ABSTRACT

The Food and Drug Administration maintains the authority to regulate the labeling of children’s over-the-counter cough and cold medications. FDA’s primary interests in this area are to protect children from incidences of adverse events due to over-dosing and to ensure that medications are administered correctly so that the patient may receive the proper therapeutic dose. Labeling is only effective if it can be accurately interpreted and followed by caregivers. Published literature and a qualitative pilot study completed in 2010 suggest that caregivers are dissatisfied with the current dosing instructions of children’s over-the-counter cough and cold medications. The purpose of this study is to quantitatively examine the findings of previously completed research and to determine the effect of caregiver functional health literacy on their ability to accurately interpret product labeling. Recommendations to enhance FDA’s regulations by modifying current product labeling requirements are made.

INDEX WORDS: Labeling, OTC, Cough, Cold, Pediatric, Children, Medication, Comprehension, Literacy, Caregiver, FDA, Regulatory Affairs, 21 CFR 341, TOFHLA
QUANTITATIVE ANALYSIS OF CAREGIVER COMPREHENSION OF CHILDREN’S’ OVER-THE-COUNTER COUGH AND COLD MEDICATION DOSING INSTRUCTIONS

by

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B.A. University of Georgia, 2000

A Thesis Submitted to the Graduate Faculty of The University of Georgia in Partial Fulfillment of the Requirements for the Degree

MASTERS OF SCIENCE

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2011
QUANTITATIVE ANALYSIS OF CAREGIVER COMPREHENSION OF CHILDREN’S’ OVER-THE-COUNTER COUGH AND COLD MEDICATION DOSING INSTRUCTIONS

by

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Maureen Grasso
Dean of the Graduate School
The University of Georgia
August 2011
DEDICATION

This master’s thesis is dedicated to my father, Norris S. Gaynor. My father devoted his entire professional career to the public education system and in so doing, improved the lives of children and educators through the development and implementation of policies and procedures. Upon his retirement in 2006, Norris Gaynor was acknowledged by the Georgia General Assembly under House Resolution 738 noting his 37 years of service and for being recognized as one of Governor Sonny Perdue’s Top 100 High Performance Principals. He opened and was the principal of Summit Hill Elementary School, which received the Governor’s Single Statewide Accountability System (SASS) Platinum Award for two consecutive years under my father’s direction. Norris Gaynor taught his children the paramount importance of receiving a quality education to build a foundation for lifelong success and I thank him for selflessly offering his support and dedication to my pursuit of higher education.
ACKNOWLEDGEMENTS

I would like to thank Caitlin Senter, for supporting my desire to conduct my thesis research based on the results from her pilot study completed in 2010.

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CHAPTER 1
INTRODUCTION

Over-the-counter cough and cold medications are commonly used among adults and pediatric populations in the United States to control and relieve symptoms associated with various respiratory illnesses. A doctor’s prescription, which would normally contain pertinent dosing information specifically tailored to the unique patient based on age and weight, is not required to purchase medications over-the-counter. The consumer must therefore assume the responsibility of proper dosing and administration of over-the-counter, or non-prescription drugs. In the absence of a doctor’s prescription, clear and concise labeling is required to effectively communicate important information to consumers. Consumers primarily rely on the labeling on the product and marketing materials to effectively communicate the benefits and risks associated with the use of each medication in addition to the dosing instruction. Children are the most vulnerable population to consider because they rely on the decisions made by their caregivers in both product selection and administration. It is reported that 95 million units of children’s over-the-counter cough and cold medications are sold each year. While these preparations are generally considered safe and effective, misdosing due to caregiver mistakes can lead to adverse events such as overdosing and allergic reactions in children. Caregiver comprehension and interpretation of over-the-counter dosing instructions are critical components to ensure safety and effectiveness of these medications.

The Food and Drug Administration maintains the authority to regulate the labeling of children’s over-the-counter cough and cold medications. The FDA’s primary interests in this
area are to protect children from incidences of adverse events due to over-dosing and to ensure that medications are administered correctly so that the patient may receive the proper therapeutic dose. Since January of 2000, poison-control centers in the United States have recorded an excess of 750,000 calls from concerned caregivers resulting from the use of pediatric cough and cold medications.\(^2\) In 2007, at the Nonprescription Drug Advisory Committee meeting of the FDA’s Division of Drug Risk Evaluation, the FDA reported that their review had revealed 123 deaths over the past several decades in children under six years of age after using one of these products.\(^2\) It was estimated in 2008 that 211,209 children under the age of 12 visited the emergency room in the United States because of adverse reactions to over-the-counter medications or nutritional products.\(^2\)

The FDA maintains 21 CFR Part 201.66, which describes the label requirements for format and content of over-the-counter drugs that may deviate from the established monograph, and was last amended in 2009. Furthermore, the FDA maintains regulatory authority over the establishment and updates to the OTC monograph, 21 CFR 341. The monograph details the requirements and conditions that must be met for a medication to be generally recognized as safe or effective.\(^3\) The FDA also informs consumers of changes and recommendations through consumer updates on its website. The FDA has issued several consumer updates on the use of over-the-counter medications in children, intended at educating the public. Recent updates have aimed to educate caregivers on how best to follow the appropriate directions, usage and age recommendations for children’s over-the-counter medications.\(^4\)

The movement to update children’s over-the-counter cough and cold medication labeling can be traced back to March of 2007, where the FDA was petitioned to review the effects of these medications in pediatric populations. The original monograph established in 1976
endorsed using adult cough and cold medications in children at lower (fractional) doses by extrapolating a lower dose based on age rather than requiring safety and efficacy to be proven in pediatric populations. The petition was led by the Commissioner of Health for Baltimore at the time, Dr. Joshua Sharfstein, spawning a joint meeting between the FDA’s Pediatric Committee and the Nonprescription Drug Advisory Committees in October, 2007 where the movement to understand safety and efficacy of these preparations in children began. The meeting resulted in a unanimous vote to discontinue the use of extrapolation to derive proper dosing amounts for children under the age of two, and that studies proving clinical efficacy in children should be required. The majority of participants voted that the FDA should immediately recommend that the use of these medications be suspended in children under six.

In 2008, the FDA released a statement saying, “FDA strongly recommends that over-the-counter (OTC) cough and cold products should not be used for infants and children under 2 years of age because serious and potentially life threatening side effects could occur.” The Consumer Healthcare Products Association (CHPA), and associated product manufactures took action in 2008 to update their product labels indicating their medications should not be used in children under the age of four years. Concurrently, the manufactures made an effort to update the tamper resistant packaging of these products. The most recent consumer update from the FDA was published in 2009 and states, “FDA knows of reports of serious side effects from OTC cough and cold medicines in children 2 to 11 years of age, but we haven’t completed our review of information about the safety of these products in children of this age,” indicating that the FDA is still accepting input into the revision of the monograph and other regulations for children’s over-the-counter cough and cold medications.
Direct-to-consumer advertising of children’s cough and cold medications are not reviewed or overseen by the FDA. The Federal Trade Commission maintains oversight responsibility for over-the-counter product advertising and does not require the same statements of benefit versus risk that are required for prescription drug product direct-to-consumer advertising. There is a concern that children’s cough and cold medications are falsely advertised to consumers as safe and effective without having substantiated these claims with the FDA. Many of these marketing materials state that the ingredients in the medications are recommended by physicians.¹

In addition to questions related to the safety and efficacy of these products in children, there is also growing concern that the FDA’s requirements do not address caregiver comprehension variations in the general public. There have been growing efforts to prove that variations in caregiver comprehension have the potential to lead to incidence of adverse events in children and that labeling should be amended to account for these differences. The FDA has recently issued a new guidance document to help sponsors conduct label comprehension studies for over-the-counter medications. These studies are sometimes required when a sponsor wants to market a new over-the-counter medication or make a significant change to current labeling or target population for an existing medication. The guidance document was developed following a meeting of the Nonprescription Drug Advisory Committee in 2006, where the group identified issues with consumer studies. The guidance document specifically states that sponsors should include comprehension testing in individuals with low literacy skills to ensure the label directions can be followed by this sub population.⁷ Label comprehension studies are generally not required when a manufacturer proposes to market a medication according to the established monograph without filing a new drug application. In general, over-the-counter drug
manufacturers strive to develop labeling that can be comprehended at a seventh grade reading level.

The primary objective for the research described in this paper is to show that current over-the-counter cough and cold medication label dosing directions are misinterpreted by caregivers. Furthermore, suggestions for label format and content improvements to address these concerns will be recommended for consideration by the FDA, the CHPA drug manufacturers and other manufacturers of over-the-counter children’s cough and cold medications.
CHAPTER 2
LITERATURE REVIEW

The Pilot Study

The primary piece of literature considered in the design of this study was Caitlin Senter’s pilot study “Caregiver’s Perceptions and Comprehension of Dosage Administration Directions for Over-the-Counter Cough and Cold Medications in Children 2 to 12 Years of Age,” completed in 2010. This qualitative study employed a focus group methodology for the data collection. Study participants recruited locally from the North Georgia area were presented with mock dosing scenarios and then discussed the effectiveness of current children’s cough and cold medication labeling. Senter collected qualitative data from caregivers of different socioeconomic status and education level who voluntarily enrolled in the focus groups. The research explored caregiver’s perceptions and comprehensions of the dosing instructions of over-the-counter cough and cold medications. The data collected was organized into convergent and divergent themes that supported or deviated from previously published literature.

The results of Senter’s pilot study converged with previously publish work finding that caregivers seek supplemental information, primarily from family members, to help clarify dosing directions of over-the-counter medications. Participants in the pilot study stated that they were confused by the dosing directions of over-the-counter medications. The study participants also indicated that they preferred dosing instructions to be presented in the form of a table, as opposed to a bulleted list. Both dosing formats are currently accepted by the FDA monograph. Participants also suggested that comprehension of the Directions section could be further
enhanced by moving it to the top of the label. An identified outcome of the pilot research was that caregivers desire consistency between physician/pharmacist recommendations and over-the-counter drug labeling.

The study concluded that caregivers are confused by the dosing directions of these medications and that modifications should be made to the label to improve comprehension. The results indicate that the Directions section of the product label should be presented in a table format, and be located at the top of the label, above the Active Ingredients. The study also concluded that caregivers most often seek information from family members who work in the medical profession when they encounter discrepancies in dosing information.

Senter’s study was qualitative in nature, and thus the sample size was small and isolated to a single geography. The demographics of the respondent pool were not diverse. Senter also noted that although education and income levels were considered in the pilot study, the functional health literacy of respondents was not considered. Senter concluded that further research should consider a larger sample size over a broader geographic area and should also test the functional health literacy of respondents.

