AGE DIFFERENCES IN SEARCH TIME FOR TWO OVER-THE-COUNTER (OTC) DRUG LABEL FORMATS

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Abstract

This study compared older and younger adults' knowledge acquisition and search times for information on older and newer over-the-counter (OTC) drug label formats. The results showed that younger adults were faster than older adults. The younger group performed significantly faster with the newer formatted labels than the older formatted labels, whereas the older adults yielded no difference between the two formats. Potential directions for future research are discussed.

INTRODUCTION

Population estimates indicate that by 2040, 77 million people in the U.S. will be over the age of 65 and can be classified as senior citizens (U.S. Census Bureau, 1996). Approximately 80% of all U.S. seniors (aged 65 and over) have one chronic health condition and 50% have at least two (Arslan, Atalay, & Gokce-Kutsal, 2002). With the onset of these health concerns, many older adults turn to prescription and over-the-counter (OTC) medications for relief. On average, older adults use four to five prescription medications concurrently which they may supplement with OTC drugs (Moore & Beers, 1992). It is not uncommon for older adults' medication regimens (schedules for consummation at specific times) to include 10 or more medications (Park & Kidder, 1996).

As a group, older adults commit more than 1.9 million medication errors annually according to a recent estimate (Gurwitz, 2003). Some of the most frequent errors include consuming an incorrect dose, failing to avoid contraindications, and inappropriately combining prescription medications with OTC medications. Some of these errors may be the result of non-optimal labeling (Wogalter, Magurno, Dietrich, & Scott, 1999). Given the cognitive and perceptual changes associated with aging, the adequacy of drug labels used by older adults is worth assessing.

One reason for the errors may be related to the well-documented perceptual and cognitive declines that co-occur with age (Craik & Salthouse, 2000; Park & Schwartz, 2000). For example, presbyopia or other age-related vision problems may limit the reading and subsequent encoding of warnings printed on the medication packaging due to small print sizes. Also, older adults may not remember that they have already taken the appropriate number of doses of their medication.

Poorly designed drug information labels may decrease the likelihood that an older adult will comprehend instructions and correctly take a medication (e.g., Morrow, Leirer, & Sheikh, 1988, Wogalter & Vigilante, 2003). One consideration is the ordering of content. A study by Vigilante and Wogalter (1997) had participants arrange or order sections of OTC drug labels (headings such as "Warnings and Directions") and text associated with the sections while considering several different scenarios of exposure to the drug (i.e., purchasing, consuming, administering to others, emergencies, and all situations). They found that, in general, both younger and older adults preferred sections on OTC labels ordered as: indications, warnings, directions, active ingredients, safety seal, inactive ingredients, storage instructions, manufacturer information, and bar code. The eventual orders used by the FDA when developing their 'Drug Facts' guidelines, which took effect in May of 2002 are similar, though not identical to that described by Vigilante and Wogalter (1997).

In the U.S., OTC drug labels must adhere to requirements set forth by the Food and Drug Administration (FDA). Under 21 C.F.R. 201.66, the FDA is charged with regulating the format and content of OTC drug labels (FDA, 2001). These "newer" drug labels must meet the FDA's regulatory format requirements. These requirements however, still allow flexibility in that they do not specify everything that may be necessary to capture attention and to convey information to consumers. The newer FDA format requirements contain characteristics that human factors/ergonomics (HF/E) research would suggest to be better than the older format (i.e., consistent format, headings, bullet points, etc.). However, this combination of features has not been tested. The present research investigated whether the new label design differentially affects the ability of young and older adults to acquire information. More specifically, the present research was conducted to determine whether response time and accuracy of information acquisition for the new label benefits both age groups.

METHOD

Participants

Twenty young adults (aged 18 to 25 years) and 20 older adults (aged 65 to 80 years) participated. The younger participants (M = 18.75, SD = 1.48) were recruited from introductory psychology courses and received class credit for their participation. The older adults (M = 71.55, SD = 1.48) were recruited from the Raleigh-Durham area of North Carolina through a variety of methods such as a newspaper advertisement and announcements at local senior centers and flea markets.

Stimuli

As Table 1 illustrates, sixteen older and newer label OTC drug products were used as stimuli. These labels consisted of the outside packaging of the product as would be seen by consumers when purchasing the drug prior to initial use. For example, stimuli did not include the internal label located on a bottle inside a box but did include the external label located on the outside of the box. These products included classifications such as pain relievers (e.g., Extra Strength Tylenol®) and antihistamines (e.g., Benadryl Allergy and Sinus®), as well as others (see Figure 1 for example older and newer labels). There were 16 name brand products, each with a representation of older and newer labels; thus, 32 exemplar stimulus labels were available for inclusion as stimuli. These products (older and newer) were of the same medicines with the same quantity (e.g., 50 tablets for both) purchased during the three-year transition period prior to May of 2002 when both label types were available to consumers.

