Connecting Pharmacy and Literacy: The North Carolina Medication Information Literacy Project

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The purpose of this study was to involve pharmacy students in a project designed to evaluate the comprehension of consumer-directed, the counter (OTC) medication information. This project was conducted statewide in North Carolina and was coordinated through an alliance of the University of North Carolina at Chapel Hill School of Pharmacy and the North Carolina Area Health Education Centers (AHEC) Program. Two other goals of this project were to expose pharmacy students to research and provide collaborative experience for AHEC-based faculty. The project was implemented over a three-month period during the fall of 1998 and included completion of patient comprehension surveys. Each study participant read an example of OTC patient instructions. Afterwards, students asked questions directly related to the OTC information. Surveys of 878 participants were completed. A comprehension score was calculated based on eleven questions obtained from the participant response form. Comprehension scores ranged between 6.7 and 8.4 using a scale that was based on the eleven questions worth one point each. Students were also asked to provide feedback by survey regarding how participant selection was conducted and a debriefing session allowed for discussion about project experience and improvement. This study indicates that OTC medication instructions are difficult to interpret for many consumers, that student participation in a community research project is a useful learning experience, and that geographically dispersed faculty can conduct collaborative research.

INTRODUCTION

Health care systems today require that patients be able to read and understand medication information. Inadequate literacy skills can be a barrier to good health care. In general, individuals with the lowest literacy have poorer health, higher expenses for health care, more outpatient visits, and a greater likelihood of hospitalization than those with better-developed reading skills(1). The high rate of illiteracy in the United States was illustrated by the 1992 National Adult Literacy Survey (NALS), which examined reading skills of 26,000 adults(2). Extrapolating the NALS data, it is predicted in North Carolina that nearly 22 percent (1.1 million) of the state’s residents demonstrate “level one functional literacy skills” (level one = lowest and level five = highest). These adults would likely have serious literacy difficulties and need significant instruction.

Functional health literacy is the ability to read and comprehend information on medication bottles, appointment slips, and other essential health-related materials required to function as a patient. A person’s functional health literacy may be worse than their general literacy(3). The NALS did not specifically test health literacy. However, there have been a number of studies, which have addressed a patient’s health literacy(4-6). Together, these studies found that many patients do not have adequate health literacy skills to function successfully in health care systems.

The marginally literate person can sound out a sentence, but may not be able to understand the meaning or be able to respond to written instructions. It has been reported that nearly 42 percent of hospitalized patients surveyed, were unable to comprehend directions for taking medicine on an empty stomach(4). It is estimated that the average reading level of the American public is at seventh- to eighth-grade level. According to research, consumers need to read at the ninth-grade level to accurately interpret information on over-the-counter (OTC) medication labels(7).

In 1995, OTC and diagnostic agents amounted to over 20 billion dollars in sales for the United States(8). The majority of OTC sales are to the elderly, especially for cough and cold products. Safe and effective use of these products is not only dependent on adherence to directions, but to the understanding of warnings and contraindications that accompany the OTC product. Currently, this information varies in content and format on OTC product labels. The information is often written with language that is at a greater reading level than the reading ability of the consumer. Additionally, the print size, layout and design, and lack of diagrams may reduce readability. The end result is potential consumer misuse of OTC medications leading to an adverse effect or treatment failure. Comprehension of medication information, including preoperative instructions, consent forms and advance directives has been studied in various populations(4,6). However, we found no studies regarding comprehension of OTC medication information.

North Carolina is divided into nine Area Health Education...
Centers (AHEC) regions and each AHEC provides clerkship training for approximately 12 pharmacy students per year. The main objective of this project was to assess patient comprehension of an OTC medication insert, while jointly involving faculty and students in a meaningful research project on a statewide level. Equally important goals were to give students experience in administering a literacy survey regarding medication information, while exposing them to a process of conducting community-based research. A project was designed and implemented through the University of North Carolina at Chapel Hill School of Pharmacy and the North Carolina AHEC Program.

