This is to certify that the
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APPLYING CHANGE DETECTION TO TEST THE NOTICEABILITY OF COMPONANTS OF MEDICAL LABELS

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CARLY JEAN DEHENAU

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APPLYING CHANGE DETECTION TO TEST THE NOTICEABILITY OF COMPONANTS OF MEDICAL LABELS

By

Carly Jean DeHenau

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ABSTRACT

APPLYING CHANGE DETECTION TO TEST THE NOTICEABILITY OF COMPONANTS OF MEDICAL LABELS

By

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Perception is an active, computationally demanding process that requires cognition as well as perception and attention involves looking at specific features of the environment in a more detailed and focused manner. Inattentional blindness occurs when a stimulus that is not attended is not perceived, even though a person is looking directly at it. Given the documented prevalence of medication error and the criticality of the information contained on the labeling that accompanies medication, research was conducted using change detection to measure the ability of TALL Man lettering to garner attention in labels.

Two populations were targeted for this study, those who were employed as healthcare professionals and those who were not. There was a significant interaction between graphic presentation (TALL Man vs traditional) and profession ($P=0.0243$). Time to change detection was decreased for all professions when the change was presented in a TALL Man presentation as compared to the traditional text. However, the magnitude of this difference and its significance was greatest for nurses ($P<0.0001$). A main effect of ordered group was evident on time to detect the change ($P<0.0001$), a significant positional effect of change was detected on time to detect the ($P < 0.0001$), and there was marginal evidence ($P=0.0821$) for a difference between word pairs when the dependent variable was time to change detection.

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CHAPTER 1 - LITERATURE REVIEW

Introduction

Most people believe perception to be a straightforward process, that our perceptual systems are passive agents that automatically transfer the world into an internal representation. Under this view, all that is required for visual perception to occur is for a visually resolvable stimulus to impinge on the eye. In reality, perception is an active, computationally demanding process that requires cognition as well as perception. If you have ever had your mind wander as you drove a car and missed an important road sign signaling an exit, despite the fact that it was highly visible, then you have experienced the complexities of cognition and perception.

Perception is a process that involves many steps which includes: environmental stimulus, attended stimulus, stimulus on the receptors, transduction, processing, perception, recognition, and action. These steps occur in a continuous cycle and do not have a beginning or an end[2] (See Figure 1). The term environmental stimulus includes all things in the environment that we may, or may not, see. Once something becomes the center of our attention it is referred to as an attended stimulus. When there is stimulus on the receptors it creates an image on the back of the eye, called the retina (See Figure 2). At this point, the energy is transformed from one type of energy to another through a

process called transduction. The energy is then processed in a way that affects electrical responses in neurons of the brain. Perception is the conscious sensory experience of any stimulus. Recognition is the ability to categorize the object and give it meaning, which influences the viewers' actions, which includes any type of movement. Knowledge is any information brought to the situation by the viewer.

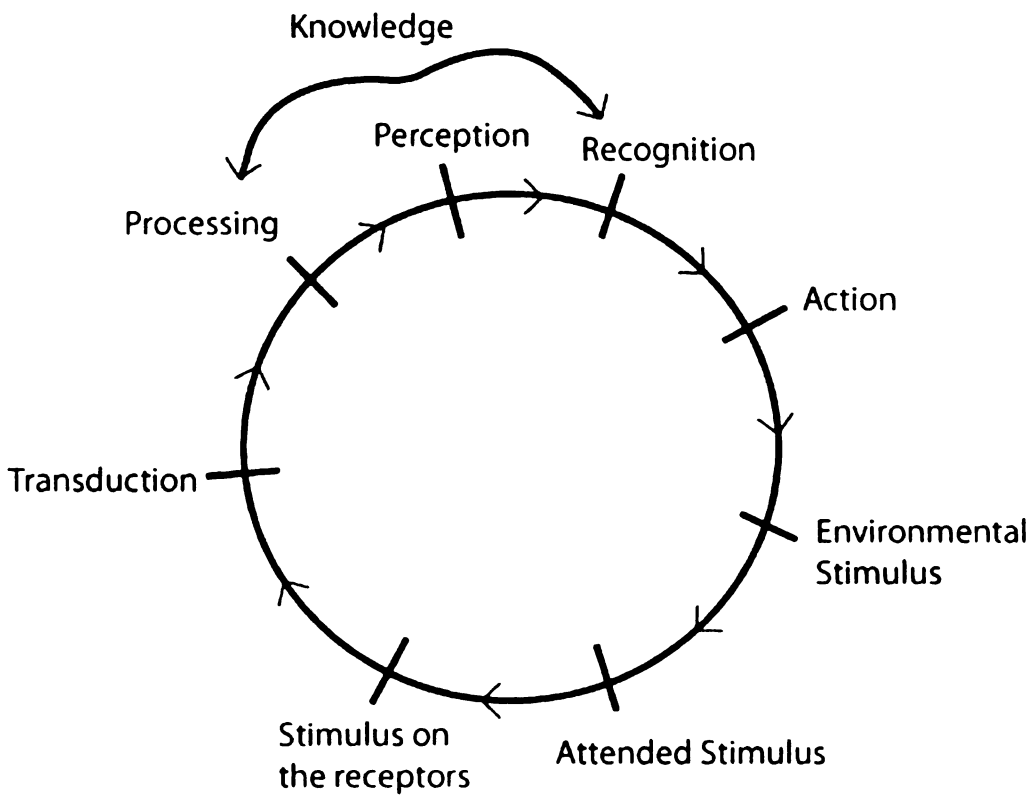

Figure 1 – Cycle of Perception

Although perception can be studied with any of the five senses, this discussion is limited to the sense that is most commonly used to gather information from product labeling, vision. To properly understand some of the

complexities of the process of perception, an understanding of the basic physiology of the eye is needed.

The anatomy of the eye and brain, and how they work together, is an important part of how we perceive stimuli. The retina in the back of the eye has two different kinds of receptors for receiving information. The fovea is in the center of the retina and only has cone receptors. The rest of the retina has both cone receptors and rod receptors, but many more rod receptors than cone receptors. Cone receptors are responsible for collecting specific and detailed data, such as defined shape and color. They are less sensitive to stimuli than rod receptors are. Rod receptors are responsible for general perception of stimuli. While rod receptors are unable to detect color or definition, they are more sensitive to the stimuli in the perception process[2].

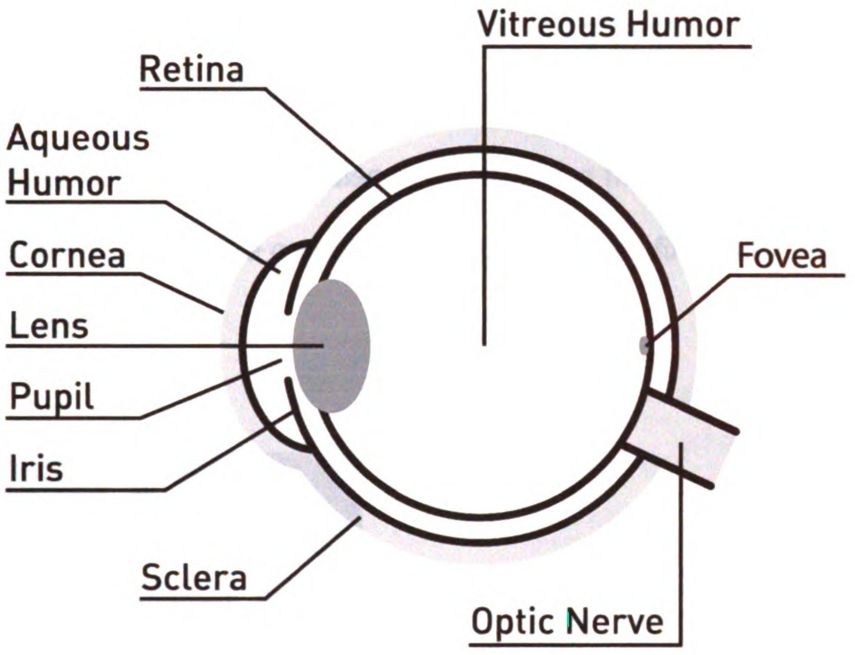

Figure 2 - Cross Section of the Eye adapted with permission by de la Fuente [1]

After the initial reception by the retina, the signals are transmitted from the cone receptors and rod receptors to the brain. The rod receptors are better able to get information to the brain because of convergence, which is the term used when many neurons send signals to a single neuron. A neuron has to reach a certain threshold to be activated, and once it is activated it can send the information on to the brain. Because cone receptors do not converge, many times, they do not reach the threshold necessary to activate.

A phenomenon called inhibition occurs when one neuron decreases the activity in another neuron next to it. The intersections of the white stripes between nine black squares (See Figure 3), called the Hermann grid [3], appear

to have gray dots in them, but when you cover up the surrounding area to the intersection the gray dots are no longer there. Inhibition can explain some visual illusions, but there are also some illusions that cannot be explained. This means that vision is more complex than just neurons firing next to each other on the way to the brain.

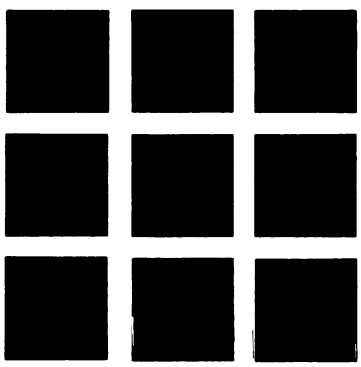

Figure 3 - Hermann Grid

There are different pathways information travels in the brain that respond to what and where (See Figure 4). The "what" pathway is the route that information, in the form of electrical signals, travels so that the stimulus is identified. It is also called the ventral pathway, and leads to the temporal lobe. The "where" pathway is the route information goes to tell where the object is located in space, also called the dorsal pathway, and leads to the parietal lobe. More recently it has been suggested that the "where" pathway should be called the "how" pathway, because it is for taking action.

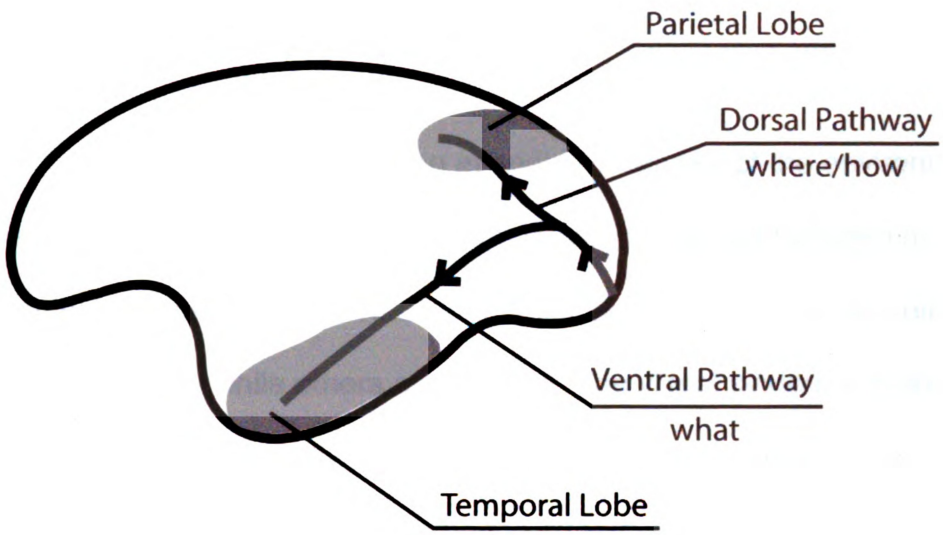

Figure 4 - Lobes in the Brain

These pathways in the brain pass by other areas in the brain that influence perception. The neurons in these other areas are specialized to recognize different features, such as faces, places, and bodies; this is called feature detecting. These specialized neurons can only respond to that stimulus feature.

Neurons can be adapted to view a certain type of stimulus if presented to it for a prolonged amount time. Whether these neurons are shaped by evolution or by the experiences of a particular person is yet to be agreed upon. Another point of disagreement is if there are single neurons that identify a certain stimulus, called specificity coding, or if there are groups of neurons that identify a stimulus, called distributed coding.

Attention

Attention involves looking at specific features of the environment in a more detailed and focused manner. Attention can be divided between multiple stimuli or attention can be selective. During selective attention, focus is directed toward certain objects, while others are ignored. The visual system is designed to operate on selective attention, because we cannot possibly focus on everything at once. Our brains would become too overwhelmed, which is why we have the fovea, which is small, to capture detailed information and eye movement to help facilitate focus on a larger area.

When observers are shown a scene for a fraction of a second they perceive the scene as a whole and get the gist of it, but not the specifics. Attention is necessary to get specific and detailed information. Inattentional blindness occurs when a stimulus that is not attended to is not perceived, even though it is in plain sight[2].

Theories Explaining Perception of Objects

There are several theories that attempt to explain the complexities of object perception:

The Gestalt laws and principals;

Perceptual segregation;

Feature integration theory;

Theory of unconscious inference;

Likelihood principle.

The Gestalt Laws

The Gestalt laws of perceptual organization represent a series of rules that aid researchers in understanding how people organize small parts into wholes. There are six of these rules.

1. The law of good figure- "every stimulus pattern is seen in such a way that the resulting structure is as simple as possible."
2. The law of similarity -"similar things seem to be grouped together."
3. The law of good continuation -"points that , when connected, result in straight or smoothly curving lines are seen as belonging together and the lines tend to be seen in such a way as to follow the smoothest path."
4. The law of proximity or nearness - "things that are near each other appear to be grouped together."
5. The law of common fate - "things that are moving in the same direction appear to be grouped together."
6. The law of familiarity - "things are more likely to form groups if the groups appear familiar or meaningful."[2]

The Gestalt laws were written in the early 1900s, so more recently, psychologists have developed additional principals. The principal of common region is "elements that are within the same region of space appear to be grouped together." The principal of uniform connectedness suggests that "connected regions of visual properties such as lightness, color, texture, or motion are perceived as a single unit." The principal of synchrony is "visual events that occur at the same time will be perceived as belonging together." Although these laws and principals are generally accepted, they do not apply to every case and are considered more rules of thumb.[2]

Feature Integration Theory

"Binding is the process by which features such as color, form, motion, and location are combined to create our perception of a coherent object."[2] Attention plays a critical role in binding, according to feature integration theory, because before attention is focused on the object color, motion, form, and location are separate. Focusing attention on the object binds the features into one coherent object.

