FINAL PROGRESS REPORT

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Project Title:
The elderly and OTC labeling information:
A randomized controlled experiment test

STRUCTURED ABSTRACT

Purpose: This study employed a randomized, controlled, 2 x 2 x 2 x 2 factorial design to develop a questionnaire to test the effects of OTC risk labeling information on elderly consumers' overall risk perceptions of using OTCs and their likelihood of using different sources for additional information beyond the label.

Scope: A judgment sample of 39 elderly subjects was recruited from Mississippi and Florida.

Methods: Risk information was manipulated in four ways: (1) cold product vs. pain reliever; (2) two vs. four side effects on label; (3) dry skin vs. diabetes as pre-existing health problem; and (4) absence vs. presence of those problems as contraindication on label. Subjects were asked to imagine having a pre-existing health problem, to read an OTC label to treat a minor condition, and to use that scenario to answer questions. In-depth interviewing was used to assess questionnaire readability, completion time, item difficulty/nonresponse, and survey packet design.

Results: The majority of subjects were Caucasian and female. They reacted favorably to the survey topic and design. However, the questionnaire needed to be redesigned, because the elderly subjects had difficulty (1) imagining themselves in the scenarios; (2) recalling information; (3) distinguishing between different risk manipulations; and (4) understanding labeling terminology inconsistent with words used by healthcare professionals. It is critical, therefore, to design valid questionnaires that can test experimentally manipulated information in elderly subjects with diminished cognitive functioning. Questionnaires should be pretested in age-specific groups to evaluate subjects' understanding prior to actual field distribution.

Key Words: elderly, OTC, risk perceptions, information source, label

PURPOSE

Objectives of Study: (1) To understand how the elderly utilizes risk information on over-the-counter (OTC) package labels to form their overall risk perceptions of using an OTC drug product; (2) to determine the sources of drug information they would use to find out more about an OTC beyond the package label; and (3) to develop and design a survey instrument specifically for the elderly to improve the conceptualization and operationalization of consumers' risk perceptions of OTC products

SCOPE

Background: Currently, there is a trend by the US Food and Drug Administration (FDA) toward switching more prescription drugs to over-the-counter (OTC) status (Rizzo et al., 2005). An assumption underlying the switch is that consumers should be able to utilize and depend solely on risk and benefit information on OTC package labels without consulting a healthcare professional when deciding whether or not to use an OTC. Several descriptive studies report that consumers generally perceive OTCs to be safe when used as directed and that consumers are confident in their ability to self-treat minor ailments (CHPA, 2001). However, some consumer surveys found that less than 10% of consumers read the label for side effects or warnings when buying or taking an OTC for the first time (NCPIE, 2002).

There is also concern regarding the safety of prescription-to-OTC switches for vulnerable patient groups, such as the elderly (Francis et al., 2005). The elderly is the largest group that uses prescription and OTC medicines, and the group is more vulnerable to drug adverse effects due to multiple or inappropriate medications (Francis et al., 2005). The use of laxatives in an older rural community was significantly associated with a greater number of physician visits, emergency room visits, hospitalizations during the past 6 months, and number of prescription drugs (Stoehr et al., 1997). Thus, there is a need to better understand how elderly consumers make use of OTC risk labeling information in their OTC decisions in order to improve the quality and safety of OTC medication use by the elderly. Many elderly consumers also do not discuss OTC medication use with healthcare professionals (Lamy, 1989). Further investigation on how consumers' risk perceptions of warning labeling information for OTC products influence information search and sources may prove useful to healthcare professionals, such as pharmacists, in providing better OTC patient counseling.