METHODS

The project was conducted in the fall semester of 1998. Each of the 117 full-time pharmacy students was asked and encouraged to survey 10 patients or customers in two out of three clerkship rotations (totaling 20 interviews per student) during a three-month period. A project packet, including guidelines for students, preceptors and AHEC faculty was developed and used for this project. Inclusion criteria included individuals who could speak English, were alert and oriented, and were 12 years of age or older. Prior to project implementation, students attended an orientation session in their AHEC, where data collection forms and instructions for the protocol were reviewed. In addition, AHEC faculty presented a complete simulated patient interview session. The Institutional Review Board at the University of North Carolina at Chapel Hill approved this study exempt, but a voluntary abbreviated informed consent statement was implemented. Students read the informed consent statement to each participant, which was then signed by the study participant or their parent.

Patients or customers were chosen for participation in this study by convenience. Many individuals were selected as they came into the pharmacy or clinics and the student preceptor was encouraged to help in participant selection. Student feedback regarding how individuals were selected for the study participation was collected (Appendix A). Demographic data were collected on all individuals approached. If the participant either could not read, did not have their reading glasses, or chose not to participate further, the student thanked the individual for their participation and the process ended. If the participant agreed to continue, then the comprehension survey was completed.

A commonly used OTC medication, Tylenol® Allergy/Sinus, was selected for use in this study. Information on the package insert was used in this project and was renamed Systemo® Allergy/Sinus (Appendix B). The medication information for Systemo® Allergy/Sinus was extracted directly from the Physician Desk Reference for Non-Prescription Drugs(9). Except for the font size, the information in Appendix B was exactly the same as contained in the OTC Tylenol® Allergy/Sinus package insert. The material to be read was divided into four general sections including medication instructions, indications, cautions and potential side effects. It was typed in 14 point Times New Roman font except for the last section, which was matched to the font size of a typical consumer box of Tylenol® Allergy/Sinus and typed at eight point Times New Roman. The reason the package insert was typed in a larger font size was to assure that participants could read the information for comprehension. The last section regarding directions for medication administration was typed in a similar font size found in the OTC package insert to evaluate only if the participant could read the small print size.

The students gave each participant the typed version of the Systemo® Allergy/Sinus insert. Once the participant completed reading each section, the students asked specific questions for that section and recorded answers on the participant response form. The participant was asked to read one section of the medication insert and the students recorded total reading time in minutes and seconds. Participants were allowed to refer back to the written information to locate answers to the questions, if necessary. This was incorporated to help alleviate any pressure the participant might feel if they were expected to remember everything from just one reading. Our purpose was to determine if they could understand and comprehend what they read, not if they could memorize what they read.

Students documented one answer on the participant response form that reflected the participant’s response (Appendix C). Students did not read the possible choices except in certain sections that specifically indicated them to do so on the participant response form.

Comprehension scores for participants were calculated using questions from the participant response form. The participant response form used by students while conducting each survey contained questions specifically related to the OTC Systemo® Allergy/Sinus material including medication instructions, indications, cautions and potential side effects. Three questions involved the definition of a health care professional, dosing in a child and the print font size, which were not included in the analysis. The comprehension scores were based on the total number of the eleven questions answered correctly and each correct question was assigned a value of one.

When the process was completed for each participant, students also completed a questionnaire designed to facilitate student reflection and feedback regarding the project. AHEC faculty conducted a debriefing session with students at the end of the three months data collection period to gain feedback about the process and the students’ experiences (Appendix D).

Frequency and percentage distributions were used to describe demographic and other characteristics of the study sample information with frequency data reported. One-way analysis of variance was used to examine differences in comprehension scores by characteristics of the participants. Student’s t-test was used to evaluate independent groups divided by age less than and greater than 50 years of age.