Typical features of the older OTC drug labels included portions of text appearing in all uppercase lettering, paragraphs of text in block format, and section headings embedded in the first sentence of each paragraph. Newer OTC drug labels included dividers separating text sections, italicized section headings appearing above each text section, bulleted keywords and phrases, and a greater amount of white-spacing compared to the older drug labels.

Medication stimuli were completely counterbalanced such that all participants saw only half of the 16 products in Table 1. This deviation from the procedure used by Shaver and Wogalter (2003) was necessary because pilot tests with older participants indicated the need to shorten the experimental session to combat fatigue effects. Participants were exposed to eight different products (four products with the older label format and another four products with the newer format). Eight of the products in Table 1 were assigned to set A and the remaining eight were assigned to set B. Participants saw products from either set A or B, but not both. They did not review both the older and newer label of the same product. All products were used an equal number of times across the participants in the experiments.

To reflect the counterbalancing of the stimuli, four 8-page answer booklets were created. On each page, there were ten product specific questions. Four of the pages were allocated to represent old label formats whereas the remaining four represented new label formats. Attempts were made to avoid questions that could be answered with high accuracy without actually looking at the labels. Questions were designed so that they could be answered with a yes-no or a one to two word response.

Table 1

Two stimulus labels (old and new) for 16 OTC drug products and their associated primary indications

	OTC Drug	Primary Indication
(1)	Anusol®	Hemmoroidal relief (suppositories)
(2)	Eckerd® COOL	Sore throat lozenges
(3)	Ibuprofen®	Fever and Pain
(4)	NyQuil®	Cold and Cough
(5)	Alka-Seltzer®	Acid Indigestion and Pain
(6)	Tinactin®	Antifungal Foot Cream
(7)	Extra Strength Tylenol®	Minor aches and pains
(8)	Benadryl®	Allergy & Sinus Headache
(9)	Mylanta®	Antacid
(10)	Eckerd® Allergy and Sinus	Allergy and Sinus
(11)	Extra Strength Bayer®	Arthritis regimen
(12)	Preparation H®	Hemmoroidal relief (cream)
(13)	Extra Strength Doan's®	Back relief
(14)	Sleepinal®	Sleep aid
(15)	Vicks DayQuil®	Stuffy nose and sinus
(16)	Neo-Synephrine®	Decongestant spray

Ibuprofen

Pain Reliever / Fever Reducer **Tablets, USP**

WARNING: ASPIRIN SENSITIVE PATIENTS. DO NOT TAKE THIS PRODUCT IF YOU HAVE HAD A SEVERE ALLERGIC REACTION TO ASPIRIN, E.G. ASTHMA, SWELLING, SHOCK OR HIVES, BECAUSE EVEN THOUGH THIS PRODUCT CONTAINS NO ASPIRIN OR SALICYLATES, CROSS-REACTIONS MAY OCCUR IN PATIENTS ALLERGIC TO ASPIRIN.

INDICATIONS: For the temporary relief of minor aches and pains associated with the common cold, headache, toothache, muscular aches, backache, for the minor pain of arthritis, for the pain of menstrual cramps and for reduction of fever.

DIRECTIONS: Adults: Take 1 tablet every 4 to 6 hours while symptoms persist. If pain or fever does not re-

spond to 1 tablet, 2 tablets may be used but do n exceed 6 tablets in 24 hours, unless directed by a docto The smallest effective dose should be used. Take wi food or milk if occasional and mild heartburn, ups stomach, or stomach pain occurs with use. Consult doctor if these symptoms are more than mild or if th persist. **Children:** Do not give this product to childre under 12 except under the advice and supervision a doctor.

WARNINGS: Do not take for pain for more than 10 da or for fever for more than 3 days unless directed by doctor. If pain or fever persists or gets worse, if ne symptoms occur, or if the painful area is red or swo len, consult a doctor. These could be signs of seriou illness. If you are under a doctor's care for any seriou conditions, consult a doctor before taking this produc As with aspirin and acetaminophen, if you have ar condition which requires you to take prescription drug or if you have had any problems or serious side effec from taking any non-prescription pain reliever do n take IBUPROFEN TABLETS without first discussing with your doctor. If you experience any symptoms whic are unusual or seem unrelated to the condition for whic


Drug Facts

Active ingredient (in each tablet) **Purposes**

Ibuprofen USP, 200 mg ..... Pain reliever/fever reducer

Uses Temporarily relieves minor aches and pains due to: • headache • toothache • backache • muscular aches • common cold • minor pain of arthritis • menstrual cramps
Temporarily reduces fever

Warnings

Allergy alert: ibuprofen may cause a severe allergic reaction which may include:
• hives • asthma (wheezing) • facial swelling • shock

Alcohol warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take ibuprofen or other pain relievers/fever reducers. Ibuprofen may cause stomach bleeding.