Context: During the past three decades, risk perceptions of drugs have not been studied extensively; even fewer studies have targeted OTC drugs specifically (Sangasubana, 2003; Strutton et al., 1992). Also missing from current research is a systematic examination of the effects of product

characteristics, such as labeling information, on consumers' perceptions of OTC risk (Charupatanapong, 1994; Strutton et al., 1992). Additionally, limited earlier research has examined the relationship between consumers' risk perceptions of OTC warning labeling information and the types of information sources used (Sangasubana, 2002). Several problems have also been identified in the measurement of perceived risk (Dowling, 1986; Mitchell, 1999; Stone and Gronhaug, 1993). Some researchers have conceptualized perceived risk as a unidimensional construct or have used single-item measures of perceived risk (Arndt, 1976; Ross, 1975). Finally, many OTC studies are mostly descriptive, without any theoretical framework (APhA, 1997; CHPA, 2001; Suveges, 1992). Thus, there is a need for more research and better measurement of consumers' risk perceptions of OTCs, especially for the elderly, who are high-risk patients with diminished cognitive ability.

METHODS

Study Design: This study employed a completely randomized, controlled, 2 x 2 x 2 x 2 factorial design to test the effects of OTC risk labeling information on consumers' overall risk perceptions regarding a hypothetical OTC product and their likelihood of using different drug information sources for additional information beyond the OTC package label.

Participants/Setting: This study examined how the elderly (those who are 65 or older) evaluated risk in using OTC drugs and utilized drug information sources based on key risk information provided on OTC package labels. Judgment sampling techniques were used to recruit subjects from community settings, such as local aging programs, church groups, retirement homes, and walk-in university-affiliated healthcare facilities, in two states: Mississippi and Florida.

Measures: ***Independent variables:*** Risk was defined as exposure to the possible harmful effects of taking an OTC product. Adapting from perceived risk frameworks in marketing from Bettman (1973) and Dowling and Staelin (1994), we chose the following four independent variables to manipulate risks associated with the information provided on the OTC package label and in the health scenario. Each experimental treatment consisted of two levels (low vs. high risk), resulting in a total of 18 treatment combinations: 16 treatment and two control groups (Table 1). Each subject was randomly assigned to a treatment group and given an OTC label and scenario to read. Ten hypothetical OTC labels and six health scenarios were created for the study (Figure 1, Table 2).