RESULTS

A total of 975 participants were approached and 878 completed the entire study. A total of 22 participants elected not to take part in the study because they could not read by their report, 33 did not have their reading glasses and 37 chose not to participate. Fifty-two of 117 students (44.5 percent) collected data for this project. Participants surveyed included 543 women and 330 men along with five who did not specify gender. The age breakdown is provided in Table I. There was an even distribution among age classes with a small amount of participation for the 12 to 20 year old category. Education level is also provided in Table I, with most individuals surveyed having at least some high school education. Most of those surveyed saw a doctor once a year and 67.8 percent took a medicine of some kind on a daily basis (Table II). When asked about reading ability, the majority of participants (92.2 percent) thought they could read at least fairly well (Table III).

The results by age indicate that the highest scores were achieved in the 20 to 29 year age group and the lowest score
Based on the student interview, most (82 percent) thought the person was convenient to approach. Most responses indicated that the person seemed approachable, 16 percent of participants indicated that they had some difficulty reading the smaller print contained in the Directions for medication use (Appendix B). A total of 19.6 percent of participants indicated that they had some difficulty, if any, in reading the smaller print contained in the Response Sheet (Appendix C) included a question regarding ability to read significantly correlated (P<0.05) with comprehension scores (Table III). When the data were divided into those who were less than or equal to 50 years of age and those who were greater than 50 years, there was a statistically different (P<0.05) comprehension score (8.0 ±1.7 versus 7.2 ± 2.0, respectively) for each group. The Student’s t-test was used to evaluate the two independent groups. There were no differences between comprehension scores related to gender among males by age, but females less than 50 years had comprehension scores that were higher (P<0.05) than those 50 years or greater (8.1 ± 1.6 versus 7.3 ± 1.9, respectively). In addition, the Participant Response Sheet (Appendix C) included a question regarding difficulty, if any, in reading the smaller print contained in the directions for medication use (Appendix B). A total of 19.6 percent of participants indicated that they had some difficulty and 4.4 percent responded that they had a lot of difficulty reading this section.

Each student completed a one-page survey on each participant (n=975) regarding information about the person selected to participate in the study (Appendix A). Forty-one percent of the responses indicated that the person seemed approachable, 16 percent indicated the person was convenient to approach. Most of the student responses (78 percent) revealed that the participant was positive and helpful with the study process. Based on the student interview, most (82 percent) thought the participant would comply with consumer medication information. In addition, there were 42.3 percent (22/52) of student debriefing questionnaires (Appendix D) were completed. A total of 95 percent of students indicated that the project made them more aware of the issues surrounding literacy. One AHEC center did not participate in the study and four AHEC sites had a low student participation rate.

DISCUSSION
The information obtained in this study shows that it is feasible for pharmacy students to conduct research and become exposed to the issue of patient literacy. Only 44.5 percent of potential students participated in this project. The overall response rate by students was, in part, influenced by AHEC faculty encouragement. Some faculty supported and encouraged students to complete this project, while others did not. In other situations, students could not identify appropriate patients because of the type of rotation they were completing during a particular month (e.g., intensive care unit). The results from the student reaction and action survey (Appendix A) indi-
Fig. 1. Revised over-the-counter example instructions.

cated that the students chose potential study participants based on the person seeming approachable. The majority found the research easy to implement. We achieved the primary goals of exposing pharmacy students to data collection, as well as targeting an awareness regarding the issue of literacy through this project. Further research in this setting would include the possibility of course credit to encourage participation and assessment of the students’ performance. In light of the overall low student participation in half of the AHEC sites, we would encourage full faculty participation from the onset of the project.

Each AHEC was also asked to hold a debriefing session (Appendix A) with the students to determine their perspective of this research project. The majority of the AHEC sites (eight out of 10) conducted this session with students. In general, the comments were mostly positive. Some students indicated that the project was worthwhile and an invaluable experience. Other post-study comments included the need for greater preceptor assistance in participant identification. Many students commented that the experience made them more aware of literacy and to explain medication information when counseling patients. For future projects, comments indicated that if students will be expected to collect data for research while on rotations, they would be more accepting and learn more during the process if course credit is given for the work.