**Supplementary Literature**

Additional literature influenced the design of the study as themes were identified during the search. In addition to general label comprehension among individuals from varying socioeconomic statuses, common themes arose where further study was warranted. These themes included understanding the impact of functional health literacy on label comprehension and a general confusion amongst caregivers related to age versus weight based dosing of children’s cough and cold medications. An article published in *Pediatrics & Adolescent Medicine* in 1997 by Harold K. Simon and David A. Weinkle, entitled “Over-the-Counter
Medications. Do Parents give what they intend to give?10 presents data collected from caregivers during visits to the Emergency Department at Egleston Children’s Hospital in Atlanta, GA. The study concluded that caregiver comprehension of dosing instructions is low based on mock dosing scenarios and that caregivers do not have an accurate understanding of the current weight of their children. Overall, only 30% of study participants were able to determine and measure an accurate dose for their child.10 Our current study built on this concept by examining mock dosing scenarios and directly asking participants if they have knowledge of their children’s exact weight using a validated measuring tool, such as a bathroom scale.

The American Academy of Pediatrics published an article in their official journal, Pediatrics, in 2009 entitled “Parental Misinterpretations of Over-the-Counter Pediatric Cough and Cold Medication Labels,” by Nicole Lokker, et. al.11 Lokker employed a one-on-one written survey methodology to collect data examining caregiver understanding of age based dosing and the relationship between literacy and numeracy skills and label comprehension. This study found that caregiver’s with low literacy and math skills (as measured by previously validated tools) were more likely to endorse incorrect use of over-the-counter medications in children. The results also indicated that when dosing directions are provided in age categories alone, caregivers find the labeling complicated to understand.11

Another piece of literature reviewed was “Acetaminophen and ibuprofen dosing by patients,” by Siu Fai Li, et. al. where approximately half of study subjects identified the wrong dose during a mock dosing scenario of acetaminophen and ibuprofen. In contrast to children’s cough and cold medications, pediatric acetaminophen and ibuprofen products most commonly present dosing instructions in a format that includes both age and weight ranges. The study evaluated caregiver dosing to treat fever in children and concluded that caregivers who based
medication administration on weight were less likely to misdose.\textsuperscript{12} Li, et. al.’s study also concluded that study participants with lower levels of education, performed more poorly than those who were more highly educated

Lea S. Eiland, et. al. published an article in \textit{Clinical Pediatrics}, “Caregiver’s Perspectives When Evaluating Nonprescription Medication Utilization in Children,” in 2008.\textsuperscript{13} This study employed a survey in both English and Spanish and concluded that the majority of caregivers inappropriately dose their children with various over-the-counter medications. Furthermore, Eiland, et. al. concluded that caregivers primarily rely on advice from physicians, nurses and pharmacists when making dosing and treatment decisions related to the use of over-the-counter (non-prescription) medications.

The complete results from the literature review are presented in the form a bibliography which can be found in APPENDIX A.
CHAPTER 3

METHODOLOGY

Research Hypothesis

Primarily, the researcher proposes to examine the following hypotheses on a quantitative scale:

1. Caregivers of children (two to 12 years old) incorrectly interpret product labeling and dosing instructions of children’s over-the-counter cough and cold medications (h1).
   Responses will be compared by group: (Group 1 = low income/low education and Group 2 = high income/high education).

2. Caregivers with lower Functional Health Literacy Scores are more likely to misinterpret product labeling and dosing instructions of children’s over-the-counter cough and cold medications (h2).

3. If a physician does not supply the caregiver with enough information to properly dose a child using an over-the-counter cough or cold medication, the caregiver will seek further information from family members who work in the medical profession (h3).

4. Caregivers desire the Directions section to be communicated through the use of a table format instead of a bulleted list (h4).

5. Caregivers desire to move the Directions section to the beginning of the over-the-counter label (h5).
6. Caregivers state that the over-the-counter cough and cold medication directions are unclear and they become confused as to which age dosing category their child belongs (h₆).

7. Child weight is a more accurate measure to enable caregivers to appropriately dose their children with over-the-counter cough and cold medications versus age alone (h₇).

Literature Review

A literature review was conducted to understand the depth and breadth of previously completed research on the topic. The researcher explored different sources for information including internet research and published literature searches. Included in this research was an in depth analysis of the findings from a qualitative pilot study completed by Caitlin Senter in 2010. The conclusions from the pilot study and other previous publications were used to develop the research hypotheses being studied. The objective was to accept or reject various hypotheses using a large sample size in a quantitative study. Furthermore, the researcher intended to expand upon previos research by measuring the functional health literacy level of respondents. Further clarification was sought to understand caregiver’s perceptions and opinions related to age and weight based dosing.

Survey Design

In order to conduct a quantitative study of sufficient sample size, the researcher chose to employ an on-line survey technique popularly used for market research. To collect this type of data, a researcher could employ several different survey techniques including one-on-one interviews, in person surveys, telephone surveys or an on-line survey. In order to reach a broad geographic population, a written survey was eliminated as a potential survey tool. Some researchers are hesitant to use on-line research methods because they are concerned with the
validity of the data compared to off line data collection methods; however, these methods have been tested, validated, and proven to yield results consistent with other data collection techniques.\textsuperscript{14} A web-based survey was chosen over a telephone survey because web-based data collection is more accurate, less expensive and more reliable than telephone based surveys.\textsuperscript{15} The market research company, StandPoint Group (Tucker, GA), was contacted to program and execute the on-line survey. StandPoint, who relies heavily on web based surveys, employs a panel of pre-screened respondents throughout the country whom are regularly recruited to complete surveys related to medical product design, pricing and preference. In 2010, StandPoint completed 20 health care related projects.\textsuperscript{16}

The survey questions were developed to support the acceptance of the hypotheses described above. To achieve this objective, the survey was divided into 5 parts:

1. Screening Questions
2. Label Comprehension Questions
3. General Label Comprehension Questions
4. Functional Health Literacy Exam (S-TOFHLA)
5. Demographic Questions

The screening questions were designed to screen out those potential respondents that did not meet the pre-set inclusion criteria from StandPoint’s panel of respondents. Inclusion/exclusion criteria were based on the groups included in Senter’s pilot study.

Label graphics and corresponding comprehension questions were presented that mirrored those that were included in Senter’s pilot study. Specifically, two different children’s’ over-the-counter cough and cold medication labels were presented, Triaminic® Cough & Sore Throat and Robitussin® Children’s Cough & Cold Long Acting. These are the same products that were
used in the pilot study, so they were therefore used again to eliminate sources of variability. To test the respondent’s ability to comprehend the dosing instructions presented on the label, the respondent was asked to identify the proper amount and frequency of administration based on a mock dosing scenario from a multiple choice list.
Fig.1: Triaminic® Cough & Sore Throat Label
The general label comprehension questions were designed to access respondent’s opinions and preferences on over-the-counter medication label design and how dosing information is presented to the caregiver. Respondents were presented with multiple mock variations of the Triaminic® Cough & Sore Throat label to compare for formatting questions. These mock labels are presented in Appendix B. Additional questions were administered to address caregiver comprehension and practice regarding age versus weight based dosing.

The survey also included the administration of the Test of Functional Health Literacy of Adults (TOFHLA) exam. Published literature suggests that caregivers with low literacy levels are more likely to misinterpret dosing instructions and commit dosing errors. Senter’s pilot study did not include the administration of a literacy exam to study participants, and it was suggested that future research include the use of a validated tool for assessing health literacy. Therefore, the TOFHLA tool was employed in this survey. TOFHLA was developed and validated by Joanne R. Nurss, Ph.D, et al. to measure the functional health literacy of
individuals for use by health care providers and researchers. The TOFHLA exam can be administered in English or Spanish, however the focus of this study was on subjects whose primary language is English, therefore, the test was administered in English only. The TOFHLA exam can be administered in a full length or short version. When the two versions were compared in a group of 211 patients, Chronbach’s Alpha (internal consistency) was 0.97. The correlation (Spearman) for the S-TOFHLA with the REALM (Rapid Estimate of Adult Literacy in Medicine Test) was 0.81 as compared to 0.91 for the full length TOFHLA exam. For this study, the short version of the exam (S-TOFHLA) was chosen to minimize survey time and because literacy was used as a descriptive variable in the research. The S-TOFHLA test employed in the survey presented a reading comprehension test to participants in order to assess their ability to read passages that might be encountered in a health care setting. The standardized 36 multiple choice, fill in the blank questions which make up the exam, have been selected from a set of instructions normally given to a patient about to undergo an upper gastrointestinal series test. The questions are normally presented to the respondent on a paper exam, and therefore this study relied on some modifications in order to administer the exam online. To achieve this result, the question groupings were maintained and shown to the respondent on the same screen as they would be if the exam were to be administered on paper.

Additional demographic questions were asked at the end of the survey to record respondent ethnicity, marital status and geographic location. The results were tested by demographic group to look for statistical significance between groups.

Institutional Review Process

Prior to subject recruitment, the survey design was submitted to the University of Georgia’s Institutional Review Board (IRB) for review and approval which is a required element
to ensure the protection of Human Subjects per University policy and federal law as set forth in 45 Code of Federal Regulations (CFR) Part 46\textsuperscript{19}. A draft of the survey was submitted to the review board to demonstrate the language of the questions that would be asked as well as an explanation of how the rights of each subject would be protected. The IRB application also detailed the researcher’s plans to protect the anonymity of the research subject, how the data would be protected, copies of signed investigator agreements, and as detailed information on the anticipated risks and benefits posed to the research subject. The IRB application, survey design, and materials were approved on May 25\textsuperscript{th}, 2011.

Subject Recruitment

StandPoint Group maintains a community forum (“panel”) from which potential respondents are recruited for various market research studies being conducted. Most of the market research that StandPoint facilitates is related to medical product development. Anyone is allowed to join the panel (initially recruited from banner ads, pop-ups, search links and website co-marketing), however StandPoint uses technology based techniques to avoid duplication and fraud. The reliability of the panel is ensured through the use of digital fingerprinting as each member is assigned a unique, non-identifiable ID code. StandPoint incents respondents by offering “points” which can be redeemed for gift certificates or cash. The incentive offered to respondents to participate in this study was 100 points valued at less than $1.00 (this was fully disclosed in the IRB informed consent packet).

StandPoint launched the survey by sending out an email link to members of the respondent panel. By clicking on the link, potential respondents were taken to the customer landing page which described the study to the potential participant and gave them an opportunity to participate or decline based on the information presented. The potential respondent answered
a series of screening questions, designed to screen out those potential respondents who did not meet the pre-set inclusion criteria. The entire panel is represented by approximately 800,000 individuals.

Specific inclusion and exclusion criteria were developed and were applied to the existing panel to find the required number of respondents. Respondents were recruited to fill two unique groups in accordance with the pilot study completed in 2010. The differences between the groups are detailed in Table 1.