Perceptual Segregation

Perceptual segregation is when an object or group of objects is separated from the rest of the scene. Figure-ground segregation is how humans perceive

many scenes. The figure is the object that stands out from the background, and the contour separating the figure from the ground appears to belong to the figure. The ground is the rest of the scene and is seen as uniform material. Also, humans respond more to verticals and horizontals called the "oblique effect"[2].

Theory of Unconscious Inference and Likelihood Principle

There are many ideas about how intelligence affects our perceptions. The theory of unconscious inference says that some perceptions are made by assumptions we unconsciously make about an environment. The likelihood principle states that we perceive the most likely object from the image that we receive. There are two different types of perceptual processes: bottom-up processing and top-down processing. Bottom-up processing is solely based on incoming information. Top-down processing is based on knowledge that the observer already has and the incoming information. Many perceptions are influenced by the knowledge that a person has, sometimes even without them knowing it. Perceptual recognition has been described as an association between an incoming stimulus event (e.g., reading a medication order, label, or package) and a recognized "template" that is stored in long-term memory (e.g., recalling previous similar drug orders, labels, or packages).[4]

Categories of Study Related to Visual Perception and Attention

Perception can be studied at different levels of analysis: psychophysical and physiological. The psychophysical level of analysis involves presentation of a stimuli followed by a request for a response from the observer, and is the relationship between stimulus and perception. The physiological level of analysis involves presenting a stimuli and measuring the neurological response in the brain, and is the relationship between stimulus and physiology. Some studies use both psychophysical and physiological levels of analysis to develop a more complete understanding of perception and response to a given stimuli.

Methodological approaches are considered when researchers want to characterize the psychophysical level of interaction between subject and stimulus include recognition and visual search. Recognition is a simple method in which an observer is asked what a stimulus is and the observer responds; the dependent variable in these types of studies are the number of correct responses. Visual search methodologies involve requesting the observer find a certain stimulus in as little time as possible; the dependent variable in these types of studies is primarily the time to find the stimulus of interest.

To measure the ability of textual formatting to garner attention in labels, we employed a psychophysical technique that is commonly used in the field of visual psychology. This technique is referred to as change detection, or a flicker

task. "Change detection is presenting one picture, then a blank field, followed by the same picture but with an item missing, followed by a blank field and so on."[2, 5] (See Figure 5)

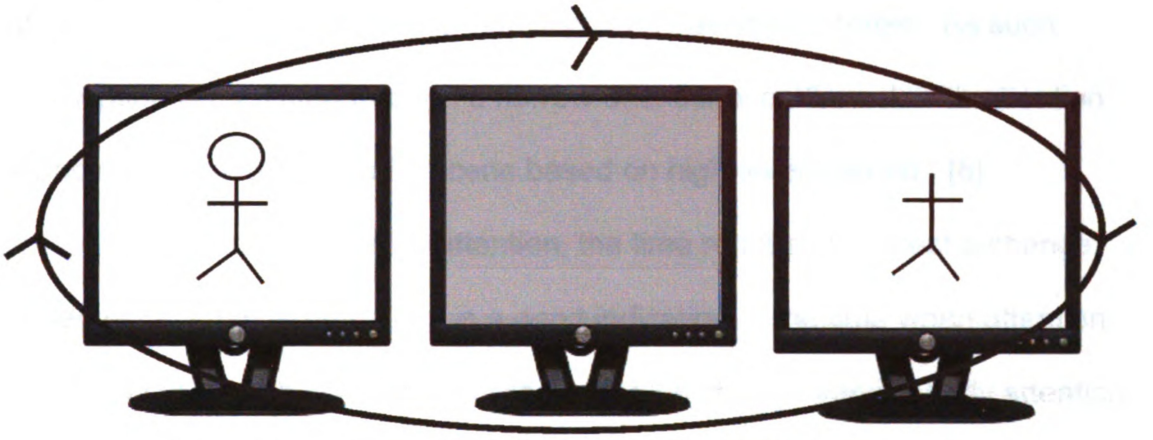

Figure 5 – Timing of Change Detection Software

During the change detection task, participants are instructed to find the change in the scene as quickly as possible. As such, the dependent variable is the time to detect a change.

Change blindness is the difficulty of detecting changes in a scene [5-6]. People think that they do not experience change blindness, because they think abrupt changes rarely occur in real life, this is called change blindness blindness [2]. Many experiments show that the disruption of attention is the reason we miss the changes.[5, 7]

Studies in visual cognition suggest that observers "never form a complete, detailed representation of their surroundings," and that in the absence of localized motion signals, attention is guided based on interest. As such, "perception is mediated through a narrow attentional bottleneck with attention attracted to various parts of a scene based on high-level interest." [8]

Given this reliance on attention, the time required to detect a change (when using change detection) is a good indication of the time when attention first selected that object. Faster detection of the change implies early attention to the changed property, which can also provide insights about the viewers' "attentional scan-paths" [8-9]. As such, change detection has been used to measure the locus of attention (a combination of perception and cognition) much as eye tracking measures the fixation of the eye (i.e. perception) [8-9].

Research indicates that change blindness, or the inability to detect a change, occurs for a variety of reasons. This includes when two disparate scenes are separated by a blank screen (the flicker change detection technique) [8, 10-13], eye blinks [14], saccades [15-17], camera cuts [18] or occluding events[19]. It can also be produced when multiple "mud-splashes" hit the screen simultaneous with the change [20] , or when changes occur extremely slowly [21]. All of these techniques have one thing in common; the change fails to produce a sudden and unique visual transient, which would otherwise capture attention to the location of the change.

In other words, in our field of vision, overall scenes appear to be in focus, but change blindness experiments show otherwise. If we are not cued to look at a specific area we miss changes, and that shows that only a small part of our environment is actually encoded in detail.[2, 6]

A recent study was conducted using change detection on food labels. Researchers tested varied information on food labels including: fat content, best before date, recycling information, and organic information. The research team conducted an additional study to test two graphic presentations: textual and graphic symbol. The study showed the fastest detection of the change was for the organic information and the slowest was for the fat content. These detection times were contradictory to a self report survey, where the participants were asked which information on the label was the most important to them. An additional study indicated that the information on the label determined the time to detect rather than the graphic presentation of either textual or graphic symbol. The study concluded that the results are positive and suggest that incorporating change detection as a measure of attention blindness in future studies, in addition to self-report instruments, might be a fruitful approach[22].

Given the documented prevalence of medication error and noncompliance, and the criticality of the information contained on the labeling that accompanies medication, we chose to conduct research using change detection to the labeling of look-alike, sound-alike drugs.

Look-Alike, Sound-Alike Drug Names and Medication Error

Many drug names can look or sound like other drug names, which leads to confusion and potentially harmful medication errors.[23-26] Among other types of adverse events, the subject of medication error has received significant national attention since publication of two reports from the Institutes of Medicine (IOM), which focused on medication errors in the US. [27-28]

It's estimated that one in four medication errors involve products that sound or look alike.[23-25] ISMP [Institute for Safe Medication Practices] receives 1200-1500 reports each year involving serious complications resulting from the use of drugs. Approximately 25% of these (300-400) are related to drug name confusion and another 25% related to labeling and packaging issues.[29] Reports submitted to the United States Pharmacopeia Medication Errors Reporting (MER) and MEDMARX programs underscore how similarity in a products drug name, label, or packaging can lead to errors. From January 2000 to March 2004, there were 31,932 reports submitted to MEDMARX that listed one or more causes of error were related to look-alike or sound-alike drug names, packaging, and/or labeling and approximately 2.6% of these reports were categorized as harmful to the patient[4].

As a result of statistics such as these, the FDA is turning more attention to reducing errors from lookalike and sound-alike drug names. Some action items

were developed as a result of the Institute of Medicine report. But the problem exists, and it will probably get worse as we keep adding more drug products into the crowded market of drug names[25].

All drug names have a chemical name that chemists use, but these names have limited usability for practicing healthcare professionals. Many drugs have code designations and/or trivial names that are used during research and development, which may cause confusion once the drug has established generic and brand names. Each drug is assigned a generic (non-proprietary) name, which is essential for communication about that product regardless of other names that are used for the drug. Pharmacopeias have also proposed pharmacy equivalent names for complicated products, such as combination products. These names, while not official, are sometimes useful to help simplify drug names and thereby reduce confusion for pharmacists. Finally, brand names, also called proprietary or trade names, are trademarked names developed when the drug is marketed [23, 29-30].

The similarity of all these names between all drugs increases the risk of drug name confusion errors.[24] Sound alike and look alike drug names can lead healthcare professionals to unintended interchanges of drugs that can result in patient injury or death. The existing medication system is flawed because its safety depends on human perfection. Simplicity, standardization, differentiation, lack of duplication, and unambiguous communication are human factors

concepts that are relevant to the process, but these principals have often been ignored in drug naming and labeling of packaging[29].

A significant contributor to the problem is that many drugs are from similar families and are used in similar manners. Consider, for example, ephedrine and epinephrine. Not only do these drug names look similar, but their use as vasoconstrictors makes storage near each other likely. Both products also may be packaged alike in 1 mL ampoules or vials. [31]

The inherent problems with this have been realized in the form of serious adverse events. One such instance was illustrated in a labor and delivery unit, where,

> "a healthy young woman became hypotensive after epidural anesthesia was administered. A nurse immediately called the obstetrics resident to inform him of the patient's condition. The resident, known to be "difficult" at times, became angry and snapped at the nurse as he ordered ephedrine 10 mg to be given slow IV push. When processing the order, the nurse, who was anxious because of the physician's behavior, made a mental slip and thought of "epinephrine." With only a few ampuls [ampoules] of epinephrine 1 mg on the unit, she decided to borrow more from the nursery. She found a 30 mL vial of epinephrine 1:1,000 (1 mg/mL), per withdrew 10 mL, and returned to administer that amount to the patient. Almost immediately, the patient developed tachycardia, severe hypertension, and pulmonary edema. Fortunately, an anesthesia staff member was present and recognized the problem immediately. The patient was treated successfully and the baby was delivered safely." [31]

> "An eerily similar scenario played out recently at a different hospital where yet another patient was hypotensive from epidural

> anesthesia. A nurse called pharmacy to report that her automated dispensing cabinet didn't have enough epinephrine to administer a 5 mg IV dose. A pharmacist immediately reviewed a copy of the order in which the physician had clearly prescribed ephedrine 5 mg IV. The reporter noted that, had there been enough epinephrine in unit stock, a 5 mg dose might have been given. We've [Institute of Safe Medication Practices] also received reports where diluted ephedrine was administered in error instead of epinephrine. In one case, a patient received an irrigation solution during an orthopedic procedure where ephedrine, not epinephrine, was added to a 3 liter container. In yet another hospital, ephedrine was used to compound an epinephrine infusion."[31]

Another such example concerns chlorpropamide and chlorpromazine. "One patient died and another developed serious symptoms after receiving 750 mg of chlorpropamide (Diabinese), instead of 75 mg of chlorpromazine (Thorazine)."[25]

TALL Man lettering as a Solution

In 2001, the FDA/Office of Generic Drugs began a "Name Differentiation Project". This program was designed to promote the use of TALL Man lettering, the use of small and large letters, in drug names to visually differentiate between drugs with very similar names[32].

The use of TALL Man lettering is gaining wide acceptance[33-34]. It has been recommended that TALL Man lettering be used to differentiate a standard set of look-alike drug name pairs on pharmacy-generated labels, drug selection screens, shelf labels, medication administration records, and order sets. [31-36]

The Joint Commission, National Association of Boards of Pharmacy, and other safety-conscious organizations have promoted the use of TALL Man lettering as a means of reducing confusion between similar drug names[34].

Research regarding the effectiveness of TALL Man lettering formats in preventing medication error is limited in nature, but what does exist tends to suggest that it is a positive step for healthcare. Studies are varied in approach, using methods that range from surveys to eye tracking, but fairly consistently agree that TALL Man has the potential to positively impact the problem.

Studies of the Efficacy of TALL Man Lettering

The Institute of Safe Medication Practices conducted a survey on their website to gather information about the use of TALL Man lettering. Out of 451 survey responses, the vast majority of respondents (87%) agreed that the use of TALL Man lettering helps reduce drug selection errors, and two-thirds (64%) reported that TALL Man lettering has actually prevented them from dispensing or administering the wrong medication. Half to three-quarters of respondents who have used TALL Man letters felt that this strategy was effective in reducing the risk of errors, depending on where it was used. Between a quarter and a third of respondents were undecided about the effectiveness of TALL Man lettering, but very few reported that TALL Man lettering was an ineffective strategy in reducing the risk of errors[34].

The Standards Development subcommittee of the Safe Medication Use (SMU) Expert Committee of the United States Pharmacopeia also collected data on the effectiveness of TALL Man lettering. Responses totaled 900 from the state association constituents. Of these, 840 (93%) were actively involved in patient medication activities. 777 (92%) of these 840 were aware of TALL Man lettering, and 547 (70%) of the 777 say TALL Man Lettering is being used in their organizations[37].

Psychophysical studies have results congruent to the survey work presented above, finding that highlighting sections of words using TALL Man lettering can make similar drug names easier to distinguish, resulting in fewer errors among products with look-alike names[38-39]. One such study employed eyetracking on a computer screen using an array of products as stimulus material.

In the eyetracking experiment, one drug from each pair of lookalike sound alike drugs was presented as a target to search for (e.g., chlorpromazine), and the other drug was present in the array as a distractor (e.g., chlorpropamide). It is critical to note that the target was never present in the array. The array consisted of the distractor plus 19 other drug products. It was found that participants were less likely to incorrectly indicate that a target drug was present in an array when the name contained TALL Man lettering. The eye movement data directly

corresponded with the error data ,that is, when participants made more errors, they also made more fixations and spent longer fixating on the distractor drug name in the array[39].