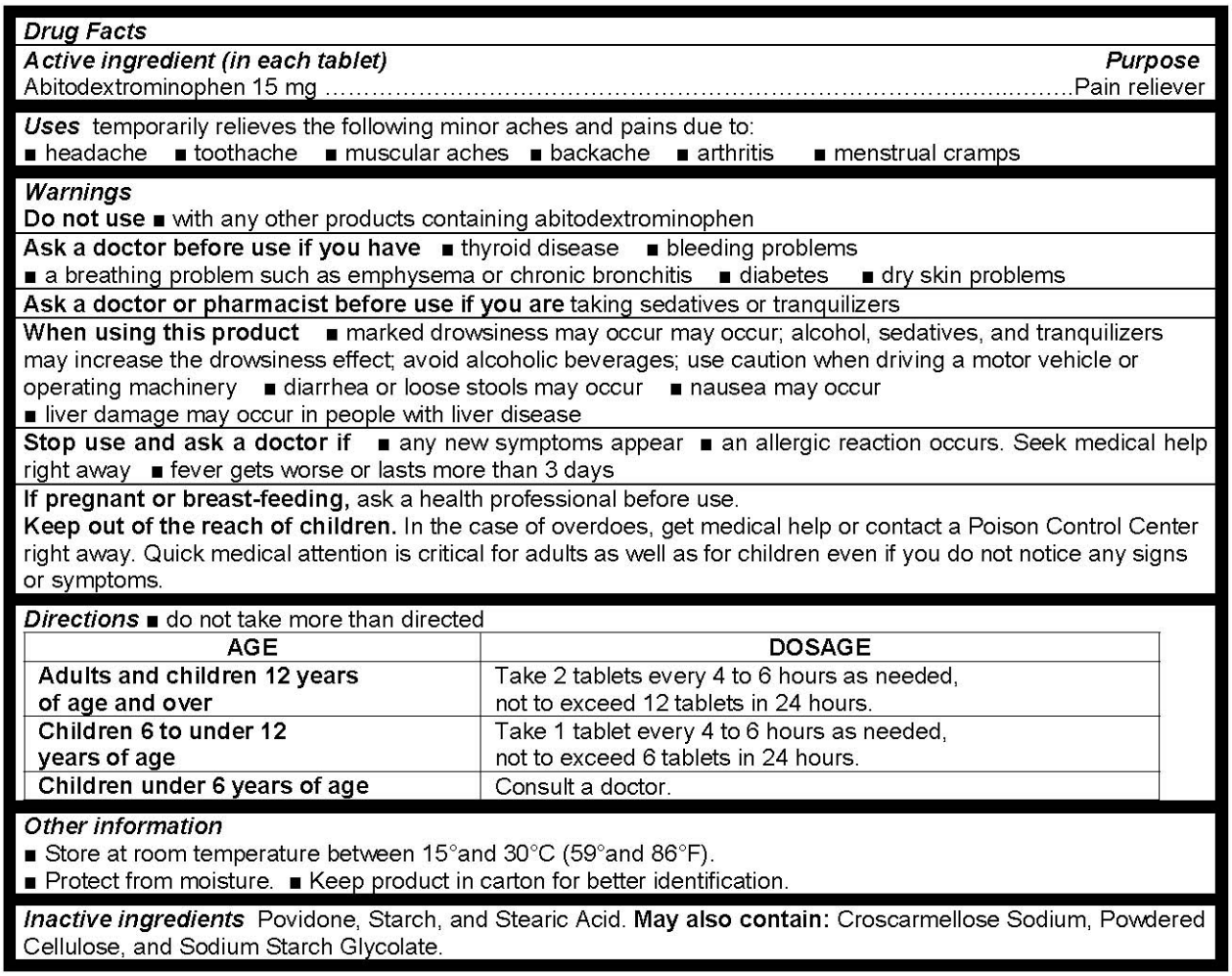
1. Product-Category Risk (PCR): This variable was manipulated by varying the level of risk perceived by consumers for a particular product class or category on the OTC label: ***pain relievers*** (high risk) vs. ***cold products*** (low risk).

2. Product-Specific Risk (PSR): This variable was manipulated by varying the level of risk perceived by consumers for a particular brand in a product class on the OTC label: ***four side effects*** (high risk) vs. ***two side effects*** (low risk).
3. Situational-Specific Risk (SSR): This variable was manipulated by varying the level of risk perceived by consumers for a pre-existing health problem that they were asked to imagine they currently had in the health scenario: ***diabetes*** (high risk) vs. ***dry skin*** (low risk).
4. Presence of SSR information on label: This variable was manipulated by varying the ***presence*** or ***absence*** of the pre-existing health problems (i.e., dry skin and diabetes) as contraindications on the OTC label.

Table 1: Description of treatment combinations

Treatment Group	PCR Product Class	PSR # of Side Effects	SSR Health Problem	SSR Information on Label
1	Pain reliever	2	Dry skin	No
2	Cold product	2	Dry skin	Yes
3	Pain reliever	2	Diabetes	No
4	Cold product	2	Diabetes	Yes
5	Pain reliever	4	Dry skin	No
6	Cold product	4	Dry skin	Yes
7	Pain reliever	4	Diabetes	No
8	Cold product	4	Diabetes	Yes
9	Pain reliever	2	Dry skin	Yes
10	Cold product	2	Dry skin	No
11	Pain reliever	2	Diabetes	Yes
12	Cold product	2	Diabetes	No
13	Pain reliever	4	Dry skin	Yes
14	Cold product	4	Dry skin	No
15	Pain reliever	4	Diabetes	Yes
16	Cold product	4	Diabetes	No
Control group 1	Pain reliever	0	None	No
Control group 2	Cold product	0	None	No

Figure 1: An example of an OTC label



Drug Facts

Active ingredient (in each tablet) ***Purpose***
Abitodextrominophen 15 mg .....Pain reliever