Table 1: Inclusion/Exclusion Criteria

<table>
<thead>
<tr>
<th>Inclusion Criteria Group One</th>
<th>Inclusion Criteria Group Two</th>
<th>Exclusion Criteria All Groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men &amp; Women</td>
<td>Men &amp; Women</td>
<td>Older than 50 years</td>
</tr>
<tr>
<td>Ages 24-50</td>
<td>Ages 18-50</td>
<td>Younger than 18 years</td>
</tr>
<tr>
<td>Must have at least 1 child in the current household ages 2 – 12</td>
<td>Must have at least 1 child in the current household ages 2 – 12</td>
<td>Households with children outside the desired age range or no children at all</td>
</tr>
<tr>
<td>Minimum education level of a Bachelor’s degree</td>
<td>Maximum education level of a High School degree (or GED)</td>
<td>Households with 6 or more children within the desired age range</td>
</tr>
<tr>
<td>English as primary language</td>
<td>English as primary language</td>
<td>Individuals who claim a language other than English as their primary language</td>
</tr>
<tr>
<td>Minimum household annual income of at least $52,029.00²⁰</td>
<td>Household annual income of less than $52,029.00²⁰</td>
<td>Subjects who are unable or unwilling to provide informed consent</td>
</tr>
</tbody>
</table>

The purpose of this study, as well as the pilot study completed in 2010, was to assess the level of comprehension and opinions of “caregivers.” Caregivers were defined as adults at least 18 years of age who provide care to at least one child within the age range of two to 12 years.
The study also attempted to understand the impact of education and income levels on label comprehension, and therefore minimum and maximum education levels were established, and the respondents were divided into two groups. Respondents were further characterized by their reported household income level and placed in one of two groups according to the median household income for the United States reported in the 2008 U.S. Census\(^2\). The groups were modeled to be similar to the groups included in the pilot study. The recruitment also focused on filling additional quotas set forth according to the statistical design of the study.

The survey landing page was designed to inform the potential subject of the risks and benefits associated with participation in the survey. Those participants that were unwilling to give their informed consent to participate in the survey were terminated and were not allowed to complete the survey. The survey launched on June 6\(^{th}\), 2011 and completed with 353 responses on June 20\(^{th}\), 2011.

**Statistical Rationale**

A sample size of 170 respondents in Group 1 and 170 respondents in Group 2 were targeted to achieve 80% statistical power to detect a difference between the group proportions of 0.15 (15%). The proportion in Group 1 was assumed to be 0.50 (50%) under the null hypothesis and 0.65 (65%) under the alternate hypothesis. Because preliminary quantitative data was not available to suggest what the actual outcome might be, a proportion of 0.50 presented the most conservative level to test. The significance level of this test (alpha) was targeted at 0.05 (95% confidence level). The statistical test was designed to detect a 15% difference between groups in critical questions which was deemed to be an impactful result, in light of the lack of preliminary data to suggest a possible outcome. Additionally, detecting a 15% difference between groups allowed for a manageable and reasonable sample size. The PASS (Power Analysis Statistical
software was used to calculate the sample size and group requirements for a
statistical test:

Table 2: PASS Sample Size Calculation

<table>
<thead>
<tr>
<th>Two Independent Proportions Power Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Numeric Results of Tests Based on the Difference: P1 – P2</td>
</tr>
<tr>
<td>H0: P1-P2=0. H1: P1-P2=D1&lt;&gt;0.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sample</th>
<th>Sample</th>
<th>Prop</th>
<th>H1</th>
<th>Prop</th>
<th>Diff</th>
<th>Diff</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>Power</td>
<td>N1</td>
<td>N2</td>
<td>P1</td>
<td>P2</td>
<td>D0</td>
<td>D1</td>
<td>Alpha</td>
</tr>
<tr>
<td>0.8004</td>
<td>170</td>
<td>170</td>
<td>0.65</td>
<td>0.50</td>
<td>0.00</td>
<td>0.15</td>
<td>0.05</td>
</tr>
</tbody>
</table>

Report Definition

'Power' is the probability of rejecting a false null hypothesis. It should be close to one.

'N1 and N2' are the sizes of the samples drawn from the corresponding populations.

'P1' is the proportion for group one under H1. This is the treatment or experimental group.

'P2' is the proportion for group two. This is the standard, reference, or control group.

'D1: Diff. if H1' is the difference P1 – P2 assuming the alternative hypothesis.

'Target Alpha' is the probability of rejecting a true null hypothesis that was desired.

'Actual Alpha' is the value of alpha that is actually achieved.

'Beta' is the probability of accepting a false null hypothesis.

Data Analysis

StandPoint Group was assigned the responsibilities of survey programming and data
collection. To ensure the validity of the data, the StandPoint team, the researchers, the Principal
Investigator, and the Thesis Committee completed a survey test prior to launch. The data was
continuously monitored throughout the fielding of the survey. Upon completion of the survey,
the data was downloaded and reviewed by StandPoint’s project manager to ensure the accuracy
of the data set. StandPoint provided a Microsoft® Excel Workbook (Microsoft® Office 2010)
upon the completion of data collection that contained the responses for each subject. This output
was imported to the statistical program JMP (Version 9.0) which was used to analyze the data.
The number of responses was double checked against the number of respondents. During the
review, open-ended responses for the mock dosing scenarios that did not make sense (i.e.
random strings of letters, answers out of context) were removed as well as any numerical outliers. Open ended responses were then grouped into 5 separate themes, “per directions,” “current usage/opinion,” “avoid adverse events,” “adjust by age,” and “adjust by weight.” Open ended response groupings were coded separately by two individuals and discrepancies were resolved by an independent reviewer. Upon completion, the StandPoint project manager had the entire data set reviewed by additional StandPoint staff members.

The primary statistical analysis techniques that were used to analyze the data included contingency tables, the Chi² statistic and the binomial exact test (Fisher’s Test). The contingency table was used to provide a means of summarizing counts and percentages. Tables are structured in a two-dimensional contingency table formed by classifying subjects by the two variables. Demographic groupings were compared to possible responses for each question. For example, consider Survey Question 5: “How often would you administer the dose you identified in your answer to Q4?” The following contingency table demonstrates how the table was constructed to compare possible responses in each of the two groups (note that “Group 1” or “Group 2” could be replaced with any actual demographic being tested in the table, i.e. age groupings, gender, income level, education level, etc):
Table 3: Example Contingency Table Summarizing Counts and Percentages

<table>
<thead>
<tr>
<th>Count Total %</th>
<th>Once every 10 hours</th>
<th>Once every 12 hours</th>
<th>Once every 4 hours</th>
<th>Once every 6 hours</th>
<th>Once every 8 hours</th>
<th>Row Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 1</td>
<td>3</td>
<td>2</td>
<td>140</td>
<td>22</td>
<td>4</td>
<td>171</td>
</tr>
<tr>
<td></td>
<td>0.88</td>
<td>0.58</td>
<td>40.94</td>
<td>6.43</td>
<td>1.17</td>
<td>50.00</td>
</tr>
<tr>
<td></td>
<td>60.00</td>
<td>66.67</td>
<td>49.82</td>
<td>52.38</td>
<td>36.36</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1.75</td>
<td>1.17</td>
<td>81.87</td>
<td>12.87</td>
<td>2.34</td>
<td></td>
</tr>
<tr>
<td>Group 2</td>
<td>2</td>
<td>1</td>
<td>141</td>
<td>20</td>
<td>7</td>
<td>171</td>
</tr>
<tr>
<td></td>
<td>0.58</td>
<td>0.29</td>
<td>41.23</td>
<td>5.85</td>
<td>2.05</td>
<td>50.00</td>
</tr>
<tr>
<td></td>
<td>40.00</td>
<td>33.33</td>
<td>50.18</td>
<td>47.62</td>
<td>63.64</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1.17</td>
<td>0.58</td>
<td>82.46</td>
<td>11.70</td>
<td>4.09</td>
<td></td>
</tr>
<tr>
<td>Column Total</td>
<td>5</td>
<td>3</td>
<td>281</td>
<td>42</td>
<td>11</td>
<td>342</td>
</tr>
<tr>
<td></td>
<td>1.46</td>
<td>0.88</td>
<td>82.16</td>
<td>12.28</td>
<td>3.22</td>
<td></td>
</tr>
</tbody>
</table>

The Chi\(^2\) statistic, X\(^2\), was calculated to test the null hypothesis of independence (i.e. there is no dependence on grouping and the pattern of responses). In the example, the Chi-Square test statistic of 1.45 had a p-value of 0.8354 indicating that there is no significant difference in the pattern of responses for the two groups.

Table 4: Example Chi-Square Test Statistic

<table>
<thead>
<tr>
<th>Tests</th>
<th>N</th>
<th>DF</th>
<th>-LogLike</th>
<th>RSquare (U)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>342</td>
<td>4</td>
<td>0.73431250</td>
<td>0.0034</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test</th>
<th>ChiSquare</th>
<th>Prob&gt;ChiSq</th>
</tr>
</thead>
<tbody>
<tr>
<td>Likelihood Ratio</td>
<td>1.469</td>
<td>0.8322</td>
</tr>
<tr>
<td>Pearson</td>
<td><strong>1.450</strong></td>
<td>0.8354</td>
</tr>
</tbody>
</table>

Some questions were reduced to a 2 x 2 table (comparing two groups where there were only two possible outcomes), and the contingency table output highlighted the percent correct and percent incorrect responses. Fisher’s exact test was calculated for these 2 x 2 tables. In this case, the Chi\(^2\) test looks at the difference between what is observed and what would be expected due to random chance (25% in each cell, highlighted in yellow). For example:
Table 5: Example 2x2 Contingency Table

<table>
<thead>
<tr>
<th></th>
<th>Correct</th>
<th>Incorrect</th>
<th>Row Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Group1</strong></td>
<td>58</td>
<td>113</td>
<td>171</td>
</tr>
<tr>
<td><strong>Col %</strong></td>
<td>16.96</td>
<td>33.04</td>
<td>50.00</td>
</tr>
<tr>
<td><strong>Row %</strong></td>
<td>46.77</td>
<td>51.83</td>
<td></td>
</tr>
<tr>
<td></td>
<td>33.92</td>
<td>66.08</td>
<td></td>
</tr>
<tr>
<td><strong>Group2</strong></td>
<td>66</td>
<td>105</td>
<td>171</td>
</tr>
<tr>
<td><strong>Col %</strong></td>
<td>19.30</td>
<td>30.70</td>
<td>50.00</td>
</tr>
<tr>
<td><strong>Row %</strong></td>
<td>53.23</td>
<td>48.17</td>
<td></td>
</tr>
<tr>
<td></td>
<td>38.60</td>
<td>61.40</td>
<td></td>
</tr>
<tr>
<td>**Column Total</td>
<td>124</td>
<td>218</td>
<td>342</td>
</tr>
<tr>
<td><strong>Row %</strong></td>
<td>36.26</td>
<td>63.74</td>
<td></td>
</tr>
</tbody>
</table>

The p-value was 0.4311 indicating shift in the percentages of responses between the two groups.