In a different experiment, which consisted of two phases, participants were given a "same/different" judgment task in which they were presented with a pair of lookalike sound alike drug names on a computer screen and had to indicate, as quickly and as accurately as possible, whether the two names were the same drug name presented twice or if they were two different drug names[38]. Unlike the eye tracking study and the surveys previously discussed, results of the experiment indicate that name pairs containing TALL Man letters are not easier to distinguish from each other than other name pairs that are presented in lowercase.

In a second phase of the same experiment, participants, who were different from those tested in the first phase, performed the same task except for they knew that TALL Man lettering was used in an attempt to make similar names less confusable with each other[38]. Results suggest that if participants are aware of the purpose of TALL Man lettering, they can more easily tell the difference between drug name pairs with TALL Man lettering than between lowercase drug name pairs. Taking results from the first experiment into account, this would suggest that TALL Man lettering can be effective if participants are aware of its purpose[38].

The "same/different" study also tested bolding, coloring, underlining, enlarging and italicizing the different portions of the drug names. Printing sections of the names in color or any other form of differentiation did not aid recognition, and there was no significant benefit of a TALL Man lettering and color combination over using TALL Man lettering alone[38].

CHAPTER 2 - METHODS

The objective of this study is to add to the body of work that qualifies TALL Man lettering as method that should be used to differentiate lookalike sound alike drum names, and to evaluate the change detection "flicker task" method so it can possibly be used in future labeling studies.

Methods employed in the recruitment, testing and subsequent data storage and handling were approved under IRB 09-623. To participate, subjects had to be at least 18 years of age or older and were screened for a history of seizure. Additionally, they could not be legally blind.

Two populations were targeted for this study: those who were (or had been) employed as healthcare professionals and those who were not. The healthcare population was recruited from three locations: (1) in Westlake, Ohio, an area in close proximity to the Cleveland Clinic, (2) at the National Center for Patient Safety in Ann Arbor, MI, and (3) through the College of Nursing at Michigan State University (East Lansing, MI). The nonhealthcare population represented a convenience sample consisting primarily of students and University employees. All participants were recruited with email fliers and by word of mouth (see Appendix A for flier).

Researchers provided participants with a verbal explanation of all test procedures. All participants were provided with a consent form (approved under IRB 09-623 - see Appendix A) which they were asked to review and sign. This consent form mentions that participants may withdraw from the study at any time without penalty. Details regarding contact information for both experimental questions and treatment issues are provided at the end of the consent form. Each participant was then assigned a participant number. The participants were asked if they require corrective eye wear for reading. If they indicated this to be the case, they were asked to wear it.

An Adobe flash program created by the research team was used for all testing. During a trial, a "standard image" continuously alternates with a "test image," with a brief, gray screen separating the presentation of said images. Each of the two alternating images are displayed for 240 milliseconds, and the gray blank between the images is displayed for 80 milliseconds (see figure 6); these timings are based on the work of Rensink et al[7].

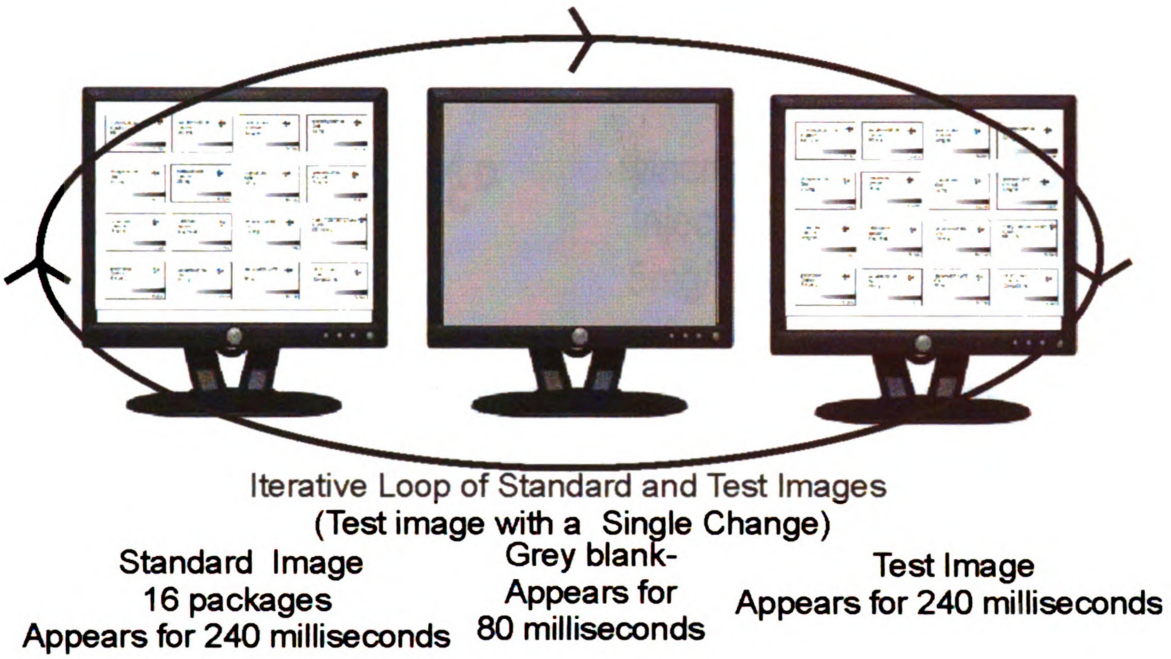

Figure 6 - Timing of Change Detection Software

Prior to collection of recorded data, each participant was tested using three pairs of images that allowed them to become familiar with the technique and become comfortable with how the study worked (See figure 7). Participants were seated comfortably in front of a laptop computer, a Sony Vaio laptop with an Intel Centrino processor 1.86GHz, 1 GB of RAM, and a 15" Widescreen with X-Brite technology. This was followed by the instruction, "This is a demonstration of the change detection software that will be used throughout testing. You will see two images flash over one another with a single change between the two. We are trying to see how long it takes people to notice the change in these images. Please hit the space bar on the computer as soon as you notice the change."

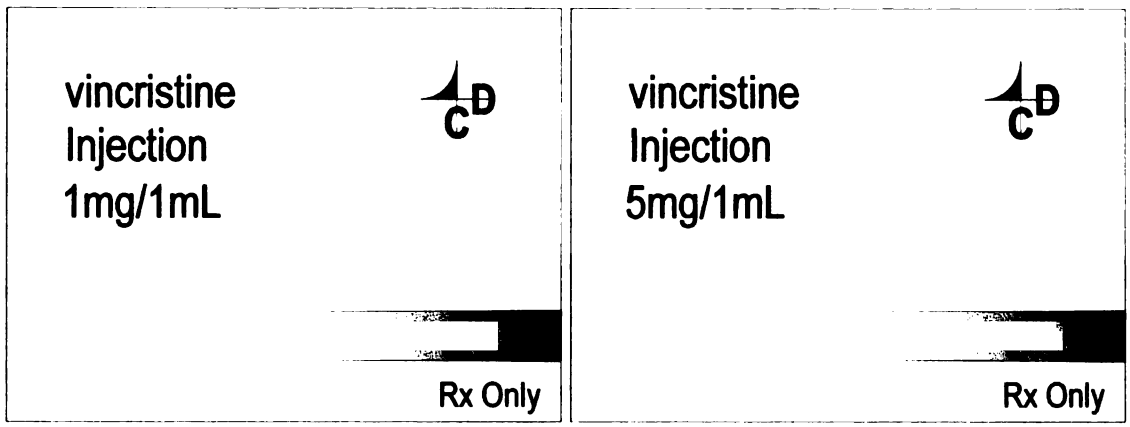

Figure 7 - Demo Pair; Standard Image and Test Image

After a participant indicated that they had found the change, by pressing the space bar, they were asked to identify the change by clicking on the area of the image that was changing using the mouse cursor. If they identified the change correctly, the dependent variable, time to detect, was recorded by the software and they continued testing by viewing a new pair of images. If they failed to click on the area of the image that was changing, the software returned to that pair again until they indicated the change correctly. In the event this happened, the dependent variable, time to detect, was the sum of all attempts collected for a given pair. If the participant took more than 2 minutes to identify the change, in either a single attempt or multiple attempts, the researcher ended the attempt, indicated the change, recorded two dependent variables (1)time as 120 seconds; (2) the binary variable, fail to detect, and the participant moved on to the next image pair.

The stimulus materials (2 images in a pair and 16 labels per image) were created using Adobe Illustrator CS4; all images were 800 pixels wide by 600 pixels tall. Each individual label within each image measured 175 pixels by 108 pixels spaced evenly. Image pairs were presented as a four x four label configuration (see Figure 9 for the standard image of one test pair). Within each label the brand name, route of administration, and dosage were created with Arial font in type size 12, and the RX statement was also Arial font in type size 9 (See Figure 10). Images were converted to a jpg file format so that they would be recognized by the change detection software.

Based on information obtained from the website of the Institute for Safe Medication Practices (ISMP) eight pairs of look-alike, sound-alike names were selected; in other words a total of 16 drug names were tested. Additionally all of the eight word pairs selected have been approved for use by the FDA in TALL Man formats (see Table 1). Drug names were chosen so that the dissimilar portion of the names appeared in varied locations of the word (beginning, middle, and end). Each word pair was presented in two levels of graphic presentation (TALL Man and traditional-See Figure 8 for the two graphic presentation levels of the same word pair), for a total of 16 pairs (8 word pairs by 2 levels of graphic presentation).

8 Word Pairs by Graphic Presentation	
TALL Man Orientation	
acetoHEXAMIDE	acetaZOLAMIDE
chlorproMAZINE	chlorproPAMIDE
clomiPHENE	clomiPRAMINE
DAUNOrubicin	DOXOrubicin
dimenhyDRINATE	diphenhydrAMINE
medroxyPROGESTERone	methylTESTOSTERone
predniSONE	prednisoLONE
vinBLAStine	vinCRIStine
Traditional Orientation	
acetohexamide	acetazolamide
chlorpromazine	chlorpropamide
clomiphene	clomipramine
daunorubicin	doxorubicin
dimenhydrinate	diphenhydramine
medroxyprogesterone	methyltestosterone
prednisone	prednisolone
vinblastine	vincristine

Table 1 – Look alike sound-alike drug name pairs

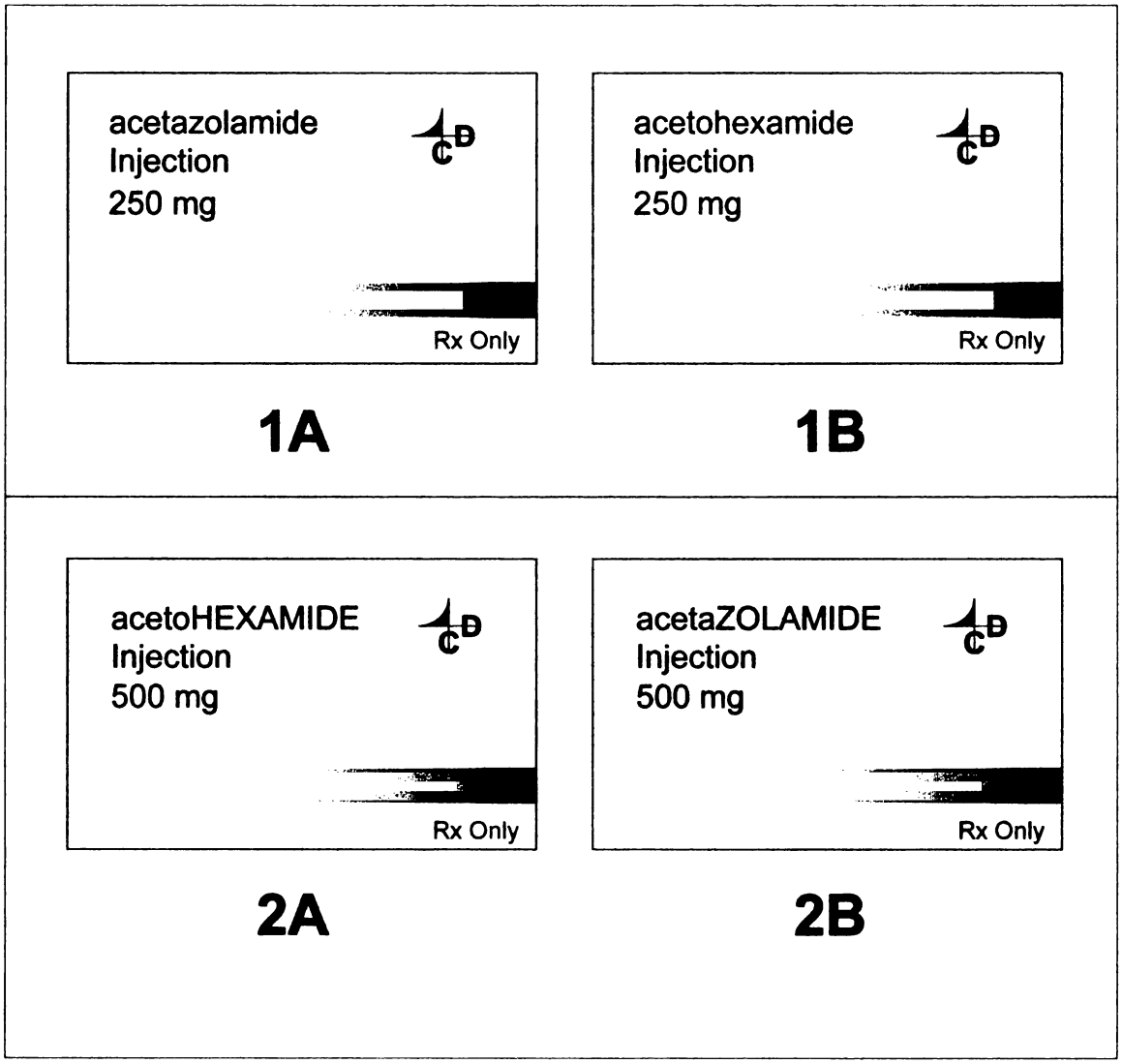

Figure 8 - Two graphic Presentations of Word pair - 1A flashes against 1B - 2A flashes against 2B

In other words, a single image contained 16 labels that flashed against another image with 16 labels (See Figure 9). A single change was present as the image pair "flickered". Changes were classified as "critical" if they involved the drug names in either of the graphical formats (TALL Man or traditional); for example, chlorpropamide and chlorpromazine (flashing one against the other in the lower case graphic presentation). Another critical change occurred when the

lookalike sound alike names were presented in the TALL Man presentation (chlorproPAMIDE would flash against chlorproMAZINE). The dependent test variables were was the time it took participants to notice the change and the binary variable, detected, yes/no.