Uses temporarily relieves the following minor aches and pains due to:
■ headache ■ toothache ■ muscular aches ■ backache ■ arthritis ■ menstrual cramps

Warnings
Do not use ■ with any other products containing abitodextrominophen

Ask a doctor before use if you have ■ thyroid disease ■ bleeding problems
■ a breathing problem such as emphysema or chronic bronchitis ■ diabetes ■ dry skin problems

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers

When using this product ■ marked drowsiness may occur may occur; alcohol, sedatives, and tranquilizers may increase the drowsiness effect; avoid alcoholic beverages; use caution when driving a motor vehicle or operating machinery ■ diarrhea or loose stools may occur ■ nausea may occur
■ liver damage may occur in people with liver disease

Stop use and ask a doctor if ■ any new symptoms appear ■ an allergic reaction occurs. Seek medical help right away ■ fever gets worse or lasts more than 3 days

If pregnant or breast-feeding, ask a health professional before use.
Keep out of the reach of children. In the case of overdoes, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions ■ do not take more than directed

AGE	DOSAGE
Adults and children 12 years of age and over	Take 2 tablets every 4 to 6 hours as needed, not to exceed 12 tablets in 24 hours.
Children 6 to under 12 years of age	Take 1 tablet every 4 to 6 hours as needed, not to exceed 6 tablets in 24 hours.
Children under 6 years of age	Consult a doctor.

Other information
■ Store at room temperature between 15°and 30°C (59°and 86°F).
■ Protect from moisture. ■ Keep product in carton for better identification.

Inactive ingredients Povidone, Starch, and Stearic Acid. **May also contain:** Croscarmellose Sodium, Powdered Cellulose, and Sodium Starch Glycolate.

Table 2: An example of a health scenario

Dry skin scenario: You don't have any diagnosed health problems except that you've got very dry skin. The doctor has recommended that, after you take a shower or a bath, you should moisturize your skin because it tends to get all flaky if you don't. Yesterday, you worked all day in the garden and slightly strained your left arm while pruning the weeds. It's a bit painful and achy right now, so you decide to take a pain reliever to treat the pain yourself. However, you noticed that you're out of pain relievers, so you walk to a nearby small grocery store to buy one. You are now in the store, but it doesn't carry what you typically use, so you randomly pick a product called Pain-Arrest and start reading its package label.
Diabetes scenario: You don't have any health problems except that, for 3 years now, you have been diagnosed with diabetes. Yesterday, you worked all day in the garden and slightly strained your left arm while pruning the weeds. It's a bit painful and achy right now, so you decide to take pain reliever to treat the pain yourself. However, you noticed that you're out of pain relievers, so you walk to a nearby small grocery store to buy one. You are now in the store, but it doesn't carry what you typically use, so you randomly pick a product called Pain-Arrest and start reading its package label.

Dependent variables: After reading an OTC package label and a given health scenario, subjects were asked to rate their overall perceived risk and the likelihood of using particular information sources.

1. Overall perceived risk (OPR): Overall perceived risk was conceptualized as a two-dimensional construct consisting of the uncertainty and adverse consequences components (Bauer, 1960). The uncertainty dimension was defined as (1) the consumer's perceived confidence in his or her ability to judge the product risk and (2) the consumer's perceived probability of experiencing the loss. The adverse consequences dimension was defined as (1) the consumer's perceived importance that a loss not occur and (2) the consumer's perceived seriousness of a loss if it were to occur. Higher levels of perceived lack of confidence, perceived probability of experiencing the loss, perceived importance, and perceived seriousness would lead to higher levels of overall perceived risk. Each measure utilized a multi-item, five-point, semantic differential scale.
2. Information sources: This variable was operationalized as the likelihood of using particular sources for information beyond the provided OTC label, utilizing a multi-item, five-point, semantic differential scale. The sources were as follows: other OTC labels, friend, family, pharmacist, physician, TV/radio, and internet. It was hypothesized that, the higher the level of risk perceived by the consumer, the more likely they would use expert interpersonal sources of information, such as the physician or the pharmacist.