Table 6: Example Fisher’s Exact Test Statistic for a 2 x 2 Table

<table>
<thead>
<tr>
<th>Tests</th>
<th>N</th>
<th>DF</th>
<th>-LogLike</th>
<th>RSquare (U)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>342</td>
<td>1</td>
<td>0.40506579</td>
<td>0.0018</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test</th>
<th>ChiSquare</th>
<th>Prob&gt;ChiSq</th>
</tr>
</thead>
<tbody>
<tr>
<td>Likelihood Ratio</td>
<td>0.810</td>
<td>0.3681</td>
</tr>
<tr>
<td>Pearson</td>
<td>0.810</td>
<td>0.3682</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Fisher's Exact Test</th>
<th>Prob</th>
<th>Alternative Hypothesis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Left</td>
<td>0.2156</td>
<td>Prob(Q2 correct/incorrect=Incorrect) is greater for EduSal=Group1 than Group2</td>
</tr>
<tr>
<td>Right</td>
<td>0.8443</td>
<td>Prob(Q2 correct/incorrect=Incorrect) is greater for EduSal=Group2 than Group1</td>
</tr>
<tr>
<td>2-Tail</td>
<td>0.4311</td>
<td>Prob(Q2 correct/incorrect=Incorrect) is different across EduSal</td>
</tr>
</tbody>
</table>

Source: JMP (Version 9.0)

All demographic questions were analyzed in a similar manner to detect the difference between groups wherever a 50/50 split between groups (i.e. gender, income level, age, etc.) was achieved. The survey was structured so that if a difference of more than 70/30 was obtained in any individual demographic, additional respondents would have been recruited to augment the
data and minimize bias. The actual data set, however, exhibited a 50/50 split as desired during the initial programming, and additional responses were not required to augment the data.

When results did not show a clear majority when tested in JMP, a GLIMMEX analysis was used to compare responses to each other to determine statistical significance. SMS (Version 9.0) was used to complete these analyses. The JMP program does not provide a method to do pairwise comparisons of percentages. The GLIMMIX procedure in SAS allows for a logistic regression model to be fitted to the data and has the option to add a LSEMEANS statement which allows multiple comparisons tests to be performed.

The S-TOFHLA directions for administration and scoring are included in the workbook published by Peppercorn Books. Respondent data was collected in the master MicroSoft® Excel Workbook (Microsoft® Office 2010). The multiple choice answer to each fill-in-the-blank question was recorded and a correct response earned one (1) point and each incorrect response earned zero (0) points. Each respondent’s S-TOFHLA score represents the sum total of positive responses to yield a Reading Comprehension Raw Score. The raw scores were used to access each respondent’s Functional Health Literacy Level according to the following table:

Table 7: TOFHLA Functional Health Literacy Level

<table>
<thead>
<tr>
<th>Literacy Level</th>
<th>TOFHLA Score</th>
<th>Functional Health Literacy Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inadequate Functional Health Literacy</td>
<td>0-16</td>
<td>Unable to read and interpret health texts</td>
</tr>
<tr>
<td>Marginal Functional Health Literacy</td>
<td>17-22</td>
<td>Has difficulty reading and interpreting health texts</td>
</tr>
<tr>
<td>Adequate Functional Health Literacy</td>
<td>23-36</td>
<td>Can read and interpret most health texts</td>
</tr>
</tbody>
</table>
Disclosure

The researcher wishes to disclose the relationship with StandPoint, Group that was leveraged to complete this research. StandPoint’s owner and CEO, Kip Creel, is a personal friend of the researcher. Mr. Creel agreed to provide the tools and resources to execute the survey on behalf of the researcher pro bono. In return for StandPoint’s services, the researcher agreed to provide Mr. Creel feedback on the performance of StandPoint’s project manager who was assigned to the project.
CHAPTER 4

RESULTS

Subject Demographics

Upon completion of the on-line survey, 353 responses were obtained. An additional 495 potential respondents attempted to participate in the survey, but were rejected for not meeting the strict inclusion criteria (age, primary language, number of children, age of children, etc).

Although more biased towards the eastern half of the United States, subjects were distributed geographically throughout the U.S.

Figure 3: Geographic Distribution of Survey Respondents

Source: Google Maps available at:
http://maps.google.com/maps?hl=en&safe=active&q=map+of+zip+codes&bav=on.2,or_r_gc.r_pw.&biw=985&bih=399&rapid=tlif130859535871910&um=1&ie=UTF-8&sa=N&tab=wl
The majority of respondents reported their marital status as “married” and the most prevalent ethnicity was Caucasian. The mean age of the caregivers’ children was 7.04 years and each household reported an average of 1.62 children.

Table 8: Study Participant Demographics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Mean or Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caregiver Age Range</td>
<td></td>
</tr>
<tr>
<td>18-24</td>
<td>7%</td>
</tr>
<tr>
<td>25-30</td>
<td>28%</td>
</tr>
<tr>
<td>31-40</td>
<td>42%</td>
</tr>
<tr>
<td>41-50</td>
<td>23%</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>50%</td>
</tr>
<tr>
<td>Female</td>
<td>50%</td>
</tr>
<tr>
<td>Primary Language</td>
<td></td>
</tr>
<tr>
<td>English</td>
<td>100%</td>
</tr>
<tr>
<td>Education Level Completed</td>
<td></td>
</tr>
<tr>
<td>Technical Degree</td>
<td>4.3%</td>
</tr>
<tr>
<td>Some High School</td>
<td>7.6%</td>
</tr>
<tr>
<td>Master’s Degree or Higher</td>
<td>14%</td>
</tr>
<tr>
<td>High School Diploma</td>
<td>43%</td>
</tr>
<tr>
<td>Bachelor’s Degree</td>
<td>32%</td>
</tr>
<tr>
<td>Marital Status</td>
<td></td>
</tr>
<tr>
<td>Divorced</td>
<td>7.6%</td>
</tr>
<tr>
<td>Married</td>
<td>68%</td>
</tr>
<tr>
<td>Separated</td>
<td>1.1%</td>
</tr>
<tr>
<td>Single</td>
<td>23%</td>
</tr>
<tr>
<td>Widowed</td>
<td>0.3%</td>
</tr>
<tr>
<td>Income Level</td>
<td></td>
</tr>
<tr>
<td>Below $52,090</td>
<td>50%</td>
</tr>
<tr>
<td>Above $52,090</td>
<td>50%</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
</tr>
<tr>
<td>African American</td>
<td>11%</td>
</tr>
<tr>
<td>Asian</td>
<td>5.1%</td>
</tr>
<tr>
<td>Caucasian</td>
<td>76.2%</td>
</tr>
<tr>
<td>Native American</td>
<td>1.1%</td>
</tr>
<tr>
<td>Hispanic</td>
<td>5.1%</td>
</tr>
<tr>
<td>Other</td>
<td>0.85%</td>
</tr>
<tr>
<td>Prefer not to answer</td>
<td>1.6%</td>
</tr>
<tr>
<td>Mean Age of Children in Household</td>
<td>7.04</td>
</tr>
</tbody>
</table>

The gender demographic was split equally between males and females. As targeted, half of the respondents reported an annual household income above $52,090 and half below. The
respondents reported their level of education and were divided into two groups according to annual household income and highest level of education completed. Thus, Group 1 and Group 2 each contained 170 respondents. Within the two groups, gender was split in half between males and females.

Fig. 4: Respondent Pool

Data Exclusions

As part of the IRB requirements for the protection of Human Subjects, the survey contained mechanisms to allow respondents to skip (not answer) those questions that they were uncomfortable answering. At the end of the survey, each respondent also had the option to have their answers discarded from the data set. In one instance, a study participant opted to have all of their answers to the survey excluded from the study. From the data collected, it cannot be determined why this participant made that choice, however each participant was given the option to withdraw at any time without their answers being recorded in order to protect their rights as a
human research subject. Several participants chose not to answer certain questions. The data
tables and graphs are noted to indicate where “no response,” or a response of “I am not sure,”
was recorded. One respondent was eliminated from the S-TOFHLA analysis because he/she
skipped all of the questions and therefore received a functional health literacy score of “1.”

Mock Dosing Scenario 1

The primary purpose of the research was to assess caregiver comprehension of over-the-
counter cough and cold medication label dosing instructions. To measure this endpoint, the
survey presented medication label graphics to respondents and asked them to provide the correct
answer to a mock dosing scenario.

The first scenario involved the review of the Triaminic® Cough & Sore throat
medication, where respondents were asked to identify the correct dosing amount for a 6 year old
child. Independent of group assignment, 36% (95% CI: 31% – 42%) of respondents correctly
identified the appropriate dose and frequency for a 6 year old child (two teaspoons every four
hours). Fifty-three percent (95% CI: 48% – 59%) of respondents provided a dosing scenario
that was lower than the manufacturer’s recommendation and ten percent (95% CI: 7% – 14%)
identified a higher than recommended dose.
A contingency analysis was completed to compare the responses between Group 1 and Group 2. Among Group 1 respondents, 32.8% (95% CI: 25.9% – 40.2%) identified the correct dosing from the manufacturer’s label. Within the Group 2 respondents, 38.3% (95% CI: 31.1% – 45.9%) responded correctly. Correct dosing scenarios are highlighted in the tables below. The numbers reported in the individual cells represent the total count for that response of the population, the percent of the entire population, the column percent and the row percent.
Table 9: Contingency Analysis Triaminic Cough & Sore Throat Mock Dosing Group 1

<table>
<thead>
<tr>
<th>Count</th>
<th>1 Tbs</th>
<th>1 tsp</th>
<th>1.5 Tbs</th>
<th>1.5 tsp</th>
<th>2 Tbs</th>
<th>2 tsp</th>
<th>I am not sure</th>
<th>Row Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>I am not sure</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Once every 10 hours</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Once every 12 hours</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Once every 4 hours</td>
<td>1</td>
<td>71</td>
<td>2</td>
<td>3</td>
<td>6</td>
<td><strong>58</strong></td>
<td>1</td>
<td><strong>142</strong></td>
</tr>
<tr>
<td>Once every 6 hours</td>
<td>1</td>
<td>13</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>7</td>
<td>0</td>
<td><strong>23</strong></td>
</tr>
<tr>
<td>Once every 8 hours</td>
<td>1</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td>Column Total</td>
<td>3</td>
<td>90</td>
<td>2</td>
<td>5</td>
<td>7</td>
<td>68</td>
<td>2</td>
<td><strong>177</strong></td>
</tr>
</tbody>
</table>
Table 10: Contingency Analysis Triaminic Cough & Sore Throat Mock Dosing Group 2

<table>
<thead>
<tr>
<th></th>
<th>1 Tbs</th>
<th>1 tsp</th>
<th>1.5 Tbs</th>
<th>1.5 tsp</th>
<th>2 Tbs</th>
<th>2 tsp</th>
<th>I am not sure</th>
<th>Row Total</th>
</tr>
</thead>
<tbody>
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<td>4</td>
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<td>4.00</td>
</tr>
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<td>0.00</td>
<td></td>
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<td>11</td>
<td>78</td>
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<td>175</td>
</tr>
</tbody>
</table>

As a follow up to the mock dosing scenario, caregivers were asked to provide an open ended rationale for the dosing selection that they made. Respondents were given the option to provide an open ended response or skip to the next question, and only about half of the respondents provided an open ended response. The open ended responses were grouped by theme and analyzed. The results presented in Fig. 6 indicate 68.2% (95% CI: 61.1% – 74.7%) of respondents selected the answer based on what they believed was indicated on the label.
Mock Dosing Scenario 2