Figure 9 - Standard image of one image pair - Labels were presented in a 4 x 4 configuration

Each participant viewed each word pair twice; once in each of the two graphic presentations (TALL man and traditional), for a total of 16 critical image pairs per participant. However, in order to prevent participants from becoming sensitized to the changing names, 16 image pairs which were not of interest to the research team, or "noncritical" image pairs, were also tested. Noncritical image pairs included the change in the concentration/strength, the brand symbol, the route of administration, or the RX statement (See figure 10).

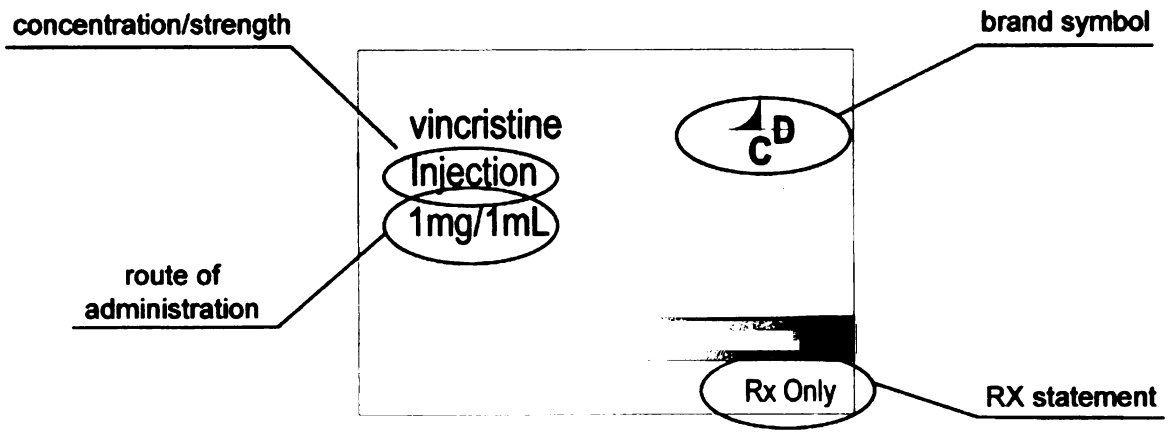

Figure 10 – Noncritical Image Pair Changes

As such, each participant viewed a total of 32 image pairs (16 critical image pairs and 16 noncritical image pairs). To prevent participant fatigue, image pairs were presented in 4 groups of 8 image pairs, with a break between each group when other information was collected (See Figure 11). The presentation of

noncritical image pairs and critical image pairs were balanced within group (See Table 2), although the order of presentation was completely randomized.

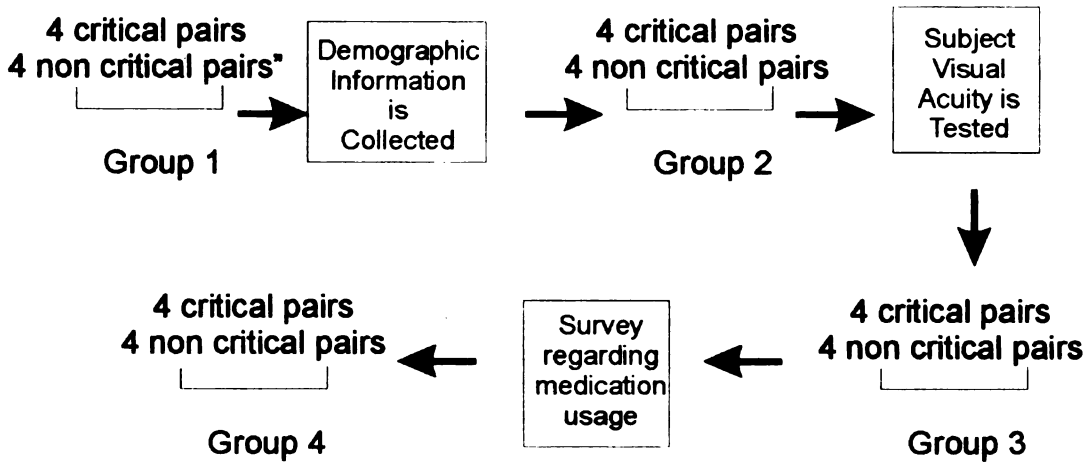

Figure 11 - Layout of Experimental Design

At the first break, the participants demographic information was collected. This included: their gender, age, profession, education level, requirements for eyewear and self declared ethnicity. After the demographic information was collected, the participant was asked to view 8 more image pairs using the change detection tool.

As another break, visual acuity was tested using a Dow Corning Ophthalmics Near Point Visual Acuity Card. Participants were instructed to hold

the test card approximately 16" from their eyes and read the lowest line on the card that they could aloud. In the event that the participant could not correctly report all letters on a given line, they were asked to read the line directly above it. This continued until they did not miss any letters. Their visual acuity was recorded (20/20, 20/30, etc.) accordingly. At this time, a refreshment break was offered. Researchers provided juice boxes and colas as well as a small snack.

Following the test of visual acuity and a snack, 8 more image pairs were tested. Following the test of the third group of image pairs, a survey was conducted asking the participant some questions involving their behavior using medications (See Appendix B). Following the break, the final group of 8 image pairs was tested.

Statistical Methods

This experiment is a split plot design. The first split is health care professionals versus nonhealth care professionals. The second split is 8 word pairs* 2 graphic presentations (TALL Man versus traditional) for a total of 16 critical pairs. It is a complete block design; to control for any effect of positioning extensive randomization was conducted. The labels in the images are split into quadrants (1-4); top left corner, top right corner, bottom left corner, and bottom right corner (See Figure 12). Then the quadrants are split into positions (1-4). The first level of randomization occurs in the positions within a given quadrant.

The second level of randomization was the quadrants of each image pair within each participant. The third randomization was the order of the all critical and noncritical image pairs for each participant (See Appendix C for more information). Each of the four groups is balanced to contain 2 TALL Man graphic presentations, 2 traditional graphic presentations, and 4 noncritical image pairs (See Table 2). Because previous work regarding the use of change detection and labels indicated both a run effect and a positional effect, the balanced randomization was necessary. [40]

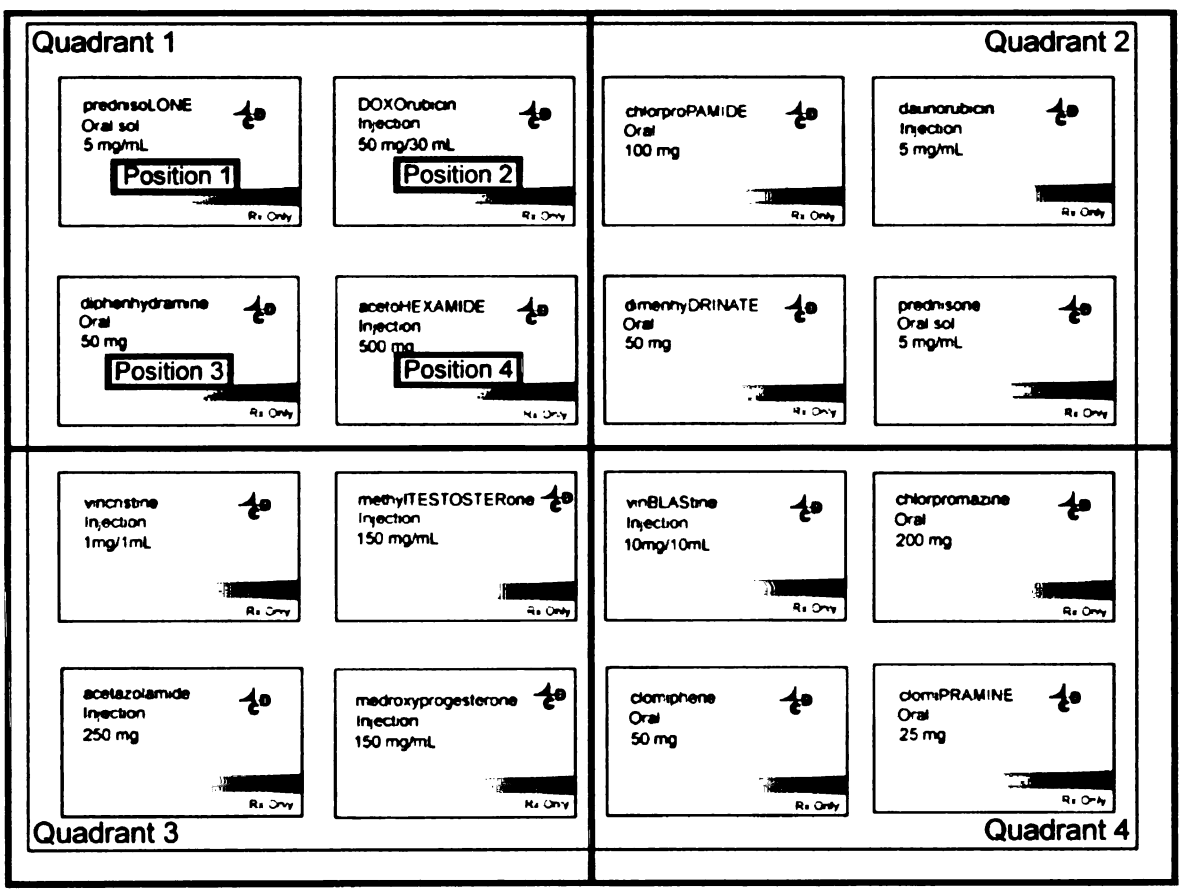

Figure 12 – Quadrants and Positions for Randomization- Quadrant and Position designations added for reader clarification and were not present on test materials

Example of a Single Group	Type of Change
predniSONE – prednisoLONE	Critical- TALL Man
daunorubicin – doxorubicin	Critical- Traditional
Graphic	Noncritical
Graphic	Noncritical
dimenhyDRINATE – diphenhydrAMINE	Critical- TALL Man
prednisone – prednisolone	Critical- Traditional
Root of Administration	Noncritical
RX Statement	Noncritical

Table 2 - Example of a Single Group

After the healthcare professionals completed the change detection testing, they were provided questions regarding their experiences (or lack thereof) with medication error, TALL Man lettering and asked to recommend solutions.

CHAPTER 3 - RESULTS AND DISCUSSION

Demographic Statistics

A total of 80 participants were tested in this research study; of these, 40 were, or had been, employed as healthcare providers. Within the healthcare providers, there were 16 who reported their profession as nursing and 24 listed other types of healthcare professions. Table 3 presents frequency counts by gender and professional status for the test population.

Twenty seven of the participants were male and 53 were female. Of the males participants, 4 were healthcare providers and 23 were non healthcare providers. Within the male healthcare providers there were 2 nurses and 2 other types of healthcare professions. Of the female participants there were 35 healthcare providers and 18 non healthcare providers. Within the female healthcare providers there were 14 nurses and 21 other types of healthcare professions.

	Non Healthcare	Healthcare (# of healthcare providers that were nurses)	Totals
Male	23	4 (2)	27
Female	17	36 (14)	53
Total	40	40 (16)	80

Table 3 - Number of participants; Male/female, healthcare/non healthcare, nurses

Table 4 presents a breakdown of the participants by age and professional status, and Table 5 provides age frequency data by gender.

	Non Healthcare	Healthcare (# of healthcare providers who were nurses)	Totals
18-24	22	4 (0)	26
25-34	10	10 (4)	20
35-49	2	11 (4)	13
50+	6	15 (8)	21
Total	40	40 (16)	80

Table 4 - Number of participants; Age Groups, healthcare/non healthcare

	18-24	25-34	35-49	50+	Total
Male	15	7	3	2	27
Female	11	13	10	19	53
Total	26	20	13	21	80

Table 5 - Male/Female in each Age Group

Of the 80 participants, 64 people indicated their first language to be English. Sixty-six participants self-declared their racial status as white, eleven as Asian, two as black, and one as Hispanic.

Positioning of Word Pairs

As referenced in the Methods section, each participant viewed 32 pairs consisting of both critical and non-critical images, and position and order of

presentation were randomized. Readers interested in the frequency of quadrant (1-4), graphic presentation (TALL Man and traditional), group, and position within quadrant should refer to Appendix C.

Dependent Variable- Time to Detect

The dependent variable, "time to detect," recorded in seconds, was modeled using a general linear mixed model fitted with the MIXED procedure of SAS software (Version 9.2 SAS, Inc., Cary, NC). The model included the fixed effects: profession (students, nurses, and "other healthcare provider"), graphic presentation (TALL Man and traditional), their two-way interaction, as well as the ordered group of presentation to the participant. Also included in the model were fixed positional effects, provided as quadrant by position combinations (see Appendix C for a complete description of the randomization methodology), and the interactions between treatment and quadrant and treatment and group. Random effects used in the model included: participant nested within profession, participant by treatment (to account for technical replications), participant by ordered group and participant by position by quadrant. Run order within group, gender, ethnicity and language were evaluated as fixed effects but were excluded from the final model based on P-value > 0.20. Age was excluded from the final model due to overparameterization/multicollinearity with the fixed effect factor profession. In order to appropriately meet model assumptions, the dependent variable (time) was log transformed.