Data Collection: There were 18 different questionnaire versions, each version corresponding to one of the treatment combinations. Each subject was randomly assigned to a treatment combination and given a survey packet containing a cover letter, a questionnaire, a prepaid return envelope, and a $1 bill. After completing the questionnaire, each subject was then interviewed by the principal investigator to assess questionnaire readability, completion time, item difficulty/nonresponse, and survey packet design (e.g., cover letter, font size, placement of $1 bill incentive, etc.). Interviews ranged from 1 to 4 hours. The interview was also conducted to assess whether the subjects would be willing and able to answer the questionnaire if the survey packet were mailed to them. They were also asked the reason for answering each question as they did. Each subject was paid $30 for participating in the interview.

Survey Instrument: The questionnaire was divided into three sections and printed using a 14-point Times New Roman font. The first section asked general questions about subject's use, perceptions of, and information sources for OTC products. The second section asked questions about using a hypothetical OTC product in a specific scenario. Subjects in each treatment group were asked to imagine that they had a pre-existing health condition (i.e., dry skin or diabetes) and that they were currently suffering from a minor condition (i.e., aching pain from a strained arm or fever, runny and

stuffy nose from a cold). Furthermore, they were asked to imagine that they had decided to self-treat and to randomly pick an OTC in a grocery store. Subjects were asked to read the OTC label displayed on the questionnaire and to use the scenario to answer questions on their risk perceptions of using the product and on the sources of information they would use. Finally, in the last section, the subjects were asked personal information, such as age, gender, educational level, and health status.

Data Analysis: Scale reliability was assessed for each multi-item measure of overall perceived risk. A composite score was also calculated for each multi-item measure. Due to the very small sample size, only descriptive statistics were calculated for each variable.

RESULTS

Questionnaire Development: Two tests of the survey instruments were completed. The first test was conducted in a group of 24 and nine seniors living in Lafayette County, MS, and Broward/Miami-Dade County, FL, respectively. The subjects' average age was approximately 73 years (S.D. = 7.36). Nearly 52% were women. The educational level breakdown was as follows: 54.6% had a 4-year college degree or higher, 24.3% had some college, and 21.3% had high school or less. All except three subjects were White.

Interview data indicated that elderly subjects reacted favorably to the survey topic and design. However, the questionnaire needed to be redesigned due to the following issues: (1) difficulty in recalling the scenarios and OTC labeling information when answering all the questions; (2) difficulty imagining themselves in the scenarios; (3) inability to understand labeling terminology, which was not consistent with words used by healthcare professionals; and (4) inability to distinguish between different risk manipulations. For example, they did not perceive OTC cold products to be less risky than OTC pain relievers, because certain cold products contain stimulants that are contraindicated in elderly users with high blood pressure.

To address the issue of the elderly's diminished cognitive ability, the questionnaire was revised with the following changes. First, a decision was made to print the OTC label on every other page of the questionnaire so that the subject could immediately refer to the information while answering the questions. Originally, the label was given on a piece of paper separate from the questionnaire. However, subjects tended to read the label only once, put it aside, and not read it again while answering the questions on the survey. Visual cues, such as text boxes, icons, and color, were also used to emphasize key information. Second, the health scenarios were printed at the top of every

other page of the questionnaire so that subjects would remember to use those scenarios instead of their own personal conditions to answer the questions. Originally, the health scenarios were only given once at the beginning of the survey. The product category of OTC antacids was considered as an alternative to replace the product category of OTC cold products. However, a decision was made instead to change the types of health scenarios and OTC product information described on the questionnaire. They were rewritten to reflect a more extreme difference between the levels of risk manipulated so that the elderly subject would be able to distinguish between information considered to be more risky versus information considered less risky.