The results of this study indicate that a large percentage of patients has some difficulty interpreting OTC medication instructions as evidenced by the overall comprehension scores (Table IV). The highest comprehension scores were achieved in the 20 to 29 year old age group. As education increased to at least a 10th grade level, there was a statistically significant difference \( P<0.001 \) in the ability to answer questions correctly. This is consistent with research that indicates at least a ninth-grade level is needed to accurately interpret OTC medication labels(7). The participant’s self-perception of reading ability significantly correlated \( P<0.001 \) with comprehension scores (Table III). We chose to break the group into those less than or equal to 50 years of age and those greater than 50 years, because about half of the group fell in each of these categories. Comprehension scores were higher for individuals 50 years or less, and women in this category had higher comprehension scores when compared to women or men greater than 50 years of age. A limitation of this research includes the use of a convenience sample instead of a randomized sample. Another drawback of these data is the fact that all students did not perceive the importance of completing the project to the same degree.

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References

APPENDIX A, UNC-CH PHARMACY STUDENT
PROJECT 1998-1999

Student Reactions/Actions
Student Name: ____________________ Participant Number____ Site __________ AHEC ___________ Date _____________

DIRECTIONS: After each interview, complete this form privately, in a setting separate from the participant. Please think back to before you had any interaction with the participant as you answer.

1. How/why did you select this person? (Check ALL that apply.)
   ____ I liked how the person was dressed.
   ____ Person seemed approachable.
   ____ Person smiled and spoke to me.
   ____ I thought the person would not read well.
   ____ I thought the person would read well.
   ____ I know the person.
   ____ It was a quiet time in the pharmacy.
   ____ No particular reason.
   ____ Other (specify) _______________________________

2. How did you expect the person to respond to your survey?
   (Check the single response that most closely reflects your initial expectations.)
   ____ Positively and in a helpful manner.
   ____ With resistance.
   ____ With concern that I was asking questions that were too personal.
   ____ Quickly and without much thought.
   ____ Other (specify)______________________________

3. Did you have any preconceived notion of how well this person would read and understand the material?
   ____ Yes - Go to #4
   ____ No - Go to #6

4. If “yes,” what was your preconceived notion? (Check the response that most closely reflects your initial expectations.)
The person would ...
   ____ easily read the items
   ____ adequately read the items
   ____ struggle with reading the items

5. What was your preconceived notion about how well the person would understand written instructions? (Check the response that most closely reflects your initial expectations.)
The person would...
   ____ understand all the items.
   ____ not understand all the items.

6. Based on this interview, which of the following do you expect to occur? The person will...
   ____ comply with consumer medication information.
   ____ NOT comply with consumer medication information.

7. Was participant able to read?
   ____ YES _______ NO _______ SOMEWHAT

8. What stood out from this experience that you will take with you?

APPENDIX B.

Systemo® ALLERGY SINUS

[Part A] Directions for use: Adults and children 12 years of age and older. Two caplets, gelcaps or geltabs every six hours. Do not exceed 8 caplets, gelcaps or geltabs in any 24 hour period. Not for use in children under 12 years of age.

[Part B] Indications: Provide effective temporary relief of runny nose, sneezing, itching of the nose or throat, and itchy, watery eyes due to hay fever or other upper respiratory allergies, nasal and sinus congestion and sinus pain and headaches.

[Part C] Warnings: Do not take this product unless directed by a doctor, if you have a breathing problem such as emphysema or chronic bronchitis, or if you have glaucoma or difficulty in urination due to enlargement of the prostate gland. Do not take this product if you have heart disease, high blood pressure, thyroid disease or diabetes unless directed by a doctor. If nervousness, dizziness or sleeplessness occur, discontinue use and consult a doctor. Avoid alcoholic beverages while taking this product. As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product. Do not take this product if you are taking sedatives or tranquilizers without first consulting your doctor.

[Part D] Use caution when driving a motor vehicle or operating machinery. May cause excitability, especially in children. May cause marked drowsiness: alcohol, sedatives and tranquilizers may increase the drowsiness effect.

[Part E] Directions for use: Adults and children 12 years of age and older. Two caplets, gelcaps or geltabs every six hours. Do not exceed 8 caplets, gelcaps, or geltabs in any 24 hour period. Not for use in children under 12 years of age.