Table 6 indicates the results of the statistical analysis for the fixed effects and Table 7 indicates the results of the statistical analysis for the covariance parameter estimates. Effects that are bolded represent those that indicated statistical significance at α=0.05.

Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
Treatment	**1**	**923**	**40.40**	**<0.0001**
Profession	2	76.9	3.00	0.0557
Treatment x Profession	**2**	**905**	**3.73**	**0.0243**
Group	**3**	**239**	**8.24**	**<0.0001**
Position x Quadrant	**12**	**735**	**5.86**	**<0.0001**
Tallman x Quadrant	3	1084	1.98	0.1147
Tallman x Group	3	933	1.65	0.1759

Table 6 - Type 3 Tests of Fixed Effects

Covariance Parameter Estimates				
Cov Parm	Estimate	Standard Error	Z Value	Pr > Z
Subject x Profession	**0.04868**	**0.1726**	**2.82**	**0.0024**
Subject x Treatment x Profession	0	-	-	-
Subject x Group	0.1334	0.01956	0.68	0.2476
Subject x Position x Quadrant	**0.09018**	**0.03215**	**2.80**	**0.0025**
Word Pair	0.01710	0.1229	1.39	0.0821
Residual	0.6303	0.0477	15.46	<0.0001

Table 7 - Covariance Parameter Estimates

TALL Man Vs Traditional by Professional Status

As indicated in the Tables (6 and 7), several interaction terms showed evidence of significance. Because the effect of graphic presentation (TALL Man vs traditional) is of primary interest to this study, understanding the significant interaction between treatment and profession is important (P=0.0243). Figure 13 and Table 8 provide further insights into this interaction.

Time to change detection was decreased for all professions when the change was presented in a TALL Man presentation as compared to the traditional text. However, the magnitude of this difference and its significance was greatest for nurses (P<0.0001) compared to the students or other healthcare professionals.

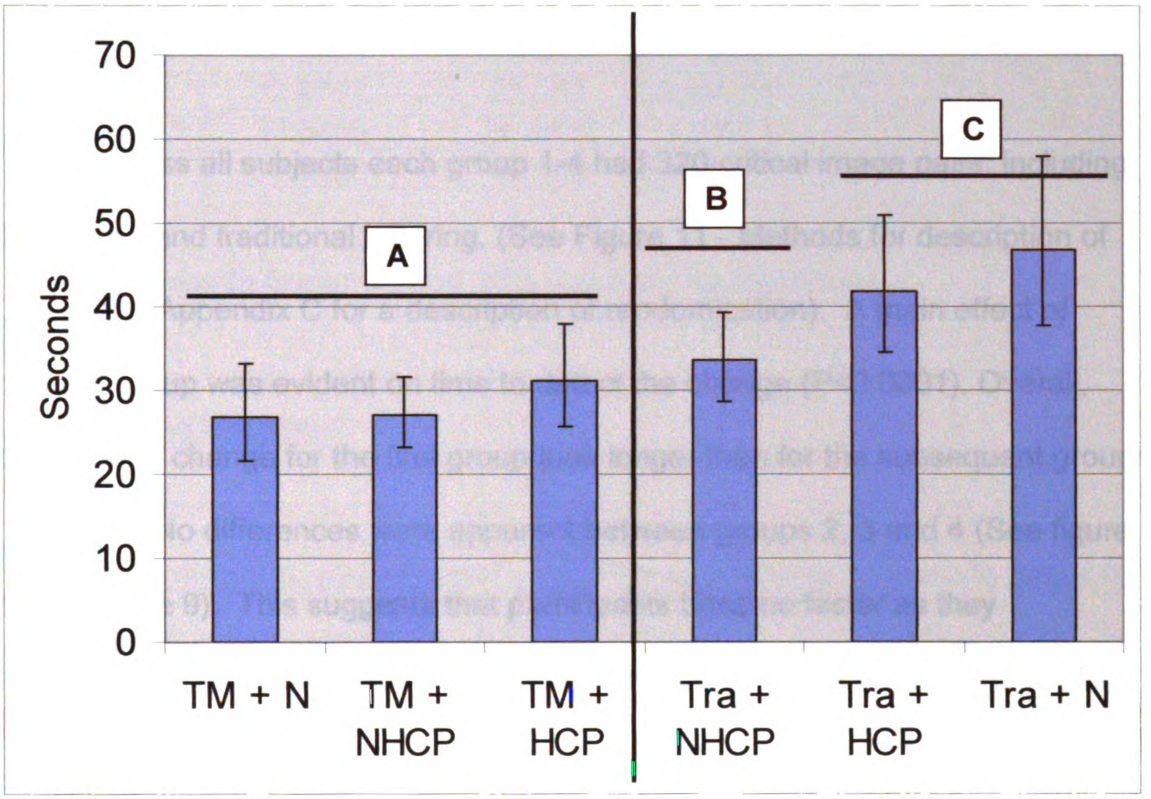

Figure 13 – Graphic presentation by profession of time to detect a change with standard error bars and significance; Different letters indicate statistical significance at α=0.05; TM = TALL Man, Tra = Traditional, N = Nurse, NHCP = Nonhealthcare Provider, HCP = Healthcare Provider

	Time in Seconds	Lower	Upper
Tallman+ Nurse	26.864	21.7011	33.2552
Tallman+ NonhealthcarePro	27.0048	23.1026	31.566
Tallman+ HealthcarePro	31.2473	25.7719	37.886
Traditional+ NonhealthcarePro	33.5817	28.6799	39.3211
Traditional+ HealthcarePro	41.911	34.5132	50.8945
Traditional+ Nurse	46.8211	37.7709	58.0397

Table 8 – Time in Seconds and 95% Confidence Intervals

Group

Across all subjects each group 1-4 had 320 critical image pairs, including TALL Man and traditional lettering. (See Figure 11 - Methods for description of Group and Appendix C for a description of randomization). A main effect of ordered group was evident on time to detect the change ($P<0.0001$). Overall, detection of change for the first group took longer than for the subsequent groups (2, 3 or 4). No differences were apparent between groups 2, 3 and 4 (See figure 14 and table 9). This suggests that participants became faster as they acclimated to the testing, and is consistent with previously published work. [40]

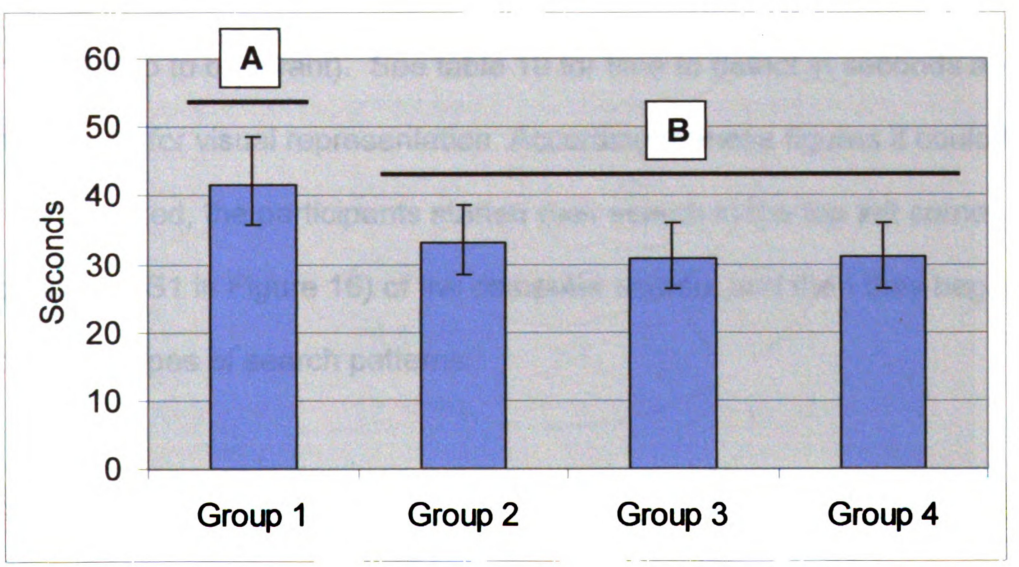

Figure 14 – Groups of time to detect a change with standard error bars and significance; Different letters indicate statistical significance at $\alpha=0.05$

	Time in Seconds	Lower	Upper
Group 1	41.5901	35.657	48.5104
Group 2	32.9792	28.257	38.4907
Group 3	30.8455	26.4423	35.982
Group 4	30.8869	26.469	36.0421

Table 9 – Time in Seconds and 95% Confidence Intervals

Quadrant and Position

A significant positional effect of change was detected on time to detect the change on the computer screen ($P < 0.0001$). This positional effect is characterized by the position and quadrant combinations, and included a total of 16 positions (see Appendix C for a discussion of positional randomization and its relationship to quadrant). See table 10 for time to detect in seconds and figure 15 and 16 for visual representation. According to these figures it could be hypothesized, the participants started their search in the top left corner (bar position 1-S1 in Figure 16) of the computer screen, and then they began many different types of search patterns.

	Time in Seconds	Lower	Upper
Quadrant 4 Position 3	52.1089	11.0216	13.978
Quadrant 3 Position 3	48.2404	13.256	18.2787
Quadrant 4 Position 4	45.5659	9.1355	11.4262
Quadrant 4 Position 1	44.3698	10.7312	14.1546
Quadrant 4 Position 2	40.7908	8.6137	10.9195
Quadrant 3 Position 4	39.5111	7.8105	9.735
Quadrant 3 Position 2	37.8503	10.7565	15.0267
Quadrant 2 Position 3	35.6234	9.3685	12.7115
Quadrant 2 Position 4	35.3615	7.1972	9.0363
Quadrant 1 Position 4	34.4737	8.4982	11.2785
Quadrant 3 Position 1	33.3975	6.7805	8.5077
Quadrant 1 Position 3	31.8691	7.3949	9.6292
Quadrant 2 Position 2	30.6114	5.5667	6.804
Quadrant 2 Position 1	28.7356	7.7128	10.5426
Quadrant 1 Position 2	19.1047	3.7605	4.6822
Quadrant 1 Position 1	12.1089	2.3723	2.9503