The revised survey instrument was tested in another group of six seniors in Broward/Miami-Dade County, FL. The sample consisted of four women and two men, all over the age of 70 years. Only one subject had a 4-year college degree; the remaining had some college or high school education. Interview data indicated that the subjects reacted favorably to the revised survey design. They were able to recall information from previous parts of the questionnaire and to distinguish between the different types of risk manipulated in the health scenarios and OTC labels.

Study Findings: Only findings from the first survey instrument test (n = 33) will be presented in this report, because the sample size (n = 6) in the second survey instrument test was very small and insufficient for data analysis. Findings are categorized as follows: (1) assessment of multi-item measure scale reliability, (2) overall perceived risk, and (3) information sources.

Scale Reliability: New multi-item measures for overall perceived risk were created and adapted from single and multi-item measures used in existing literature. Study findings indicated good scale reliability for all multi-item measures used in the study, with Cronbach's alpha ranging from .80 to .90.

Table 3: Scale reliability for multi-item measures

Measure	Cronbach's Alpha	Number of Items
Probability of experiencing a loss	.798	7
Perceived lack of confidence in ability to judge product risk	.788	6
Perceived importance that a loss not occur	,907	7
Perceived seriousness of a loss if it were to occur	.902	7

Overall Perceived Risk Comparisons: Composite scores for probability of loss, importance of loss, and seriousness of loss could range from 7 to 35. Composite scores for lack of confidence could range from 6 to 30. *Note: There was only one subject in the treatment combination.

Table 4: Means (Standard Deviations) of Overall Perceived Risk Measures for Pain Relievers

	Pain Reliever							
	Dry Skin				Diabetes			
	2 Side Effects		4 Side Effects		2 Side Effects		4 Side Effects	
	Info Presence	Info Absence	Info Presence	Info Absence	Info Presence	Info Absence	Info Presence	Info Absence
Probability of loss	16.5 (.71)	19.0 (2.83)	16.5 (6.95)	22.0 *	28.0 (7.07)	20.0 (1.41)	17.0 (2.83)	15.0 (5.66)
Lack of confidence	20.5 (2.12)	16.5 (.71)	20.8 (8.54)	19.0 *	14.0 (7.07)	12.0 *	19.5 (10.61)	22.5 (3.57)
Importance of loss	35.0 (.00)	34.5 (.71)	26.5 (8.70)	30.0 *	33.0 (2.83)	30 *	31.5 (.71)	29.5 (7.78)
Seriousness of loss	30.0 (2.83)	34.5 (.71)	31.75 (4.72)	32.0 *	34.0 (.71)	30 *	35.0 (.00)	32.5 (3.54)

Table 5: Means (Standard Deviations) of Overall Perceived Risk Measures for Cold Products

	Cold Product							
	Dry Skin				Diabetes			
	2 Side Effects		4 Side Effects		2 Side Effects		4 Side Effects	
	Info Presence	Info Absence	Info Presence	Info Absence	Info Presence	Info Absence	Info Presence	Info Absence
Probability of loss	14.0 (4.24)	22.0 *	21.5 (7.78)	18.0 (8.49)	24.0 *	22.5 (13.44)	15.5 (9.19)	14.5 (6.37)
Lack of confidence	19.5 (.71)	21.0 *	19.0 (7.07)	20.0 (2.83)	19.0 *	22.5 (2.12)	23.0 (2.83)	23.0 (8.48)
Importance of loss	31.5 (4.95)	32.0 *	34.0 (1.41)	35.0 (.00)	35.0 *	33.5 (2.12)	16.0 (8.49)	31.5 (3.54)
Seriousness of loss	32.5 (.71)	33.0 *	34.0 (1.41)	34.0 (.00)	34.0 *	31.0 (4.24)	21.5 (7.78)	31.0 (1.41)

Information Source Comparisons: Likelihood ratings for using different sources of information could range from 1 to 5 (1 = not at all likely, 5 = most likely). *Note: There was only one subject in the treatment combination.