The second mock dosing scenario presented asked respondents to identify the correct dosing for a six year old child for Robitussin® Cough & Cold Long-Acting. Overall, 75% (95% CI: 70% – 79%) of respondents correctly identified the appropriate dose and frequency for a six year old child (two teaspoons every six hours). Eight percent (95% CS: 5% – 11%) of respondents provided a dosing scenario that was lower than the manufacturer’s recommendation and 12% (95% CI: 8% – 16%) identified a higher than recommended dose.
A contingency analysis was completed to compare the responses between Group 1 and Group 2. Among Group 1 respondents, 74.7% (95% CI: 67.6% – 80.9%) identified the correct dosing from the manufacturer’s label. Within the Group 2 respondents, 74.4% (95% CI: 67.2% – 80.8%) responded correctly. Correct dosing scenarios are highlighted in the tables below.
Table 11: Contingency Analysis Robitussin Cough & Cold Long-Acting Mock Dosing Group 1

<table>
<thead>
<tr>
<th>Count</th>
<th>Total %</th>
<th>Col %</th>
<th>Row %</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1 Tbs</td>
<td>1 tsp</td>
<td>1.5 Tbs</td>
</tr>
<tr>
<td>I am not sure</td>
<td>0.00 0.00 0.00 0.00 0.00 1.12 5.06</td>
<td>6.18</td>
<td></td>
</tr>
<tr>
<td>Once every 12 hours</td>
<td>0.00 0.56 0.00 0.00 0.00 1.12 0.00</td>
<td>1.69</td>
<td></td>
</tr>
<tr>
<td>Once every 4 hours</td>
<td>0.00 0.00 0.00 0.00 0.00 87.50 0.00</td>
<td>4.49</td>
<td></td>
</tr>
<tr>
<td>Once every 6 hours</td>
<td>0.56 3.93 0.56 1.12 4.49 74.72 0.00</td>
<td>85.39</td>
<td></td>
</tr>
<tr>
<td>Once every 8 hours</td>
<td>0.66 4.61 0.66 1.32 5.26 87.50 0.00</td>
<td>85.39</td>
<td></td>
</tr>
<tr>
<td>Column Total</td>
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<td>178</td>
<td></td>
</tr>
</tbody>
</table>
As a follow up to the mock dosing scenario, caregivers were asked to provide an open ended rationale for the dosing selection that they made. About half of the respondents provided an open ended response when asked. The open ended responses were grouped by theme and analyzed. The results presented in Fig. 8 indicate that 88% (95% CI: 83.5% – 91.1%) of respondents selected the answer based on what they believed was indicated on the label.
**S-TOFHLA Results**

The S-TOFHLA exam was administered to study participants as part of the on-line survey to assess the functional health literacy level of each participant. The distribution of scores is reported in Table 13.

<table>
<thead>
<tr>
<th>Literacy Level</th>
<th>TOFHLA Score</th>
<th>Functional Health Literacy Description</th>
<th>Study Participants (% of total)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inadequate Functional Health Literacy</td>
<td>0-16</td>
<td>Unable to read and interpret health tests</td>
<td>2.6%</td>
</tr>
<tr>
<td>Marginal Functional Health Literacy</td>
<td>17-22</td>
<td>Has difficulty reading and interpreting health texts</td>
<td>0.3%</td>
</tr>
<tr>
<td>Adequate Functional Health Literacy</td>
<td>23-36</td>
<td>Can read and interpret most health texts</td>
<td>97%</td>
</tr>
</tbody>
</table>
For the first mock dosing scenario (Triaminic® Cough & Cold) where only 35% of respondents answered correctly, a nominal logistic regression was performed to determine what potential input variables (demographic and respondent group information) significantly contributed to the accurate prediction of correct dosing. The only term that had a significant Chi² value was the functional health literacy score indicating it as a potential predictor of the respondent answers to the mock dosing scenario (p-value <0.0001). The prediction profiler graphs presented below indicate the likelihood of providing one of the three possible outcomes (Correct Dose, Low Dose, High Dose) as a function of health literacy.

Of those respondents who received a score of “Inadequate Functional Health Literacy,” the logistic regression analysis model predicts that 68.4% would respond to the mock dosing scenario by providing a dose that was too low and 30.3% would provide a dosing scenario that was too high. The remaining 0.13% is predicted to choose the correct dose. In Fig. 9, the red intersecting line labeled “16” represents the upper limit of the range for that functional health literacy score.
Of those respondents who received a score of “Marginal Functional Health Literacy,” the analysis predicts that 72% of respondents would answer the mock dosing scenario by providing a dose that was too low and 23% would provide a dosing scenario that was too high. Four percent of these respondents would provide the correct dosing scenario. In Fig. 10, the red intersecting line labeled “22” represents the upper limit of the range for that functional health literacy score.
Of those respondents who received a score of “Adequate Functional Health Literacy,” it is predicted that 47% would respond to the mock dosing scenario by providing a dose that was too low and seven percent would provide a dosing scenario that was too high. Forty-five percent of these respondents would provide the correct dosing scenario. In Fig. 11, the red intersecting line labeled “36” represents the upper limit of the range for that functional health literacy score.
For the second mock dosing scenario, no factors had a significant Chi$^2$ value, therefore indicating no statistically significant association with any demographic including functional health literacy. Therefore, functional health literacy cannot be used as a predictor of responses in the Robitussin® Cough & Cold Long Acting mock dosing scenario.

**Caregiver Trusted Sources of Information**

Respondents were asked what action they would take if the dosing instructions on the over-the-counter medication label did not match the recommendation they had received from the child’s physician, nurse or pharmacist. Fifty-seven percent of respondents said they would call the physician, nurse or pharmacist for further clarification which was a significantly higher response rate versus all other response options (p value = 0.0008). Twenty-seven percent of respondents said they would dose per the manufacturer’s instructions, six percent said they would call a family member who works in the medical profession, three percent said they would
search the internet for more information, 3 percent said they would not use the medication and four percent said they were not sure what they would do.

Fig. 12: Respondent Action When Dosing Instructions Do Not Match

Physician/Nurse/Pharmacist Recommendations

Caregivers Preference of Dosing Directions Formatting

When caregivers were asked to compare two different versions of dosing instructions to determine if the respondents believed a table or a bulleted list was a more effective means of communicating dosing directions, 96% (95% CI: 93.2% – 97.5%) significantly preferred the table format (p-value <0.0001). This response rate is also significantly higher than a 50% selection rate for table versus bulleted list (p-value <0.0001).
Caregivers Preference of Dosing Directions Location

When comparing four different mock versions of the Triaminic® Cough & Cold label, 52% (95% CI: 46.9% – 57.4%) of respondents indicated that they felt the directions could be most effectively communicated if the Directions section were placed “at the top of the label”, above the active ingredients. Thirty-three percent (95% CI: 30.0% – 37.8%) preferred the Direction section be located “between the Uses and Warnings sections”, 11% (95% CI: 8% – 14.5%) prefer it be “at the bottom of the label”, four percent (95% CI: 2.7% – 7.1%) chose “between the Warnings and Other Information section”, and three percent (95% CI: 1.6% – 5.7%) of the respondents were not sure.
These results were tested using the GLIMMIX procedure in SAS (Version 9.0) in order to perform a multiple comparison of the five potential responses. The selection “At the Top of the Label” was significantly higher when compared to any of the other options (p-value < 0.0001 for all comparisons).

**Caregivers Confusion Related to Age/Weight Based Dosing**

After again reviewing the dosing instructions of the Triaminic® Cough & Cold label (which present the dosing instructions by age only), the majority of respondents (65.8%; 95% CI: 60.6% – 70.6%) believe the dosing instructions as they are today are presented “very clearly” on a scale of 1-5, where 1 = “not at all clearly” and 5 = “very clearly” (p-value = <0.0001).

Twenty-seven percent rated the directions as “4” (95% CI: 22.5% – 31.8%), five percent chose a rating of “3” (95% CI: 3.4% – 8.2%), two percent chose a rating of “2” (95% CI: 0.6% – 3.4%), and less than one percent chose a rating of “1” (95% CI: 0.2% – 2.1%).
Caregivers Understanding of Child Weight

The survey results indicate that 71% (95% CI: 66.3% – 75.9%) of respondents currently know the exact weight of their children using an accurate measuring tool, such as a bathroom scale. Twenty-one percent (95% CI: 16.5% – 25.1%) of respondents do not know, and eight percent (95% CI: 5.7% – 11.6%) are not sure (p-value < 0.0001).

Fig. 16: Respondents Knowledge of Exact Weight
When respondents were asked which method would enable them to most accurately dose their children (age, weight, or weight and age), 53.2% (95% CI: 47.9% – 58.4%) responded that they would prefer the dosing directions to be based on a combination of the child’s age and weight. Twelve percent (95% CI: 9.9% – 16.2%) preferred weight alone, 29% (95% CI: 24.1% – 33.7%) preferred age and six percent (95% CI: 3.8% – 8.9%) responded that they were not sure.

Fig. 17: Respondent Preference for Accurate Dosing

These results were tested using the GLIMMIX procedure in SAS (Version 9.0) in order to perform a multiple comparison of the four potential responses. Although not significantly different than the aggregate of the other responses, the selection “By Weight & Age” was significantly higher when compared to any of the other three options individually (p-value <0.0001 for all comparisons).

Respondents answer to preference for accurate dosing (age, weight, or age & weight) was compared to the answers they provided regarding the clarity (scale of 1 – 5) of the Triaminic® Cough & Cold medication dosing instructions in a contingency table analysis. The majority of
respondents prefer dosing instructions to be presented by age and weight, yet 35.1% these same respondents claimed the dosing instructions of the Triaminic® Cough & Cold label (which present the dosing instructions by age only) were presented “very clearly” (95% CI: 30.0% – 40.4%).

Table 14: Contingency Analysis of Age/Weight Preference vs. Current Label Clarity

<table>
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<th>By weight</th>
<th>By weight and age</th>
<th>I am not sure</th>
<th>Row Total</th>
</tr>
</thead>
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<td>5.85</td>
<td></td>
</tr>
</tbody>
</table>

Sixty-eight percent (95% CI: 63.3% – 73.1%) of respondents indicated that if they were caring for a child that was over-weight for his/her age, they would not adjust the manufacturers dosing instructions for that child (p-value <0.0001). Six percent (95% CI: 3.8% – 8.9%) of respondents would decrease the recommended dose and 15% (95% CI: 11.8% – 19.4%) would increase the recommended dose.
Fifty percent (95% CI: 44.7% – 55.3%) of respondents indicated that if they were caring for a child that was under-weight for his/her age, they would not adjust the manufacturers dosing instructions for that child. Thirty-three percent (95% CI: 28.0% – 38.0%) of respondents would decrease the recommended dose and six percent (95% CI: 3.6% – 8.5%) would increase the recommended dose.
These results were tested using the GLIMMIX procedure in SAS (Version 9.0)\textsuperscript{23,24} in order to perform a multiple comparison of the four potential responses. The selection “Follow Manufacturer’s Directions for Age” was significantly higher when compared to any of the other three options (p-value <0.0001 for all comparisons).