Table 10 – Time in Seconds and 95% Confidence Intervals

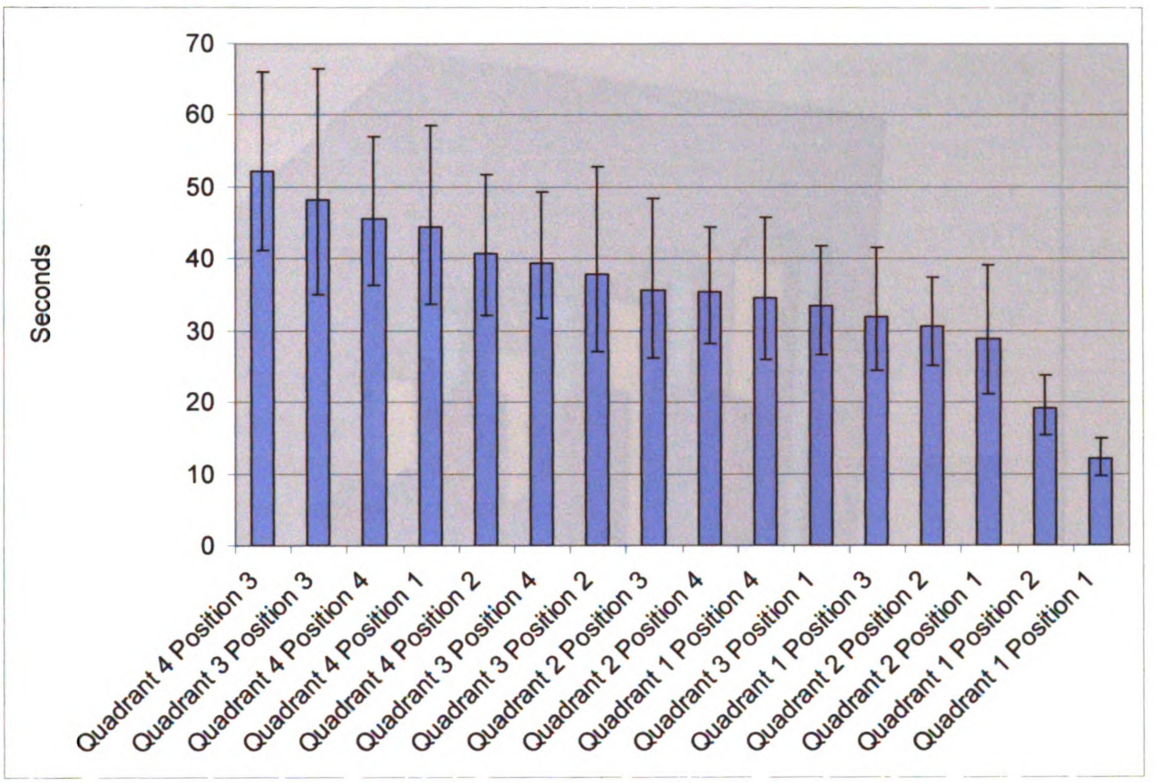

Figure 15 – Quadrant by Position Time and 95% Confidence Intervals

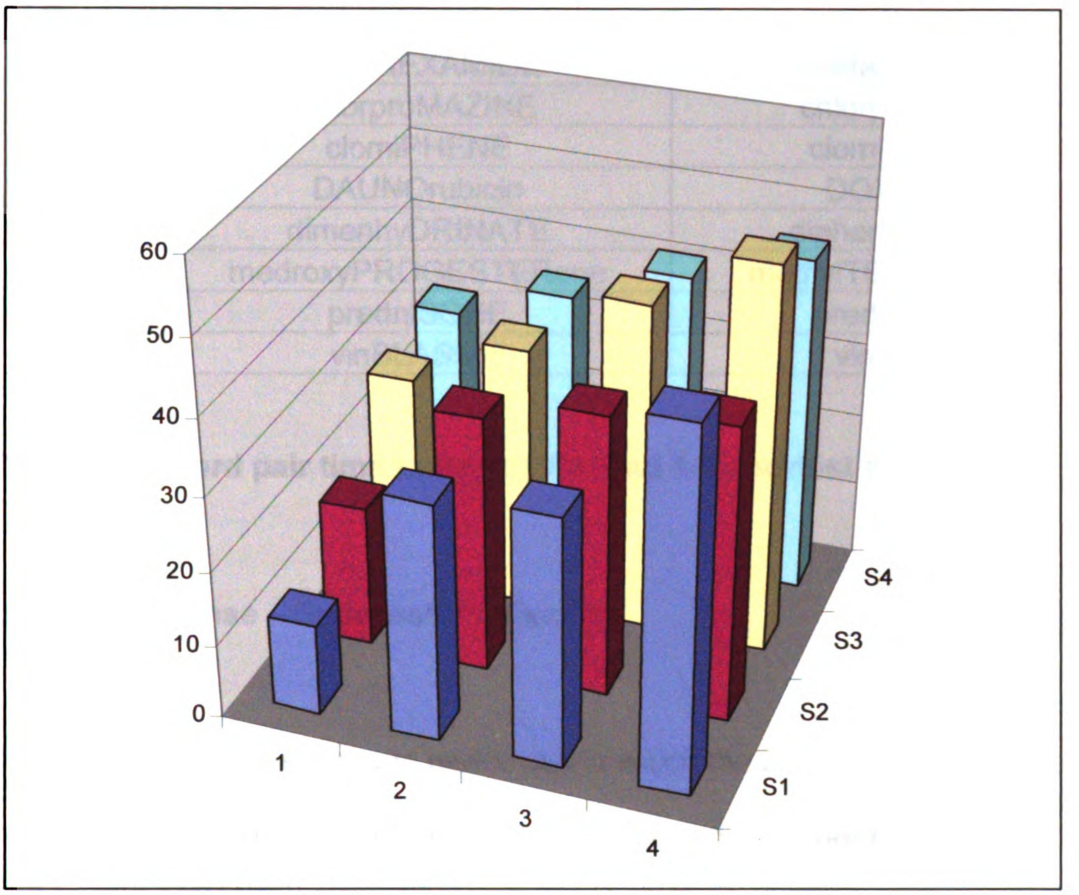

Figure 16 – Comparison of 16 positions with dependant variable time to detect; 1-S1 is top left corner, 1-S4 is top right corner, S1-S4 is the bottom

Word Pair Comparisons

There was marginal evidence for a difference between word pairs when the dependent variable was time to change detection. Pairs are ranked in Table 11 on the predicted time to change detection.

Rank	TALL Man Orientation	
7	acetoHEXAMIDE	acetaZOLAMIDE
8	chlorproMAZINE	chlorproPAMIDE
3	clomiPHENE	clomiPRAMINE
2	DAUNOrubicin	DOXOrubicin
4	dimenhyDRINATE	diphenhydrAMINE
1	medroxyPROGESTERone	methylTESTOSTERone
6	predniSONE	prednisoLONE
5	vinBLAStine	vinCRIStine

Table 11 – Word pair time to detect, Ranked 1-8 shortest to longest

Binary Response – Successful Detection

A second analysis was performed in which the binary response variable, "detection of a change," (yes/no) was modeled using a generalized linear mixed model fitted with the GLIMMIX procedure of SAS software (version 9.2 SAS Institute, Inc., Cary, NC). The statistical model included the fixed effects of profession (students, nurses and other healthcare professionals), graphic presentation (TALL Man and traditional), their two-way interaction, and the ordered group of presentation to the participant (1-4). Also included in the model were fixed positional effects, as per quadrant by position combinations. The following random effects were considered: participant nested within profession, participant by graphic presentation (to account for technical replication), participant by ordered group, and participant by position by quadrant. Run order within group, gender, ethnicity and language were evaluated as fixed effects in the model but were excluded from the final model based on the P value > 0.20.

Age was excluded from the final model due to overparameterization/multicollinearity with the fixed effect factor, profession.

Analysis results are presented in Table 12 for the model's fixed effects. Bolded effects indicate significance at a level of α =0.05.

Type 3 Tests of Fixed Effects for the Dependent Variable Successful Detection (yes/no)				
Effect	Num DF	Den DF	F Value	Pr > F
Treatment	**1**	**77**	**23.61**	**<0.0001**
Profession	**2**	**77**	**7.22**	**0.0013**
Treatment x Profession	2	77	2.10	0.1289
Group	**3**	**237**	**9.76**	**<0.0001**
Position x Quadrant	15	709	1.65	0.0554

Table 12 - Type 3 Tests of Fixed Effects for the Dependent Variable Successful Detection (yes/no)

TALL Man vs Traditional

The analysis indicated a significant effect of graphic presentation on the probability of detecting a change (P<0.0001), whereby change presented in a TALL Man format was more likely to be detected than changes presented in a traditional format (95.1± 1.4% and 85.9±3.3%, respectively). See Figure 17. Percentages of likeliness to detect are in Table 13.

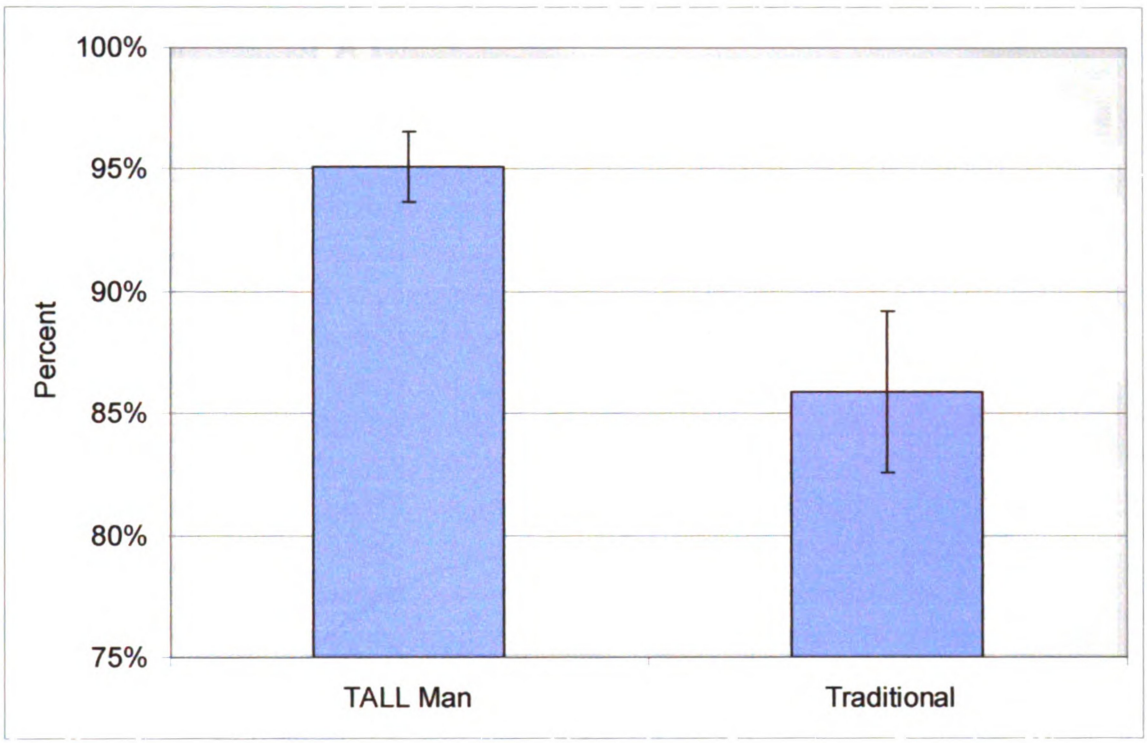

Figure 17 – Percentage of likeliness to Detect Graphic Presentation

Profession

Regardless of graphic presentation, the probability of change detection differed by Profession (P = 0.0013), whereby students were more likely to detect change than either nurses or other health care professionals (95.8±1.2, 87.2±4.0% and 89.2±3.2, respectively). No difference was apparent between nurses and other health care professionals (See figure 18).

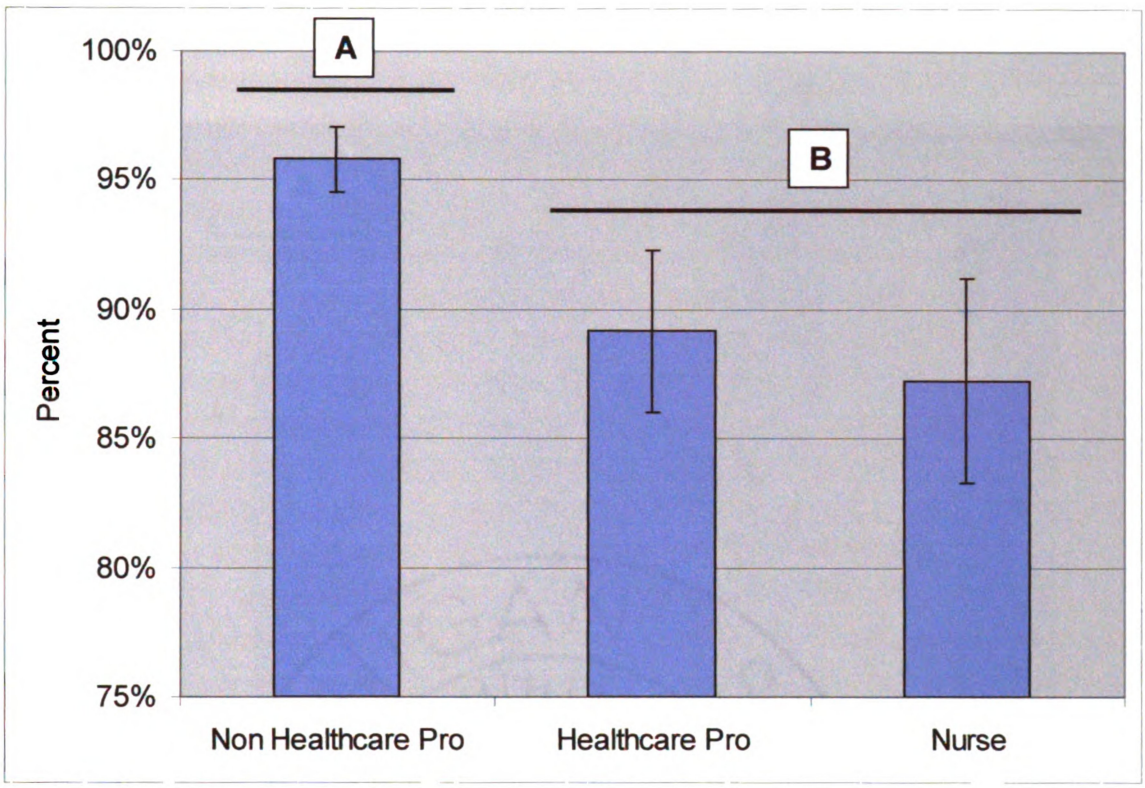

Figure 18 – Percentage of likeliness to Detect between Professions with standard error bars and significance; Different letters indicate statistical significance at α=0.05

Group

A main effect of group (see Table 13) was evident when the dependent variable was the probability of a successful detection in under two minutes ($P<0.0001$). Detection of the change was more likely if it occurred in groups 2-4 as compared with group 1. There was no evidence of difference when groups 2-4 were compared (See Figure 19). This further supports the idea that participants had a period of acclimation as they adjusted to the test.

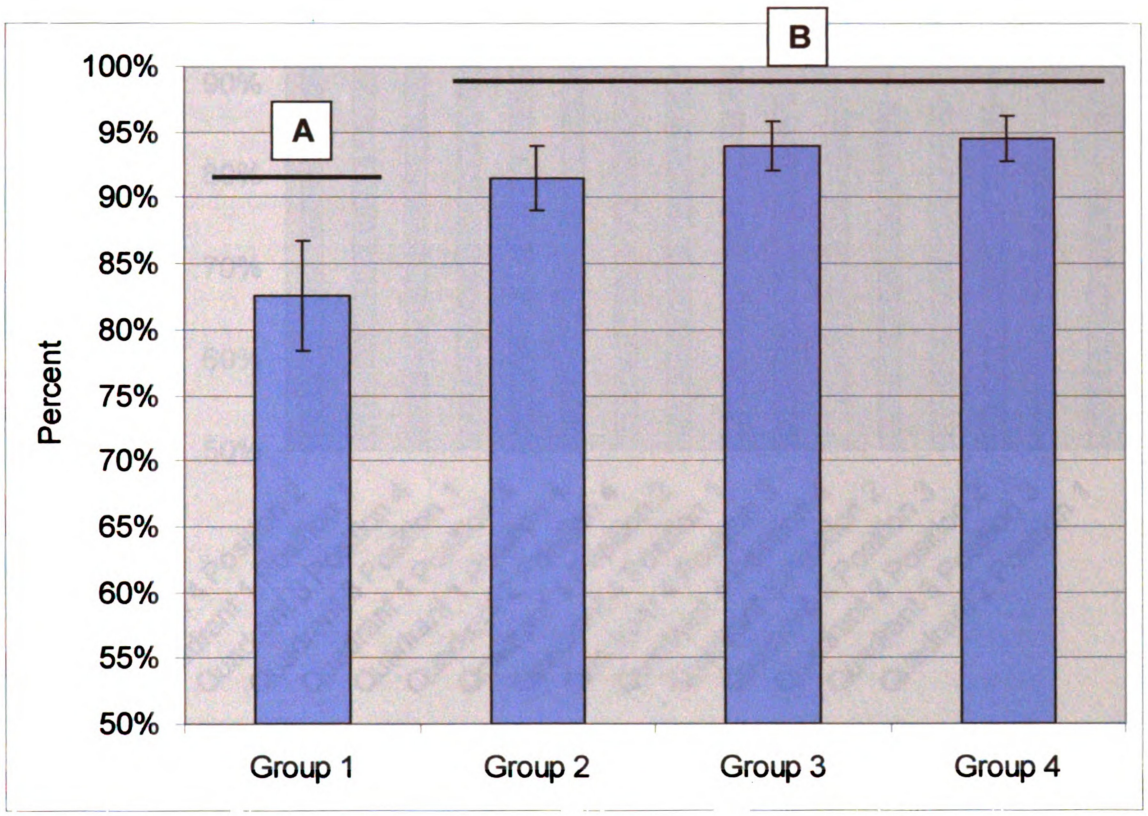

Figure 19 – Percentage of likeliness to Detect between Groups with standard error bars and significance; Different letters indicate statistical significance at α=0.05

Quadrant by Position

A marginal positional effect of change was detected on the probability of change detection (P = 0.0554). Specifically, a change in quadrant 1 was more likely to be detected than a change in quadrant 2 (P<0.05). See Figure 20.

