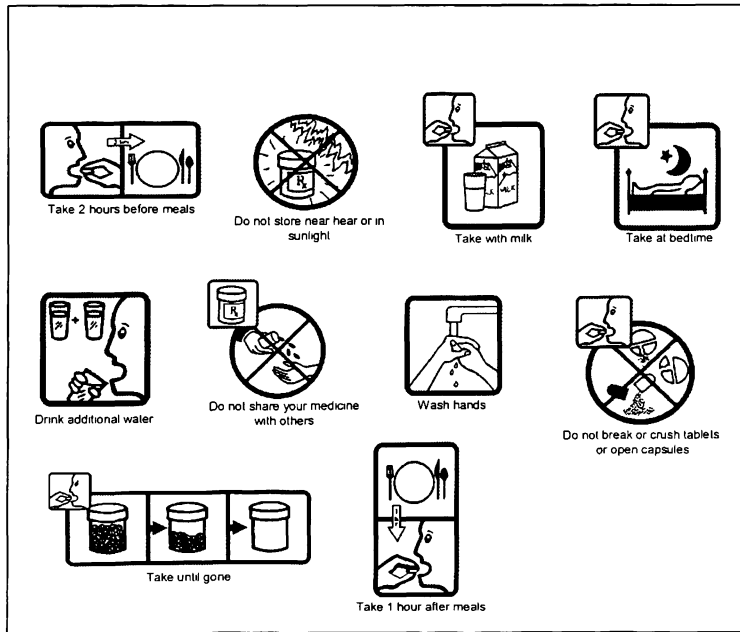




Appendix H Study Phase of Text and Pictorial Warning Labels

Pictorials & Text Condition

Part 1



Pictorials & Text Condition

Part 2