When examining the questions related to under and overweight children, only 45% (95% CI: 39.7% – 50.5%) of respondents answered that they would follow the manufacturer’s directions for dosing based on age only. The remaining respondents were either not sure which action they would take, or adjusted the dose based on the child’s weight.
Mock Dosing Scenario Comprehension

The primary purpose of the research was to assess caregiver comprehension of over-the-counter cough and cold medication label dosing instructions. The results of Senter’s pilot study mock dosing scenarios supported the previous research done by Li, et. al. which showed that approximately half of study subjects incorrectly identify the wrong dose during a mock dosing scenario with acetaminophen and ibuprofen. Qualitatively, Senter’s pilot study suggests that caregivers are confused about the proper dose to administer to children after reviewing the product label.

In the first mock dosing scenario (Triaminic® Cough & Cold), only 35% of respondents correctly identified the appropriate dose and frequency. In the second scenario (Robitussin® Cough & Cold Long Acting), the majority of respondents (74%) correctly identified the appropriate dose and frequency.

Both the Triaminic® and Robitussin® labels employ a table format for presenting the dosing directions, however, the Robitussin® table presents a dosing amount and frequency in a single cell in the same row as the child’s age. In contrast, the Triaminic® label gives the frequency directions at the top of the table in a single cell and presents only the correct dosing amount in the row with the child’s age. It is speculated that more respondents provided the correct dose and frequency in the second mock dosing scenario, but not in the first scenario because the table presented on the Robitussin® label appeared to be clearer. Furthermore, the
Triaminic® label reads, “may be given every four hours,” suggesting that caregivers should decide the frequency for themselves.

Fig. 20: Dosing Directions Label Comparison (Triaminic® vs. Robitussin®)

In all groups, the results of the study were consistent in that caregivers were more likely to choose the recommended dose or a lower than the recommended dose, suggesting that the probability of an adverse event occurring due to over-dosing is low. This finding is consistent with the results of the Simon, et. al. study which determined that “[the result] implies a marked potential for providing sub therapeutic or potentially dangerous amounts of medication.”

Where incorrect dosing scenarios occurred in Simon’s study, most caregivers chose a sub therapeutic dose.

There was no statistical difference found between groups (high income/high education and low income/low education) in either dosing scenario indicating that neither income nor education level impact the respondent’s ability to provide the correct answer. It is speculated that education level does not impact label comprehension because the FDA requires labeling of over-the-counter drugs to not exceed a seventh grade reading level. There were no associations found between demographics (age, level of education, income level, gender, number of children, ethnicity, marital status, average age of child) and performance in the mock dosing scenarios.
with the exception of functional health literacy score (discussed below). This result is not consistent with the findings of Eiland, et. al. who found a correlation between number of children and respondent’s answers to the mock dosing scenarios presented. Eiland, et. al. found that among caregivers with multiple children, 75.7% provided an incorrect answer to the mock dosing scenario, while among caregivers with only one child, only 59.9% provided the incorrect answer.\textsuperscript{14}

\textit{S-TOFHLA}

The primary results from Lokker, et. al. showed a correlation between low literacy skills and mising, but they also found that subjects with higher S-TOFHLA scores (adequate functional health literacy) were more likely to select a dosing administration different from the product labeling directions. The Lokker, et. al. study suggested that among those with higher functional health literacy, the incorrect selections were made because those respondents rely more heavily on their own judgment rather than the directions on the label.\textsuperscript{12} However, in the current study, the open ended responses indicate that although an incorrect dosing scenario was chosen, 68.2% of the respondents in mock dosing scenario 1 and 88% of the respondents in mock dosing scenario 2 thought they were choosing the correct answer. There were a small group of respondents in both scenarios who provided answers indicating that they had adjusted the recommended dose according to their child’s weight or age, thus supporting this finding from the Lokker, et. al. study.

In mock dosing scenario 1, a significant Chi\textsuperscript{2} value was found for functional health literacy score indicating it as a potential predictor of the respondent answers to the mock dosing scenario (p-value <0.0001). With increasing functional health literacy score, more respondents are likely to choose the correct dosing scenario. Because a high percentage of respondents
answered the mock dosing scenario 2 (Robitussin® Cough & Cold Long Acting) correctly (74%), the same measure of association between dosing scenario response and S-TOFHLA score cannot be made. In all scenarios, regardless of functional health literacy, respondents who answered incorrectly are more likely to under dose than over dose the child.

Further research is recommended in a sample set that is more equally split between functional health literacy groups to understand the true impact on label comprehension. Because 97% of respondents in this study fell into the “Adequate Functional Health Literacy” group, the data is biased and a different result might be observed in a more evenly distributed population.

Caregiver Trusted Sources of Information

The results of the Senter’s study suggested that, on a qualitative scale, caregivers would consult a family member for more information if the dosing directions they received from a physician, nurse or pharmacist did not match the manufacturer’s directions found on the product label. The result of the Senter’s pilot contrasts with the findings of the Eiland, et. al. study where friends and family were ranked fourth. Within the respondent pool included in this research, six percent of survey respondents did indicate that they would consult a family member who works in the medical profession, however the majority of respondents (56.9%) indicated that they would instead call the physician, nurse or pharmacist for further clarification.

Another finding of the Eiland, et. al. study was that caregivers rank all other sources of information above information found on the internet. The results of this study are consistent with this finding, where only three percent of respondents indicated that they would first consult the internet for clarification of dosing instructions.

The results suggest that the opinion of the physician, nurse or pharmacist is more often sought to clarify dosing discrepancies than other sources of information including family
members who work in the medical profession, the manufacturer’s recommended dosing or the internet. These results support the findings of the Eiland, et. al. study.14

Caregivers Preference of Dosing Directions Formatting

The Directions section of children’s over-the-counter cough and cold medications can be presented in various formats, but are most commonly presented in the form of a table or a bulleted list. The subjects interviewed in the Senter’s study preferred the Directions section to be communicated through the use of a table rather than a bullet list, because “they felt the table could be easily located due to the border.”9 The majority of respondents in the current study (96%) believe that if the Directions section of children’s over-the-counter cough and cold medications are presented in a table rather than a bulleted list, the dosing can be more effectively communicated, thus confirming the findings of the Senter’s pilot study.

Caregivers Preference of Dosing Directions Location

The Code of Federal Regulations (21 CFR 201.66) and the established monograph 21 CFR 341 describe the acceptable label content and format for over-the-counter children’s cough and cold medications. Per these regulations, the Directions location must always be located after the Warnings section and above the Other Information section. Focus group respondents in the Senter’s study were split on preference for dosing Direction location. The first group of respondents wanted to have the Directions section moved to the top of the label, so that it could be easily located. Other respondents thought the Directions section should remain where it is today, because the Warnings section currently appears above Directions which some respondents felt should always be consulted prior to attempting to administer medication to a child.9 Although the Directions sections of Triaminic® Cough & Cold is currently located near the
bottom of the label in accordance with FDA regulation, the researcher hypothesized that caregivers would prefer the Directions section to be located at the beginning (top) of the label. Our results indicated that the majority of respondents (52%) feel the directions could be more effectively communicated if the Directions section were placed “at the top of the label”, above the active ingredients, supporting the first group of respondents from Senter’s pilot study. The current research does not support the findings from the pilot study’s other group of respondents, who believed the Warnings section should be presented before the Directions section. Only four percent and eleven percent of respondents preferred the current label and another mock label (which placed the Directions section below the Warning section) respectively.

*Caregivers Confusion Related to Age/Weight Based Dosing*

The Triaminic® Cough & Cold label presents dosing information based on age only, unlike many acetaminophen and ibuprofen products which present dosing information based on a combination of age and weight. While Senter’s study concluded that caregivers find the dosing directions to be unclear when presented by age category only, the results of this study indicate that the majority of caregivers surveyed believe the dosing directions on the Triaminic® Cough & Cold label to be “very clear.” Although caregivers surveyed claim the dosing directions are “very clear,” only 35% of them were able to correctly answer the first mock dosing scenario, suggesting that they overestimate their own ability to provide the correct dosing based on age alone. An analysis of provided open ended responses for the first mock dosing scenario confirmed that the majority of respondents selected the (incorrect) answer based on what they believed was indicated on the label. Qualitatively, we know that caregivers think critically about how to adjust dosing to best suit their child’s needs based on weight and symptoms. These
results suggest that more information should be presented on the label to eliminate dosing errors even though caregivers believe the dosing instructions are already “very clear.”

Caregivers Understanding of Child Weight

The Simon and Weinkle study summarized the findings when surveys were collected from caregivers during visits to the Emergency Department at Egleston Children’s Hospital in Atlanta, GA. When those caregivers were asked if they knew the exact weight of their child, only 66% claimed that they did – even though they had just seen their children being weighed in the triage department of the hospital.11 This raises a concern that even if caregivers desire weight based dosing, they may not know their child’s exact weight at the time of administration. The qualitative data from Senter’s focus groups indicated that caregivers desired to have weight added to the age recommendations for dosing on children’s cough and cold medication labels. Caregivers in the Senter’s pilot study cited that many of their individual children were considerably smaller when compared to their classmates, and therefore were considered underweight.9 The survey responses from the current study indicate instead that the majority of caregivers have a clear understanding of their children’s current weight. Seventy-one percent of respondents indicated they have knowledge of their children’s weights using a validated measuring tool.

Only 45% of respondents answered that they would follow the manufacturer’s directions for dosing based on age only when caring for an under or overweight child. The remaining respondents were either not sure which action they would take, or adjusted the dose based on the child’s weight. This suggests that the majority of caregivers (53.2%) responded that they would prefer weight and age based labeling in order to eliminate ambiguity in the directions because they are unsure of the appropriate dose. Alternatively, caregivers may be incorrectly confident in
their own abilities to adjust medication dosing based on the weight of their own child, further supporting the need for weight and age based dosing so caregivers do not need make off label dosing decisions. Where weight ranges are used for dosing, product labeling should be updated to include a statement that advises caregivers to ensure their understanding of current weight is based on a measurement using a validated tool, such as a bathroom scale.
CHAPTER 6

CONCLUSIONS & RECOMMENDATIONS

Conclusions

The primary purpose of the research was to assess caregiver comprehension of over-the-counter cough and cold medication label dosing instructions. In the mock dosing scenarios, label comprehension was mixed. More respondents provided the correct dose and frequency in the second mock dosing scenario (Robitussin® Cough & Cold Long Acting) than the first (Triaminic® Cough & Cold), because the table presented on the Robitussin® label was clearer. However, even in the second mock dosing scenario, where performance was improved over the first mock dosing scenario, a quarter of respondents still provided an incorrect answer.

When the results were evaluated comparing the responses between Group 1 (high income/high education) and Group 2 (low income/low education) it was shown that there is no statistical difference between groups in either dosing scenario. Therefore, it can be concluded that in the studied population neither income nor education level impacted the respondent’s ability to provide the correct answer to either mock dosing scenario.