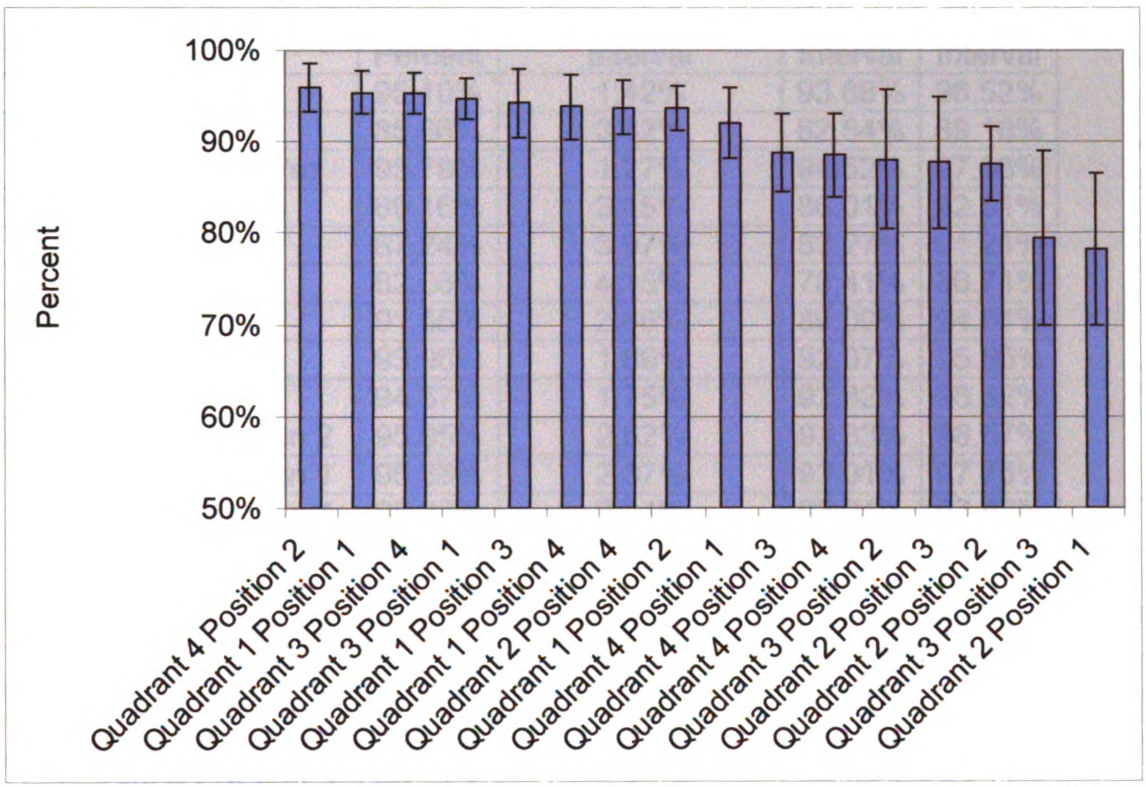

Figure 20 – Percentage of likeliness to Detect between Quadrant and Position

	Percent	+/- Confidence Interval	Lower Interval	Upper Interval
TALL Man	95.10%	1.42%	93.68%	96.52%
Traditional	85.86%	3.32%	82.54%	89.18%
Non Healthcare Pro	95.79%	1.27%	94.52%	97.06%
Healthcare Pro	89.16%	3.15%	86.01%	92.31%
Nurse	87.24%	3.97%	83.27%	91.21%
Group 1	82.56%	4.15%	78.41%	86.71%
Group 2	91.55%	2.46%	89.09%	94.01%
Group 3	93.96%	1.89%	92.07%	95.85%
Group 4	94.57%	1.75%	92.82%	96.32%
Quadrant 4 Position 2	95.95%	2.62%	93.33%	98.57%
Quadrant 1 Position 1	95.38%	2.37%	93.01%	97.75%
Quadrant 3 Position 4	95.32%	2.31%	93.01%	97.63%
Quadrant 3 Position 1	94.77%	2.22%	92.56%	96.99%
Quadrant 1 Position 3	94.21%	3.72%	90.49%	97.93%
Quadrant 1 Position 4	93.86%	3.52%	90.34%	97.38%
Quadrant 2 Position 4	93.75%	2.90%	90.85%	96.65%
Quadrant 1 Position 2	93.70%	2.49%	91.21%	96.19%
Quadrant 4 Position 1	92.11%	3.90%	88.21%	96.01%
Quadrant 4 Position 3	88.82%	4.29%	84.53%	93.11%
Quadrant 4 Position 4	88.52%	4.63%	83.89%	93.15%
Quadrant 3 Position 2	88.05%	7.66%	80.39%	95.71%
Quadrant 2 Position 3	87.76%	7.25%	80.51%	95.01%
Quadrant 2 Position 2	87.61%	3.99%	83.62%	91.60%
Quadrant 3 Position 3	79.52%	9.52%	70.01%	89.04%
Quadrant 2 Position 1	78.28%	8.40%	69.88%	86.68%

Table 13 – Percentages of likeliness to Detect; α=0.05

CONCLUSIONS AND RECOMMENDATIONS

This study makes two important contributions to the state of knowledge. (1) It suggests that change detection, or the "flicker task" can be used to evaluate the relative prominence and conspicuousness of varied label and elements and also has the potential to provide insights into the visual search behaviors of individuals. (2) This study suggests that TALL Man lettering enables people, particularly nurses, to differentiate look-alike sound alike names more quickly than traditional lettering.

This conclusion adds to a growing body of research that advocates the use TALL Man lettering as a means of reducing the prevalence of medication errors. This study directly measured the effect of TALLMAN lettering using a method that allowed us to test the ability to differentiate look-alike, sound alike word pairs when viewed by both healthcare providers and lay people. Although all populations improved their time to differentiation when look alike sound alike pairs were tested, nurses showed the greatest improvement (See Figure 13). This suggests that the TALL Man lettering may be more meaningful to healthcare providers, and supports Filiks finding that the approach is more effective when the viewer understands the intended purpose of the TALL Man format[38].

TALL Man lettering is already in use in many places of the drug supply chain. I recommend that the rest of the drug supply chain start using this method

for the recommended drug name pairs on the ISMP website[41], which are also recommended by the FDA.

Additionally, I would recommend using change detection "flicker task" in other labeling studies. It is an easy test to conduct, it is not very expensive to use, and the time it takes to analyze the results is fairly short when compared to other methods of measuring the locus of perception, such as eye tracking.

FUTURE RESEARCH

For future research regarding TALL Man lettering I would recommend having consistent age groups for the healthcare and non healthcare groups, so there is not any multicolinearity between these variables. The survey information that was collected could be used to identify other areas that affected time to detect TALL Man lettering, such as previous awareness of TALL Man lettering, involvement in an adverse event, or recognition of drug names used in the study. Other studies that could be conducted using change detection could include change of dosage numbers, route of administration, sterile or non sterile symbol, or other graphics on the label.

APPENDIX A – IRB DOCUMENTS

Recruitment Email

Re: Opportunity to participate in a research study

This email is to inform you of the opportunity to participate in a research study at the School of Packaging. You are under no obligation to participate.

To participate you must:

- Be at least 18 years of age
- Have no history of seizure
- Not be legally blind

You are being asked to participate in a research study regarding the labeling of medical products. We are using a flash program, or "Flicker" program developed at the School to conduct this research. You will be ask to look at a computer screen and hit the space bar when you detect a change in the labels. (During the flicker task a photo will alternate with a second photo that has one small change; these two photos will be separated by a brief, blank display and will continue "flickering" until you detect the change in the two). The time to detect the change will be recorded as a way to quantify how prominent the change is to the scene.

Your color blindness and visual acuity will also be tested. These tests involve viewing a series of cards. You will also be asked to fill out a brief survey which includes information about your ethnicity, gender, age, educational background, experiences and opinions about medical labels.

The test should take no longer than 1 hour. In exchange for your participation, you will receive a 3 points of extra credit for PKG 323.

If at any time you are uncomfortable with the testing or wish to discontinue the data collection process, you may discontinue participation without penalty.

If you are interested in pursuing this opportunity, please contact Laura Bix at bixlaura@msu.edu to make an appointment.

If you have questions or comments regarding this study, please contact Dr. Laura Bix, Assistant Professor or Packaging at Michigan State University at 517-355-4556 or bixlaura@msu.edu.

If you have questions or concerns about your role and rights as a research participant, would like to obtain information or offer input, or would like to register a complaint about this study, you may contact, anonymously if you wish, the Michigan State University's Human Research Protection Program at 517-355-2180, Fax 517-432-4503, or e-mail irb@msu.edu or regular mail at 202 Olds Hall, MSU, East Lansing, MI 48824.

Consent Form

School of Packaging

INSTRUCTIONS AND RESEARCH CONSENT FORM – Applying change detection to test the noticeability of components of medical labels

You are being asked to participate in a research study. Your participation in this study is voluntary. To participate in the study you must:

- Be at least 18 years of age
- Have NO HISTORY OF SEIZURE
- Not be legally blind
- Be, or have a history as, a healthcare professional OR be a healthcare professional in training

In exchange for your participation in this study, you will receive $30.

As part of this research, we will record your gender, ethnicity, educational background, age and information about your professional history. We will also test your visual acuity (20/20, 20/30, 20/40, etc.) and color blindness. These tests will be conducted by asking you to view a series of cards and asking you to decipher images to the best of your ability. You will also be asked to fill out a brief survey regarding your opinions and experiences with medication labels and medication errors. We are interested in the things that healthcare professionals look at when making choices regarding medication, and whether or not labeling design can be manipulated in ways that guides people to the correct choice of a medication.

All information will be tied to a subject number; you will not be identified by name and your confidentiality will be maintained to the maximum extent of the law. Information retrieved during this entire study will be stored in a password protected computer in a locked laboratory in the School of Packaging at Michigan State University for a MINIMUM of 3 years. The room will be accessible only to authorized researchers of Dr.Laura Bix's research team. This study will take no more than one hour, and poses little risk to your health and well being.

For change detection testing, Carly DeHenau and Anne Giordano, students at the School of Packaging, will ask you to view a series of photos on a computer screen, and will time how long it takes you to find changes in the photos. Two images will alternate on the computer screen in rapid fashion, with a blank screen between the two. One of the images is slightly different than the other, and you will be asked to hit the space bar as soon as you detect the difference in the two images. If you

correctly identified the change, the program will advance to another pair of images; if not correctly identified, the previous images will play again until you are able to detect the change. This is not a test of your speed, but of a test of the ability of the change to draw your attention.

Important:

You are free to discontinue your participation in the study at any time without penalty.

You may discontinue participation at any time and still be eligible for the $30 incentive that is offered.

There is no direct benefit to you in exchange for participating in this study. The hope is that through studies like this, we will gain an understanding of the design features that garner attention, so that this information can be used to make important information, such as directions and warnings, prominent.

There is a possible risk of seizure that is associated with viewing flashing images. If you are injured as a result of your participation in this research project, researchers from Michigan State University will assist you in obtaining emergency care, if necessary, for your research related injuries. If you have insurance for medical care, your insurance carrier will be billed in the ordinary manner. As with any medical insurance, any costs that are not covered or in excess of what are paid by your insurance, including deductibles, will be your responsibility. The University's policy is not to provide financial compensation for lost wages, disability, pain or discomfort unless required by law to do so. This does not mean that you are giving up any legal rights you may have.

Additionally, we will ask questions regarding medication errors that you have been involved with that may be uncomfortable for you to discuss or recall. Please recall that you may discontinue participation, or choose to not answer any of the questions posed and still be eligible for the $30 incentive.

The results of the study will be treated in strict confidence and that you will remain anonymous. Raw results from your trials will be available to the Institutional Review Board (IRB) at MSU and the research team that is conducting this research. Your confidentiality will be protected to the maximum extent allowable by law. Within these restrictions, results of the study will be made available to you at your request.

You may contact Laura Bix at 517-355-4556 with any questions or to report an injury. You are aware that

If you have any concerns or questions about this research study, such as scientific issues, how to do any part of it, or if you believe you have been harmed because of

the research, please contact the researcher Laura Bix 517-355-4556; 153 Packaging Building East Lansing MI 48824 bixlaura@msu.edu.

If you have questions or concerns about your role and rights as a research participant, would like to obtain information or offer input, or would like to register a complaint about this study, you may contact, anonymously if you wish, the Michigan State University's Human Research Protection Program at 517-355-2180, Fax 517-432-4503, or e-mail irb@msu.edu or regular mail at 202 Olds Hall, MSU, East Lansing, MI 48824.

I voluntarily agree to participate in the study of medical labels.

_____

Date: _____

You will be provided with a copy of your signed consent form.

I have received my $30 incentive.