APPENDIX C. PARTICIPANT RESPONSE SHEET

Participant Number_____________ Interviewers Initials __________ Site ___________ AHEC ___________ Date ___________

Part A: Please read PART A and let me know when you are ready to answer my questions.
Reading Start Time: _________ Reading End Time: ___________
REMEMBER: Allow the participant to refer to the written material when answering your questions. Do not erase or use white-out on the response sheet. To change what you have written, put a line through what you want to change, and initial it. In each case, check the one response that most nearly reflects the participant’s response. Do not read the choices except where specifically indicated. Allow participants to give their give their own answers.

1. Based on what you read, how often should you take this medication?
   - every six hours
   - don’t know
   - other (specify) ___________________________

2. What is the most of this medication that you can take in 24 hours?
   - 8 caplets
   - don’t know
   - other (specify) ___________________________

3. Based on your daily schedule, when would you take this medication to be sure to take it correctly?
   - every 6 hours
   - 3-4 time a day while I’m awake (any variation that ties into their lifestyle)
   - don’t know
   - other (specify) ___________________________

4. Can children take this medication? (Check only one response.)
   - children 12 years old or older can take this medication
   - yes
   - no
   - don’t know
   - other (specify) ___________________________

5. If a child is 10 years old but the size of an average 14-year old, what would you do about giving the child this medicine?
   - give the normal dose for a child over 12 years old (adult dose)
   - ask a health care professional about what I should do
   - give 1/2 the normal dose
   - give a children’s medication
   - don’t give it

6. Based on what you read, what is this medication used for?
   - allergy/sinus pain/headache/runny nose/itchy eyes (any of these listed)
   - don’t know
   - other (specify) ___________________________

7. For which of the following symptoms would you use this medication? (Read these choices slowly and check any “yes” responses)
   - hay fever
   - common cold
   - sinus headache
   - other (specify) ___________________________

8. Based on what you read, when should you consult a health care professional?
   - If I have nervousness/am pregnant/am sleepy (any of these problems)
   - I just stop taking and don’t consult anyone
   - If I have problems
   - If it doesn’t work
   - other (specify) ___________________________

9. Who would you call a health care professional? (Check all that apply)
   - doctor
   - nurse
   - pharmacist
   - don’t know
   - other (specify) ___________________________

10. If you have a headache, should you take this medicine if you also have ....? (Read these choices slowly and check any “yes” responses)
    - diabetes
    - high blood pressure
    - arthritis
    - heart disease
    - other (specify) ___________________________

Part D: Please read PART D and let me know when you are ready to answer my questions.

11. Based on your reading, what kinds of side-effects might this medication cause? (Check all that apply)
    - dizziness
    - increase appetite
    - nervousness
    - drowsiness only

12. If you took this medication and had side-effects, which of these activities would be dangerous to do? (Read these choices slowly and check any “yes” responses)
    - driving a car
    - watching television
    - using a power lawn mower

13. If you took this medication and you felt drowsy, it might cause you to feel more drowsy is you ...? (Read these choices slowly and check any “yes” responses)
    - drank a beer
    - took sleeping pills
    - ate a meal
    - took a tranquilizer

Part E: Please read PART E and let me know when you are ready to answer my questions.

14. How much, if any, difficulty did you have in reading the smaller print?
    - A lot
    - Some
    - Not much
    - None

Thank you for your time today. You’ve helped me a lot. Is there anything that I can answer for you related to this?
APPENDIX D. ORIENTATION AND DEBRIEFING
SESSIONS WITH AHEC FACULTY

Student Name ___________________________ AHEC__________
Sites: 1) __________ 2) ____________  Date__________________

DIRECTIONS: Complete this form after your debriefing session with your AHEC faculty.

1. What did you gain from the project orientation discussion session?
2. How can the orientation process be improved?
3. What did you gain from the project debriefing discussion session?
4. How can the debriefing process be improved?
5. What, if anything, will you do with your experience(s) from this project?
6. Is there some other project that could/should grow out of this one for future?