In all groups, caregivers were more likely to choose the recommended dose or a lower than the recommended dose, suggesting that the probability of an adverse event occurring due to over-dosing is low. Caregivers are more likely to choose a sub therapeutic dose.

In the mock dosing scenario 1 (Triaminic® Cough & Cold), the logistic model predicts that with increasing functional health literacy score, respondents are more likely to choose the correct dosing scenario. In all scenarios, regardless of functional health literacy, respondents
who answered incorrectly are more likely to under dose than over dose the child. It is recommended that this test be repeated in a more population that has a wider range of functional health literacy scores to confirm these results.

While the results of Senter’s study contrasts with the findings of the Eiland, et. al, the current research supports Eiland, et. al.’s conclusion that the majority of caregivers would more often seek the opinion of the physician, nurse or pharmacist to clarify dosing discrepancies than other sources of information including family members who work in the medical profession, and the internet.

Consistent with Senter’s pilot study, caregivers indicated that dosing directions of children’s over-the-counter cough and cold medications are most effectively communicated in a table format rather than a bulleted list. Focus group respondents from Senter’s study were split with regards to preference for Directions section location within the product label. The current research concludes that caregiver comprehension of dosing directions could be improved if the Directions section were placed “at the top of the label”, above the Active Ingredients.

While the majority of caregivers surveyed ranked the dosing directions on the Triaminic® Cough & Cold label as “very clear,” only 35% of respondents correctly identified the appropriate dose in the mock dosing scenario for this label. It is speculated that caregivers overestimate their ability to provide the correct dosing based on age alone. However, since the majority of caregivers have an understanding on child weight, weight and age information should be presented on the label to reduce dosing errors even though caregivers believe the dosing instructions are already “very clear.”
Recommendations

There are several recommendations for improving the content and format for over-the-counter cough and cold medication labels. From a regulatory perspective, structured age and weight based dosing should be required because caregivers are incorrectly confident in their abilities to adjust medication dosing based on the weight of their own child. Updates to the established OTC monograph, 21 CFR 341 (Cough, Cold Allergy, Bronchodilator, Anti-asthmatic Drug Products for over-the-counter Human Use), would require product manufactures to make these labeling changes so caregivers do not need make off label dosing decisions. Where weight ranges are used for dosing, the Drug Facts box section of product labeling should be updated to include a statement that advises caregivers to ensure their understanding of current weight is based on a measurement using a validated tool, such as a bathroom scale. Caregivers clearly prefer when dosing directions are presented in a table format rather than a bulleted list and the regulations should be updated to make the table format a requirement.

Because caregivers are confused about dosing, product manufacturers should provide additional information to supplement the label that would help explain how the medication should be administered. The source of the confusion seems to be mostly related to age and weight variations. Therefore product manufacturers could provide information related to safety and efficacy in over and underweight children. Physicians, nurses and pharmacists need to be aware that they are the most trusted source of information for caregivers dealing with dosing discrepancies.

Limitations of the Study

To eliminate sources of variability in this study and to maintain consistency with Senter’s pilot study, participants were screened out if their primary language not English. The
demographics of the respondents based on those who chose to participate were biased towards married, Caucasian individuals. The study design could be improved by including more of the excluded demographics like non-English speaking subjects and those from other ethnic groups in future research. Research in these other populations might support the need for bi-lingual labeling for non-English speaking sub populations.

The conclusions drawn relating to the Functional Health Literacy of respondents and impact on predicted responses to mock dosing scenarios could be enhanced in future studies. It has been concluded that a sampling error inadvertently occurred as a result of the survey design in the current study causing the majority of respondents to score highly on the functional health literacy exam. To improve the design, participants should be grouped by Functional Health Literacy at the beginning of the study rather than the end by using the TOFHLA exam as screening criteria. This would provide a more diverse sample set to support the conclusions made in this study.

Further research should be conducted to confirm that the Robitussin® Cough & Cold Long Acting table format, where the age and dosing amount are presented in the same row, is the most effective method for communicating dosing directions. Future research should continue to evaluate the impact of adding age and weight based dosing to support recommendations for product labeling changes and to understand the probability of overdosing in populations other than those currently studied.
APPENDIX A

LITERATURE REVIEW BIBLIOGRAPHY


APPENDIX B

STUDY QUESTIONAIRRE FOR ONLINE PROGRAMMING

QUOTA GROUPS

<table>
<thead>
<tr>
<th></th>
<th>Group 1</th>
<th>Group 2</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Income $52,090 or less</td>
<td>170</td>
<td>0</td>
<td>170</td>
</tr>
<tr>
<td>Income over $52,090</td>
<td>0</td>
<td>170</td>
<td>170</td>
</tr>
<tr>
<td>Total</td>
<td>170</td>
<td>170</td>
<td>340</td>
</tr>
</tbody>
</table>

CUSTOMER LANDING PAGE

Thank you for your interest in our study. This study is being conducted as part of a master’s thesis and is designed to better understand how you interpret over-the-counter medication labeling. The research will be used to update labeling on over-the-counter medication so that it is more easily understandable by parents and caregivers.

The first portion of the test will focus on your current over-the-counter dosing behavior. During the second portion, we will administer a standardized test that measures your ability to read standard medical instructions. This test has been developed by doctors and approved by the National Institutes of Health as a reliable indicator of patients’ ability to read health-related materials. Some of the sentences will seem straightforward. We appreciate your completing the exercise to the best of your ability so that we can accurately gauge your medical literacy.

Throughout the survey, your responses are confidential and will not be attributed to you. The survey will be reported in aggregate, and not on an individual level. Your name will not be reported with your survey responses. We appreciate your honest opinions.

The survey should take approximately 15 minutes, but could be somewhat shorter or longer depending on how you answer certain questions. Your participation in this study is voluntary, and you are free to withdraw from the survey at any time for any reason. Following the completion of the survey, you will be compensated for your time and effort.

If you have any questions before, during, or after the survey, please contact surveys@standpointgroup.com. By clicking the “Next” button below, you give your informed consent to participate in this survey.
SCREENING QUESTIONS

S1. Which range includes your age?
   a. Under 18
   b. 18 – 24
   c. 25 – 30
   d. 31 – 40
   e. 41 – 50
   f. Over 50
   [IF S1 ≠ b, c, d, OR e, TERMINATE]

S2. Which of the following is your primary language?
   a. English
   b. French
   c. Spanish
   d. German
   e. Chinese
   f. Other
   [Randomize a-e]
   [IF S2 ≠ a, TERMINATE]

S3. Which of the following best describes the highest level of education you have completed?
   a. Some high school
   b. High school diploma
   c. Some college or trade/technical school
   d. Technical degree
   e. Bachelor’s degree
   f. Master’s degree or higher
   g. Prefer not to say
   [IF S3 = g, TERMINATE]

S4. Please select the option that best describes your total annual household income.
   a. $52,090 or less
   b. More than $52,090
   c. Prefer not to say
   [IF S4 = c, TERMINATE]
S5. How many children between the ages of 2 and 12 live in your household at least 50% of the time?
   a. 0
   b. 1
   c. 2
   d. 3
   e. 4
   f. 5
   g. 6 or more
   [IF S5 =a OR g, TERMINATE]

S6. Please select the age(s) of your child(ren).
   (If you have multiple children, select all appropriate ages).
   a. 2 years old
   b. 3 years old
   c. 4 years old
   d. 5 years old
   e. 6 years old
   f. 7 years old
   g. 8 years old
   h. 9 years old
   i. 10 years old
   j. 11 years old
   k. 12 years old
QUESTIONNAIRE

Please review the labeling for Triaminic® Cough & Sore Throat before answering the following questions.

[Insert Triaminic® Cough & Sore Throat graphic]
Q1. To which of your children would you administer Triaminic® Cough & Sore Throat? (Please select all of the appropriate ages.)

a. 2 years old [IF S6=a]
b. 3 years old [IF S6=b]
c. 4 years old [IF S6=c]
d. 5 years old [IF S6=d]
e. 6 years old [IF S6=e]
f. 7 years old [IF S6=f]
g. 8 years old [IF S6=g]
h. 9 years old [IF S6=h]
i. 10 years old [IF S6=i]
j. 11 years old [IF S6=j]
k. 12 years old [IF S6=k]

Q2. After reviewing the labeling for Triaminic® Cough & Sore Throat, what dose would you administer to a 6 year old child?

[Insert Triaminic® Cough & Sore Throat graphic]

a. 1 teaspoon
b. 1.5 teaspoons
c. 2 teaspoons
d. 1 Tablespoon
e. 1.5 Tablespoons
f. 2 Tablespoons
g. I am not sure

Q3. How often would you administer [Insert response from Q2] to a 6 year old child?

[Insert Triaminic® Cough & Sore Throat graphic]

a. Once every 2 hours
b. Once every 4 hours
c. Once every 6 hours
d. Once every 8 hours
e. Once every 10 hours
f. Once every 12 hours
g. I am not sure
[IF Q2≠c AND Q3≠b]
Q4. Why did you select [Insert response from Q2] [Insert response from Q3]?
For example, this may read “Why did you select 1 teaspoon once every 2 hours?”

[Record open-ended response]

Please review the labeling for Robitussin® Children’s Cough Long Acting before answering the following questions.
[Insert Robitussin® Children’s Cough Long Acting graphic]
Q5. To which of your children would you administer Robitussin® Children’s Cough Long Acting? (Please select the appropriate child’s age. Please select all that apply.)

a. 2 years old [IF S6=a]
b. 3 years old [IF S6=b]
c. 4 years old [IF S6=c]
d. 5 years old [IF S6=d]
e. 6 years old [IF S6=e]
f. 7 years old [IF S6=f]
g. 8 years old [IF S6=g]
h. 9 years old [IF S6=h]
i. 10 years old [IF S6=i]
j. 11 years old [IF S6=j]
k. 12 years old [IF S6=k]

Q6. After reviewing the labeling for Robitussin® Children’s Cough Long Acting, what dose would you administer to a 6 year old child? [Insert Robitussin® Children’s Cough Long Acting graphic]

a. 1 teaspoon
b. 1.5 teaspoons
c. 2 teaspoons
d. 1 Tablespoon
e. 1.5 Tablespoons
f. 2 Tablespoons
g. I am not sure

Q7. How often would you administer [Insert response from Q6] to a 6 year old child? [Insert Robitussin® Children’s Cough Long Acting graphic]

a. Once every 2 hours
b. Once every 4 hours
c. Once every 6 hours
d. Once every 8 hours
e. Once every 10 hours
f. Once every 12 hours
g. I am not sure

[IF Q6≠a AND Q7≠c]

Q8. Why did you select [Insert response from Q6] [Insert response from Q7]?
For example, this may read “Why did you select 1 teaspoon once every 2 hours?”

[Record open-ended response]

Please take a moment to review the labeling and the answer the following questions.
**Q9.** How easy was it for you to locate the **dosing directions**?