_____

Date:_____

APPENDIX B - SURVEY

Medication Survey

Demographic Information

1. Gender
   ❑ Male ❑ Female

2. Profession
   ❑ Health Field Professional _____
   ❑ Student
   ❑ Other_____

3. Years of Experience in nursing or a healthcare related field _____

4. Age
   ❑18~24 ❑25~34 ❑35~49 ❑ 50+

5. Eye wear
   ❑None ❑Glasses ❑Contact lenses ❑Other

6. Highest level of Education Achieved
   ❑High school ❑Associates ❑Bachelors ❑Graduate ❑Other

7. Ethnicity
   ❑White ❑Black ❑Hispanic ❑Asian ❑Other _____

8. Native Language_____

9. Work setting (home health, nursing home, acute care facility, etc. If acute care facility, also indicate unit)_____

10. Type of shift you are currently working (12 hour, 8 hour, day shift, night shift, etc.)_____

Research Survey

Please answer the following questions:

11. In what order do you look at these components of a medication label (1-6, 1 being first, 6 being last)?

For Yourself	**For Another Person**
_____ drug name	_____ drug name
_____ dose / amount to take	_____ dose / amount to take
_____ how to take the drug	_____ how to take the drug
_____ side effects	_____ side effects
_____ manufacturers symbol	_____ manufacturers symbol
_____ color of the package	_____ color of the package

12. How often do you encounter new medications?
- ❑ every day
- ❑ every week
- ❑ 1~2 times a month
- ❑ 1~2 times a year
- ❑ never

13. What would you look for on a new medication?

14. When using a medication repeatedly, do you look at these components of a medication label (Y or N)?

For Yourself	**For Another Person**
_____ drug name	_____ drug name
_____ dose / amount to take	_____ dose / amount to take
_____ how to take the drug	_____ how to take the drug
_____ side effects	_____ side effects
_____ manufacturers symbol	_____ manufacturers symbol
_____ color of the package	_____ color of the package

15. What components of the labels have changed in the sets that you have seen to this point? Be specific.

16. Does your work facility have a system for reporting medication errors? _____

17. Estimate the number of medication errors (wrong dose, wrong patient, wrong time, wrong route of administration, wrong drug) that occur in your unit in one week's time_____

18. Estimate what percentage of these are caused by look-alike, sound alike names_____

19. Estimate what percentage of these are caused by look-alike packaging or labeling_____

20. Estimate the percentage of labels that you interact with that employ TALL man lettering._____

21. Do you find the use of TALL man lettering helpful for differentiating drugs of similar names? _____

22. List any other error- reduction strategies that you use to reduce the risk of drug name mix-ups._____

23. Have you ever been involved in an error or a preventable adverse drug reaction? _____

If so, describe what went wrong

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

Did this error reach the patient, or does it describe an error that was discovered prior to reaching the patient._____

What was the patient outcome?_____
_____
_____
_____
_____

Name of the product involved._____

Dosage form, concentration or strength, etc._____

How was the error discovered/intercepted?

_____
_____
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Please state your recommendations for error prevention_____
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acetohexamide	acetazolamide
chlorpromazine	chlorpropamide
clomiphene	clomipramine
daunorubicin	doxorubicin
dimenhydrinate	diphenhydramine
medroxyprogesterone	methyltestosterone
prednisone	prednisolone
vinblastine	vincristine

Table 14 - Circle the names of the drugs that are familiar to you

acetohexamide	acetazolamide
chlorpromazine	chlorpropamide
clomiphene	clomipramine
daunorubicin	doxorubicin
dimenhydrinate	diphenhydramine
medroxyprogesterone	methyltestosterone
prednisone	prednisolone
vinblastine	vincristine

Table 15 - Circle the names of the drugs that you have worked with

APPENDIX C – RANDOMIZATION PROCEDURE AND WORD PAIR COUNTS

Each of the 16 drug name pairs (8 word pairs by 2 graphic presentations) was randomly assigned a number (1-4) using a random numbers program in Excel. This number indicated which position the word pair would be put into for each quadrant (see Table 14 below). Additionally, each of the 16 pairs was also randomly assigned with a quadrant number (1-4) using the same program; This process was done for each participant so that word pairs always appeared in their assigned position, but different quadrants for each subject. This number combination (position - quadrant) indicated which position and quadrant each drug name pair would fall into for each participant, since each drug name pair was only viewed once per participant.

Word Pair	Graphic Presentation	Q1	Q2	Q3	Q4
1	TALL Man	3	3	4	2
1	Traditional	4	2	1	2
2	TALL Man	2	2	4	3
2	Traditional	2	2	1	1
3	TALL Man	1	2	3	4
3	Traditional	3	1	1	3
4	TALL Man	2	4	1	4
4	Traditional	2	2	1	4
5	TALL Man	4	4	4	3
5	Traditional	2	4	4	3
6	TALL Man	1	3	2	2
6	Traditional	1	3	4	1
7	TALL Man	3	2	2	1
7	Traditional	1	4	1	4
8	TALL Man	1	4	4	4
8	Traditional	4	1	3	2

Table 16 – Position quadrant combinations for each word pair

Consider participants one and two and word pair one in the TALL Man format as an example. Quadrant 3, which always corresponded with position 4 was randomly chosen for participant one. For participant two, quadrant 1, which always corresponded with position 3 for this word pair/graphic presentation combination, was the random selection for subject two. The run order of appearance of these changes was also randomized, as described in chapter 2 the methods section of this document. In summary, there were four possible places that each word pair/graphic presentation (TALL MAN vs traditional) could appear.

Quadrant	TALL Man	Traditional	Totals
1	167	170	337
2	146	173	319
3	147	154	301
4	180	143	323
Totals	640	640	1280

Table 17 - TALL Man and traditional word pairs by quadrant

Group	TALL Man	Traditional	Totals
1	160	160	320
2	160	160	320
3	160	160	320
4	160	160	320
Totals	640	640	1280

Table 18 - TALL Man and traditional word pairs by group

	Quadrant	1	2	3	4	Totals
Group						
1		42	40	42	36	160
2		49	32	39	40	160
3		44	36	31	49	160
4		32	38	35	55	160
Totals		167	146	147	180	640

Table 19 - TALL Man by group and quadrant

	Quadrant	1	2	3	4	Totals
Group						
1		44	44	34	38	160
2		43	38	40	39	160
3		43	47	37	33	160
4		40	44	43	33	160
Totals		170	173	154	143	640

Table 20 - Traditional by group and quadrant

Quadrant & Position in stimulus material	TALL Man	Traditional	Totals
Quadrant 1 Position 1	66	45	111
Quadrant 1 Position 2	47	71	118
Quadrant 1 Position 3	35	23	58
Quadrant 1 Position 4	19	31	50
Quadrant 2 Position 1	0	48	48
Quadrant 2 Position 2	65	69	134
Quadrant 2 Position 3	28	17	45
Quadrant 2 Position 4	53	39	92
Quadrant 3 Position 1	21	98	119
Quadrant 3 Position 2	43	0	43
Quadrant 3 Position 3	17	19	36
Quadrant 3 Position 4	66	37	103
Quadrant 4 Position 1	22	30	52
Quadrant 4 Position 2	49	40	89
Quadrant 4 Position 3	47	38	85
Quadrant 4 Position 4	62	35	97
Totals	640	640	1280

Table 21 - TALL Man and traditional word pairs by quadrant and position

BIBLIOGRAPHY

1. de la Fuente, J. and L. Bix, *The Physiology of Aging.* Unpublished File, 2006.

2. Goldstein, E.B., *Sensation & Perception.* 7th ed. 2007.

3. Hermann, L., *Eine Erscheinung simultanen Contrastes.* Pflügers Archiv für die gesamte Physiologie, 1870. **3**: p. 13-15.

4. United States Pharmacopia. *USP Medication Error Analysis.* 2004 [cited 2010 March 22].

5. Simons, D.J. and R.A. Rensink, *Change blindness: past, present, and future.* Trends in Cognitive Sciences, 2005. **9**(1): p. 16-20.

6. Simons, D.J. and D.T. Levin, *Change Blindness.* Trends in Cognitive Sciences, 1997. **1**(7): p. 261-267.

7. Rensink, R.A., K. O'Regan, and J.A. Clark, *To See or Not To See: The Need for Attention to Perceive Changes in Scenes.* Psychological Sciences, 1997. **8**(5): p. 368-373.

8. Rensink, R.A., J.K. O'Regan, and J.J. Clark, *To see or not to see: The need for attention to perceive changes in scenes.* Pyschological Science, 1997. **8**(5): p. 368-373.

9. Simons, D.J. and R.A. Rensink, *Change blindness: Past, present and future.* Trends in Cognitive Science, 2005. **9** (1).

10. Pashler, H., *Familiarity and visual change detection.* Perception and Psychophysics, 1988. **44**: p. 369-378.

11. Phillips, W.A., *On the distinction between sensory storage and short-term visual memory.* Perception and Psychophysics, 1974. **16**: p. 283-290.

12. Stelmach, L.B., C.M. Bourassa, and V. Di Lollo, *Detection of stimulus change: The hypothetical roles of visual transient responses.* Perception and Psychophysics, 1984. **35**(3): p. 245-255.

13. Rensink, R.A., *On the failure to detect changes in scenes across brief interruptions.* Visual Cognition, 2000. **7**: p. 127-145.

14. O'Regan, J.K., et al., *Picture changes during blinks: Looking without seeing and seeing without looking.* Visual Cognition, 2000. **7**: p. 191-211.

15. Grimes, J., *On the failure to detect changes in scenes across saccades*, in *Perception: Vancouver studies in cognitive scienes*, K. Akins, Editor. 1996, Oxford University Press: New York. p. 89-110.

16. McConkie, G.W. and C.B. Currie, *Visual stability across saccades while viewing complex pictures.* Journal of Experimental Psychology: Human perception and performance, 1996. **22**(3): p. 563-581.

17. McConkie, G.W. and D. Zola, *Is visual information integrated across successive fixations in reading?* Perception and Psychophysics, 1979. **25**(3): p. 221-224.

18. Levin, D.T. and D.J. Simon, *Failure to detect cahnges to attended objects in motion pictures* Pyschonomic Bulletin and Review, 1997. **4**(4): p. 501-506.

19. Simons, D.J. and D.T. Levin, *Failure to detect changes to people during a real-world interaction.* Psychonomic Bulletin and Review, 1998. **5**: p. 644-649.

20. O'Regan, J.K., R.A. Rensink, and J.J. Clark, *Change-blindness as a result of "mudsplashes".* Nature, 1999. **398**(6722): p. 34.

21. Simon, D.J., S.L. Franconeri, and R.L. Reimer, *Change blindness in the absence of a visual disruption.* Perception, 2000. **29**(10): p. 1145-54.

22. Gaschler, R., et al., *Change detection for new food labels.* Food Quality and Preference, 2010. **21**: p. 140-147.

23. Hoffman, J.M. and S.M. Proulx, *Medication Errors Caused by Confusion of Drug Names.* Drug Safety, 2003. **26**(7): p. 445-452.

24. Lambert, B.L., et al., *Similarity As a Risk Factor in Drug-Name Confusion Errors*

The Look-Alike(Orthographic) and Sound-Alike (Phonetic) Model. Medical Care, 1999. **37**(12): p. 1214-1225.

25. Starr, C.H., *When drug names spell TROUBLE.* Drug Topics, 2000. **144**(10).

26. Cohen, M.R., *Drug product characteristics that foster drug-use-system errors.* American Journal of Health-System Pharmacy, 1995. **52**(February 15): p. 395-399.

27. Institute of Medicine, *To Err Is Human: Building a Safer Health System*, ed. L.T. Kohn, J.M. Corrigan, and M.S. Donaldson. 1999: National Acadamies Press.

28. Institute of Medicine, *Preventing Medication Errors*. Quality Chasm Series, ed. P. Aspden, et al. 2007: National Academies Press.

29. Kenagy, J.W. and G.C. Stein, *Naming, Labeling, and packaging of pharmaceuticals.* American Journal of Health-System Pharmacy, 2001. **58**(21).

30. Boring, D., *The Development and Adoption of Nonproprietary, Established, and Proprietary Names for Pharmaceuticals.* Drug Information Journal, 1997. **31**: p. 621-634.

31. Institute for Safe Medication Practices. *"Looks" like a problem: ephedrine - epinephrine*

2003 [cited 2010 February 26]; Available from: http://www.ismp.org/Newsletters/acutecare/articles/20030417_2.asp.

32. Turkoski, B.B., *Improving Patient Safety by Improving Medication Communication.* Orthopaedic Nursing, 2009. **28**(3): p. 150-154.

33. Institute for Safe Medication Practices. *Medication Safety Alert.* 2008 [cited 2010 February 26]; October 23, 2008:[Available from: http://www.ismp.org/Newsletters/acutecare/articles/A4Q08Action.asp.

34. Institute for Safe Medication Practices. *Use of tall man letters is gaining wide acceptance.* 2008 [cited 2010 February 26]; Available from: http://www.ismp.org/Newsletters/acutecare/articles/20080731.asp.

35. United States Pharmacopia. *Practitioners' Reporting News Similar Drug Names Reported to MER.* 2004 [cited 2010 February 26]; Available from: http://www.usp.org/hqi/practitionerPrograms/newsletters/practitionerReportingNews/prn1122004-02-25.html.

36. Jeon, H.W.J., *Standardization and use of colour for labelling of injectable drugs*, in *Systems Design Engineering.* 2008, University of Waterloo: Waterloo, Ontario, Canada.

37. United States Pharmacopia. *Status of the 2005-2010 Resolutions.* 2008 [cited 2010 February 26]; Available from: http://www.usp.org/pdf/EN/members/resolutionReportDecember2008.pdf.

38. Filik, R., et al., *Labeling of Medicines and Patient Safety: Evaluating Methods of Reducing Drug Name Confusion.* Human Factors, 2006. **48**(1): p. 39-47.

39. Filik, R., et al., *Drug Name Confusion: evaluating the effectiveness of capital ("Tall Man") letters using eye movement data.* Social Science & Medicine, 2004. **59**(12): p. 2597-2601.

40. Bix, L., et al., *The use of change detection as a method of objectively evaluating labels.* Packaging Technology and Science, Under Review.

41. Institute for Safe Medication Practices. *FDA and ISMP Lists of Look-Alike Drug Name Sets With Recommended Tall Man Letters*. 2008 [cited 2010 February 26]; Available from: http://www.ismp.org/Tools/tallmanletters.pdf.