Table 6: Means (Standard Deviations) of the Likelihood of Using Different Sources of Information for Pain Relievers

	Pain Reliever							
	Dry Skin				Diabetes			
	2 Side Effects		4 Side Effects		2 Side Effects		4 Side Effects	
	Info Presence	Info Absence	Info Presence	Info Absence	Info Presence	Info Absence	Info Presence	Info Absence
Other OTC labels	3.5 (2.12)	2.5 (2.12)	4.0 (2.00)	5.0 *	2.5 (2.12)	4.0 *	3.5 (2.12)	4.0 (.00)
Friend	2.0 (.00)	2.5 (.71)	3.2 (1.71)	4.0 *	1.5 (.71)	4.0 *	3.0 (.00)	3.0 (1.41)
Family	2.0 (.00)	3.0 (.00)	3.8 (1.89)	4.0 *	1.5 (.71)	4.0 *	3.0 (.00)	4.0 (1.41)
Pharmacist	4.0 (.00)	4.5 (.71)	4.5 (1.00)	5.0 *	4.5 (.71)	4.0 *	2.5 (.71)	3.0 (1.41)
Physician	2.5 (.71)	3.5 (2.12)	3.0 (2.31)	4.0 *	4.0 (.00)	5.0 *	2.0 (.00)	4.0 (1.41)
TV/radio	1.0 (.00)	1.5 (.71)	2.8 (1.71)	2.0 *	1.0 (.00)	2.0 *	1.0 (.00)	2.5 (2.12)
Internet	1.0 (.00)	1.5 (.71)	2.2 (1.89)	2.0 *	2.5 (2.12)	2.0 *	2.0 (1.41)	1.5 (.71)

Table 7: Means (Standard Deviations) of the Likelihood of Using Different Sources of Information for Cold Products

	Cold Product							
	Dry Skin				Diabetes			
	2 Side Effects		4 Side Effects		2 Side Effects		4 Side Effects	
	Info Presence	Info Absence	Info Presence	Info Absence	Info Presence	Info Absence	Info Presence	Info Absence
Other OTC labels	3.5 (.71)	3.0 *	3.0 (2.83)	3.5 (2.1)	2.0 *	4.5 (.71)	3.5 (.71)	3.5 (2.12)
Friend	2.0 (1.41)	3.0 *	1.0 (.00)	2.0 (.00)	2.0 *	3.5 (.71)	2.0 (.00)	2.5 (.71)
Family	2.0 (1.41)	3.0 *	1.0 (.00)	2.0 (.00)	2.0 *	4.0 (1.41)	3.0 (1.41)	3.0 (.00)
Pharmacist	5.0 (.00)	5.0 *	3.0 (2.83)	5.0 (.00)	5.0 *	3.0 (1.41)	4.0 (.00)	4.5 (.71)
Physician	3.0 (2.83)	5.0 *	3.0 (2.83)	5.0 (.00)	4.0 *	3.0 (2.83)	3.5 (2.12)	3.0 (1.41)
TV/radio	1.5 (.71)	1.0 *	1.0 (.00)	1.5 (.71)	1.0 *	2.5 (2.12)	2.0 (.00)	1.5 (.71)
Internet	1.0 (.00)	1.0 *	1.0 (.00)	1.5 (.71)	4.0 *	1.0 (.00)	1.5 (.71)	1.0 (.00)

Study Participation: The survey instrument tests were conducted as face-to-face interviews with the subjects. When asked whether they would complete the questionnaire if the survey packet were instead mailed out to them, subjects raised the following concerns and issues. First, all subjects reported that the $1 bill incentive was insufficient to incentivize them into completing the questionnaire if the survey packet were mailed out to them. Most subjects gave $10 as the minimum financial incentive threshold for completing the mailed questionnaire. Second, all subjects were aware of and respected the principal investigator's academic affiliation. However, most of them reported that they would not complete a survey mailed from an unknown academic institution. Third, most subjects preferred to be personally interviewed by the principal investigator than to be mailed a questionnaire. An interviewer-administered questionnaire would allow for question-asking from the subject. This was critical for them, because there was confusion over label and scenario risk manipulations due to diminished cognitive ability. Also, subjects preferred face-to-face interviews because it was more personable than receiving an anonymous questionnaire in the mail. Finally, it was difficult for some subjects to circle or write answers because of physical impairments, such as poor vision or trembling hands.