<table>
<thead>
<tr>
<th>Not At All</th>
<th>Easy</th>
<th>Very Easy</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

**[IF Q9 = 1 OR 2]**

**Q10.** Why did you feel that it was difficult to locate the **dosing directions**?

[Record open-ended response]
Q11. Where would the dosing directions be easiest to locate?

a. At the top above the Active ingredients
b. At the bottom, below the Inactive Ingredients
c. Between the Uses and the Warnings sections
d. Between the Warnings and Other Information sections
e. The placement of the directions does not make a difference to me. As long as they are on the label, I will be able to locate them.

[Randomize a-c]
[Show graphics instead of words – StandPoint will create from labels for Triaminic® and Robitussin® labels]

Q12. Why is this placement more effective?

[Record open-ended response]
Q13. How clearly did the Directions section indicate the proper dose and schedule for your child(ren)?

<table>
<thead>
<tr>
<th>Not Clearly At All</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>Very Clearly</th>
<th>5</th>
</tr>
</thead>
</table>

Q14. How could the Directions be made clearer?

[Record open-ended response]

Q15. Which format most effectively communicates the dosing directions?

a. Bullet list

- Children under 4 years of age – Do not use
- Children 4 to under 6 years of age – 1 teaspoonful (5mL)
- Children 6 to under 12 years of age – 2 teaspoonfuls (10mL)

b. Table

<table>
<thead>
<tr>
<th>Age</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children under 4 years of age</td>
<td>Do not use</td>
</tr>
<tr>
<td>Children 4 to under 6 years of age</td>
<td>1 teaspoonful (5mL)</td>
</tr>
<tr>
<td>Children 6 to under 12 years of age</td>
<td>2 teaspoonfuls (10mL)</td>
</tr>
</tbody>
</table>

[Randomize a-b]
[Show graphics of table and bulleted directions]

Please consider ALL Children’s Over-the-Counter Cough and Cold medications you may have used in the past when answering the following questions:

Q16. Which types of dose delivery devices do you use most often when dosing your child(ren)?

a. Kitchen utensils such as a standard table spoon or soup spoon
b. Measuring spoons such as a Tablespoon or a teaspoon
c. Measuring cups such as those supplied with the medication
d. Droppers
e. Other (please specify)

[Randomize a-d]
Q17. Currently, do you know the **EXACT** weight of your child(ren) using an accurate measuring device (such as a bathroom scale)?

a. Yes  
b. No  
c. I am not sure

Q18. Suppose you were caring for a child that is **over weight** for his/her age, and this child needed an Over-the-Counter cough and cold medicine. Which of the following solutions would you employ?

a. I would increase the dose from the manufacturer’s directions based on the weight of the child  
b. I would decrease the dose from the manufacturer’s directions based on the weight of the child  
c. I would follow the manufacturer’s directions based on the age of the child  
d. I am not sure  
[Randomize a-c]

Q19. Now, suppose you were caring for a child that is **under weight** for his/her age, and this child needed an Over-the-Counter cough and cold medicine. Which of the following solutions would you employ?

a. I would increase the dose from the manufacturer’s directions based on the weight of the child  
b. I would decrease the dose from the manufacturer’s directions based on the weight of the child  
c. I would follow the manufacturer’s directions based on the age of the child  
d. I am not sure  
[Randomize a-c]

Q20. Currently, Over-the-Counter medications’ dosage directions are based on the child’s age. Which method would enable you to most accurately dose your child?

a. By age  
b. By weight  
c. By weight and age  
d. I am not sure  
[Randomize a-c]

Q21. How many times in a month do you give your child an Over-the-Counter medication (such as Benedryl®) to help them sleep (when they are not sick)?

a. Less than once per month  
b. 1-3 times  
c. 4-6 times
d. More than 6 times

Q22. Please think of the last time a child in your care had an adverse reaction/event related to an Over-the-Counter cough and cold product. Which of the following best describes how you responded?

(Please select all that apply)

a. I called my child’s physician
b. I took my child to the emergency room
c. I waited to see if the reaction resolved itself without interaction
d. I wrote a letter to the manufacturer of the medication
e. I reported the event to the FDA’s MedWatch program
f. My child has never had an adverse reaction to an Over-the-Counter cough and cold product
g. Other (please specify)

[Randomize a-f]

Q23. What was the cause of the adverse reaction?

(Please select all that apply)

a. An allergic reaction to the medication
b. A reaction between the medication and other medications my child was taking
c. Too little or too much food taken with the medication
d. The dose of the medication was too large
e. The manufacturer’s recommendation was not appropriate for the size of the child
f. Other (please specify)
g. Unknown

[Randomize a-e]

Q24. Which of the following situations have you encountered?

(Please select all that apply)

a. A physician / nurse / pharmacist recommended an over-the-counter cough and cold medication, but the manufacturer’s directions did not recommend the product for my child’s age
b. A physician / nurse / pharmacist recommended an over-the-counter cough and cold medication, but the manufacturer’s recommended dose did not match the dose recommended by the physician / nurse / pharmacist.
c. A physician / nurse / pharmacist recommended an over-the-counter cough and cold medication, but the manufacturer’s recommended schedule did not match the schedule recommended by the physician / nurse / pharmacist.
d. None of the above
e. I am not sure

[Randomize a-c]
[IF Q24=d OR e]

Q25. When the manufacturer’s dosing directions did not exactly match the physician/ nurse/ pharmacist’s, what did you do?  
(Please select all that apply)

a. I called the physician/nurse/pharmacist for clarification
b. I called a family member/friend who works in the medical profession to get their opinion.
c. I called my mother for her advice
d. I searched the Internet for more information
e. I dosed the child based on my physician/nurse/pharmacist’s recommendations
f. I dosed the child based on the manufacturer’s directions.
g. I did not use the medication
h. I am not sure

[Randomize a-g]

[IF Q24=d OR e]

Q25a. Suppose the manufacturer’s dosing directions did not exactly match the physician/ nurse/ pharmacist’s, what would you do?  

a. I would call the physician/nurse/pharmacist for clarification
b. I would call a family member/friend who works in the medical profession to get their opinion.
c. I would call my mother for her advice
d. I would search the Internet for more information
e. I would dose the child based on my physician/nurse/pharmacist’s recommendations
f. I would dose the child based on the manufacturer’s directions.
g. I would not use the medication
h. I am not sure
LITERACY COMPREHENSION QUESTIONS

You are almost done! The following questions comprise a standardized test that evaluates your understanding of health care information such as prescription labels and instructions for common medical practices. It is important for our research to have an accurate assessment of your functional health literacy so please answer the questions to the best of your ability.

Here are some medical instructions that you or anybody might see around the hospital. These instructions are in sentences that have some of the words missing. Where a word is missing, a blank line is drawn, and we provide possible words that could go in the blank as answer options. We would like you to figure out which of the 4 answer options should go in the blank, which word makes sense in the sentence. When you think you know which one it is, select the corresponding answer option and go on to the next one. Keep going until you finish all the questions.

T1. Your doctor has sent you to have a ________ X-ray.
   a. stomach
   b. diabetes
   c. stitches
   d. germs

T2. You must have an _________ stomach

   Blank G
   a. asthma
   b. empty
   c. incest
   d. anemia

T2a when you come in for ________.

   a. is.
   b. am.
   c. if.
   d. it.

T3. The X-ray will _________ from 1 to 3
   a. take
   b. view
   c. talk
   d. look

T3a. _________ to do.

   a. beds
   b. brains
   c. hours
   d. diets
T4. For supper have only a __________ snack of fruit,
   a. little
   b. broth
   c. attack
   d. nausea

T4a. __________ and jelly, with coffee or tea.
   a. toes
   b. throat
   c. toast
   d. thigh

T5. After __________,
   a. minute,
   b. midnight,
   c. during,
   d. before,

T5a. you must not __________ or drink
   a. easy
   b. ate
   c. drank
   d. eat

T5b. anything at __________
   a. ill
   b. all
   c. each
   d. any

T5c. until after you have __________ the X-ray.
   a. are
   b. has
   c. had
   d. was

T6. Do not eat __________.
   a. appointment.
   b. walk-in.
c. breakfast.
d. clinic.

T7. Do not __________
   a. drive,
   b. drink,
   c. dress,
   d. dose,

T7a. even __________
   a. heart.
   b. breath.
   c. water.
   d. cancer.

T8. If you have any __________
   a. answers,
   b. exercises,
   c. tracts,
   d. questions,

T8a. call the X-ray __________ at 616-4500.
   a. Department
   b. Sprain
   c. Pharmacy
   d. Toothache

T9. I agree to give correct information to __________ if I can receive Medicaid.
   a. hair
   b. salt
   c. see
   d. ache

T10. I __________ to provide the county information
   a. agree
   b. probe
   c. send
   d. gain

T10a. to __________ any statements
a. hide  
b. risk  
c. discharge  
d. prove

T10b. given in this _________

a. emphysema  
b. application  
c. gallbladder  
d. relationship

T10b. and hereby give permission to the _________ to get such proof.

a. inflammation  
b. religion  
c. iron  
d. county

T11. I _________ that for Medicaid I must report.

a. investigate  
b. entertain  
c. understand  
d. establish

T11a. any _________ in my circumstances

a. changes  
b. hormones  
c. antacids  
d. charges

T12. within _________ (10) days

a. three  
b. one  
c. five  
d. ten

T12a. of becoming _________ of the change.

a. award  
b. aware  
c. away  
d. await
T13. I understand _________ if I DO NOT like

   a. thus  
   b. this  
   c. that  
   d. than  

T13a. the _________ made on my case,

   a. marital  
   b. occupational  
   c. adult  
   d. decision  

T13b. I have the _________ to a fair hearing.

   a. bright  
   b. left  
   c. wrong  
   d. right  

T14. I can _________ a hearing

   a. request  
   b. refuse  
   c. fail  
   d. mend  

T14a. by writing or _________ the county where I applied.

   a. counting  
   b. reading  
   c. calling  
   d. smelling  

T15. If you _________ TANF

   a. wash  
   b. want  
   c. cover  
   d. tape  

T15a. for any family _________ ,

   a. member,  
   b. history,  
   c. weight,  
   d. seatbelt,
T15b. you will have to _________ a different application form.

a. relax
b. break
c. inhale
d. sign

T16. _________ , we will use

a. Since,
b. Whether,
c. However,
d. Because,

T16a. the _________ on this form

a. lung
b. date
c. meal
d. pelvic

T16a. to determine your _________.

a. hypoglycemia.
b. eligibility.
c. osteoporosis.
d. schizophrenia.

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**DEMOGRAPHIC QUESTIONS**

You are almost done! We only have a few more questions for you.

The following questions are for classification purposes only.

**D1. Which of the following best describes your ethnicity?**

*Please select all that apply)*

a. African American/Black
b. Asian
c. Caucasian/White
d. Native American Indian
e. Pacific Islander
f. Spanish/Hispanic/Latino
g. Other
h. Prefer not to answer

D2. Are you....
a. Married
b. Single
c. Divorced
d. Separated
e. Widowed
f. Prefer not to answer

You are now finished with the survey. Thank you for your time!
REFERENCES


16 Corenett, Theresa. Email communication dated June 28th, 2011.


23 DeCorso, Ben. Interview with Ben DeCorso, Biostatistician. June 30th, 2011.