Do not use
• if you have ever had an allergic reaction to any other pain reliever/fever reducer
• with any other pain reliever/fever reducer • with any other product containing ibuprofen

Figure 1. **Initial portions of an older (top) and newer (bottom) formatted label for an Ibuprofen product.**

Procedure

This study closely followed the procedure previously described in Shaver and Wogalter (2003) with the exception that in the present study only eight (half) of the complete set of products were reviewed by participants. Deviation from the Shaver and Wogalter (2003) procedure was due to the inclusion of older adults who became fatigued when pilot tested with the full procedure. All participants were tested individually in sessions that lasted approximately 1.5 hours. Following completion of the informed consent, participants were asked to complete a general demographics questionnaire. Each participant was then given one of four 8-page booklets (including 4 older and 4 newer labels) with each page containing 10 questions for one drug. The sets of 10 questions were different for each drug, but were identical between the two label formats associated with each drug. In instances where one format provided some information while the other format did not, that information was not asked of the participants. Table 2 shows a set of example questions.

Table 2

Example questions

(1)	What is the maximum amount you can take in one day (24 hour period)?
(2)	A doctor should be consulted if you are already taking a prescription drug for what condition?
(3)	After how many days should you discontinue use?
(4)	What phone number should be dialed if you have any questions or comments for the manufacturer?
(5)	If you consume more than three alcoholic drinks per day, is it important to seek medical advice before using this product?

Note: Each drug in the study was associated with ten questions.

Participants were told to answer all of the questions in the order they were presented by writing their answers on the page as quickly and as accurately as possible. The experimenter recorded the duration of the period required for each participant to complete the set of 10 questions. Timing began after the experimenter instructed the participant to open the booklet to the appropriate product specific page and stopped when the answer for the tenth question was completed. This 10-question procedure was followed for each of the eight products. Participants were then debriefed and given the opportunity to ask questions at the end of the experimental session.

RESULTS

A 2 (Label Format: older vs. newer) X 2 (Age Group: younger vs. older) mixed factorial design was employed with label format treated as the within-subjects variable and age used as a grouping variable. Search time (in seconds) required to complete the 10 questions for each label was also recorded by the experimenter. Each participant answered questions, which were coded as either correct or incorrect. Error was measured by examining the accuracy of answers for each page in the answer booklet.

Analyses of variance examining differences in overall search time and accuracy were conducted on the data as a function of age (younger vs. older) and format (older vs. newer). The search time analyses revealed a significant main effect for age on overall search time, $F_{(1,38)} = 246.33$; $p < .001$ where younger adults ($M = 1.79$s) were significantly faster than older adults ($M = 3.42$s). Also, a significant age X format interaction was found for search time, $F_{(1,38)} = 25.39$; $p < .001$ where younger adults had faster search times with the newer labels ($M = 1.70$ s) than with the older labels ($M = 1.89$ s). Older adults did not show a search time difference between the two types of labels (see Table 3).

No significant main effects or interactions were found for age or format on overall accuracy for the medication labels; however, errors were relatively low across age group and format.

Table 3

Mean search time per item and proportion error as a function of label format and age group

	Label Format	
Age Group	**Older** *Search time (SD)* *Error rate*	**Newer** *Search time (SD)* *Error rate*
Older	3.41 s (1.52) **0.12**	3.43 s (1.45) **0.12**
Younger	1.89 s (.62) **0.07**	1.70 s (.53) **0.06**

Note: Data presented in the form of mean search time in seconds. The numbers in parentheses are the standard deviations. Values in bold represent the proportion of errors.

DISCUSSION

This study replicated and extended Shaver and Wogalter's (2003) findings using a different group of young adults and including a critical group, older adults. The newer label format benefited younger adults but not older adults. It took significantly longer for younger adults to search the older drug labels than the newer labels, yet search time did not differ between label formats for older adults possibly due to the large amount of variance. Overall, older adults required more time to search for information and though not statistically significant, they committed almost twice the number of errors as the young adult comparison group during the knowledge acquisition task. As is consistent with previous research within the cognitive task domain (Fisk & Rogers, 1997), older adult performance in this experiment was much more variable in terms of inter-individual variance than that of the young adult comparison group. Thus, increasing the sample size might raise this age-related trend in error production to significance.

In general, one potential explanation for the older adult results may be due to the relative illegibility of the label formats. The print size on both label formats was too small for the older adults. This legibility explanation is consistent with previous perceptual research on age-related visual decline as well as cognitive research documenting that older adults simply take more time to accomplish tasks. Also, Wogalter, DeJoy, and Laughery (1999) would predict older adults may have difficulty in trying to extract component information from the label. This finding might therefore suggest that increasing the size of the printed information may decrease reading difficulties that older adults might have experienced. With added size, the newer format may then be sensitive enough to detect a benefit in older adults. In summary, it appears that OTC drug labels can be improved to assist older adults and perhaps other demographics in a manner that still complies with the FDA guidelines.

Future research may benefit from varying label sizes to determine the most useful range of font sizes. Because this range may vary across age groups, future research might focus on creating design solutions (e.g., Wogalter & Vigilante, 2003; Wogalter & Young, 1994) that consider tradeoffs between label size and limited product packaging space. Consideration of issues such as these should result in the betterment of healthcare, safety and decreased financial costs associated with medication-related errors.

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