Study Limitations: There were several limitations to this study. First, a judgment sample of seniors in Mississippi and Florida was used. It will be important to test generalizability of the findings with elderly populations in other states. Second, the sample size was very small, lacking power to conduct

any multivariate analyses. Social desirability could also be a possible source of bias in the results. Subjects might be more likely to report using a pharmacist or physician as an information source because of the principal investigator's academic pharmacy background. Another limitation is that the study was not conducted in a naturalistic setting, with hypothetical labels used in written scenarios rather than using real-time OTC decisions. Finally, conducting research among the elderly took an extensive amount of time and effort, because the study survey instrument needed to be tailored and adapted according to the needs and concerns of the target population. In-depth, face-to-face interviewing was conducted with each subject, requiring a lot of time and commitment from the principal investigator and slowing the progress of the study.

Discussion: Multi-item measures were developed for the study to address the limitations of previous researchers conceptualizing perceived risk as a unidimensional construct and using single-item measures. Even in a very small sample, scale reliability for each new multi-item measure of overall perceived risk was good. These measures should be further examined in a larger and more diverse population of seniors. The survey instrument was also designed and revised to address the needs of elderly subjects. Interview data indicated favorable reactions from the subjects to survey topic and design. However, the study's sample size was too small to make any conclusions about how the elderly utilized risk information on OTC labels to form their overall risk perceptions of using an OTC drug product. There were also insufficient data to determine the sources of drug information the elderly would use to find out more about an OTC beyond the package label. The survey instrument needs to be tested in a larger sample with sufficient power to conduct multivariate analyses and examine interaction effects between the independent variables.

The original intent of the study was to conduct pretests of the survey instrument in small samples of elderly subjects. Based on an estimate of 30% as the response rate, the revised survey instrument would then be piloted in a national sample of 612 seniors to allow for enough subjects in each treatment combination. Finally, the final survey instrument would be mailed to a larger national sample of 1,620 seniors. However, based on the study's interview data, all subjects reported that there is a need to increase the amount of financial incentives from $1 to at least $10 to encourage study participation if the questionnaire were to be mailed out to them. Furthermore, they would be more likely to complete the questionnaire if it were administered face-to-face by an interviewer.

Based on these study findings, it was expected that the response rate would be much lower than 30% if only a $1 incentive were mailed with the survey packet, thereby possibly needing to oversample and increase the sample size to more than 10,000 subjects. In order to maintain the same sample size, financial incentives need to be increased. Furthermore, based on study findings, mailed surveys

might not be the best study design for this type of research, because it tested experimentally manipulated information in elderly subjects with diminished cognitive functioning. Semi-structured, face-to-face interviews may be a more appropriate study design for this target population.
This study was not originally budgeted sufficient funds for the following: (1) a big increase in the sample size; (2) a big increase in financial incentives to encourage study participation; and (3) travel funds to allow the principal investigator to conduct face-to-face interviews with subjects nationwide. Therefore, a decision was made by the principal investigator to end the study with the development and testing of a survey instrument in a small sample of elderly subjects.

Conclusions and Implications: A survey instrument was developed and designed to understand how the elderly utilized risk information on OTC package labels to form their overall risk perceptions of using an OTC product and to determine the sources they would use for additional information beyond the label. It is critical that questionnaires are designed to address the needs of elderly subjects. The study design for questionnaire implementation should also be tailored to the needs of elderly subjects. Questionnaires should always be pretested in age-specific groups to evaluate subjects' understanding prior to actual field distribution.

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LIST OF PUBLICATIONS AND PRODUCTS

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