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# Test and Development of Pharmaceutical Pictorials

**Jennifer Snow Wolff** **Michael S. Wogalter**

*Jennifer Snow Wolff* is the owner of The Creative Factor, an information and graphic design firm located in Albany, New York. Ms. Wolff graduated with a B.A. from the State University of New York at Albany in Visual Technology and Media Effects. She has done information design consulting work in the Northeast and is working towards a graduate degree in technical communications and instructional technology.

*Michael S. Wogalter* is on the faculty in the Department of Psychology at North Carolina State University. He received a B.A. from the University of Virginia, an M.A. from the University of South Florida, and a Ph.D. from Rice University. Before coming to NCSU, he held faculty appointments at the University of Richmond and Rensselaer Polytechnic Institute. His principal research interests include safety, warnings, hazard perception, and human cognition. Mike holds memberships in several professional organizations including: Human Factors Society, American Psychological Association, American Psychological Society, Psychonomic Society, International Association of Applied Psychology, American Association of University Professors, Sigma Xi, among others. Requests for reprints should be addressed to him at the Department of Psychology, Poe Hall, North Carolina State University, Raleigh, NC 27695-7801.

## Abstract

This study tests the comprehension of a set of pharmaceutical pictorials from the U.S. Pharmacopoeia Convention. This research also documents the relatively unexplored area of pictorial redesign. Concepts not well communicated by the original pictorials were reworked with data collected from error analyses of participants' answers and drawings generated from focus group participants. Several redesigned pictorials have been developed for further testing. A set of preliminary guidelines for redesigning pictorials is offered.

## Introduction

The hazards and proper use of pharmaceutical drugs are not commonly known to most people. Often the only information available to consumers is the material found on the product label. However, for certain populations of users, this method of communication can be ineffective. The print on the labels may be too small for persons with poor vision (e.g., presbyiopics) or may not be understandable to persons lacking literacy or language proficiency.

Besides printed language, another potentially useful way to alert people to the proper use of medications is to communicate information via pictorials. Research has shown that pictorials can be identified at greater distances (smaller visual angle) than its associated-verbal message occupying the same surface area (e.g., Jacobs, Johnston, and Cole, 1975). Also, persons who do not understand the printed label could potentially acquire the information from the illustrations. These benefits, of course, assume that the pictorials are sufficiently well designed to convey the appropriate information to the user.

The U.S. Pharmacopoeia Convention (USPC) has introduced a set of pictorials that are accompanied by brief verbal labels. One purpose of the current study was to determine the understandability of these previously untested USPC pictorials.

A second purpose of the study is to document the relatively unexplored area of pictorial redesign. While attention has been given to the testing of already existing symbols and pictorials (e.g., Collins, Lerner, and Pierman, 1982; Laux, Mayer, and Thompson, 1989), little documentation exists on the procedures involved in

redesigning the pictorials after testing has shown that the pictorial is inadequate.

One reason for this lack research is that the initial testing of pictorials is often very costly (in terms of money, time, and effort). Additional work to develop and evaluate additional pictorials can be exorbitantly costly. However, it is important to determine how pictorials can be improved. The present study employs a set of relatively low-cost procedures to evaluate and redesign pictorials that fail to adequately convey their associated concept in earlier testing.

One of the major costs of testing pictorials is the collection of data from the relevant target populations (e.g., the elderly, illiterates, and non-English speakers). In the present research, this cost is reduced by performing preliminary iterative cycles of testing and redesign using easily obtainable participants. The reasonable working assumption is that if educated, literate individuals with good vision are not able to understand the pictorials, it probably indicates that the pictorials will not survive comprehension testing with more disadvantaged populations. Preparatory cycles of iterative redesign and test are used in advance of more formal test procedures involving higher-cost representative samples of the target population(s).

Because of its iterative nature, the project involves several stages. The current report presents the first six:

(1) 28 USPC pictorials were tested for comprehension;

(2) incorrect responses were examined and an artist reworked the pictorials into alternative designs;

(3) redesigned pictorials were tested for comprehension;

(4) the concepts, verbal labels and scoring criterion were reexamined;

(5) focus groups were used to gather information on alternative designs; and

(6) information gathered in Phases 4 and 5 were used to create a second set of alternative pictorial designs.

Not described in this report is a later (but not necessarily final) phase which will involve a full-scale comprehension test of randomly sampled individuals of representative target population groups.

## PHASE 1
## Initial Comprehension Testing of the USPC Pictorials

### *Method*

*Participants.* One hundred forty-three participants (103 males, 40 females) ranging in age from 9 to 60 (M=22.5, STD=8.16) from Rensselaer Polytechnic Institute and the Troy, NY community were tested.

*Materials and procedure.* Twenty-eight of the 30 USPC pictorials were tested (excluding pictorials concerning rectal and vaginal insertion). They were randomly ordered and assembled into 4-page booklets. Each page contained 6 to 8 pictorials accompanied by two blank lines below each pictorial. Pages of the booklet were randomized for each participant. Participants were asked to write the specific meaning of each pictorial in the blanks.

**FIGURE 1 Pictorials that Failed to Meet 85% Criterion in Initial Testing** (% of correct comprehension is shown in parentheses)

Do not store near heat or in sunlight (72%)

This medicine may make you drowsy (84%)

Do not break or crush tablets or open capsules (62%)

Take until gone (79%)

If you have questions, call this number (84%)

*Results and Discussion*

Responses were scored by two independent judges. Correct answers had to include the basic meaning of the description currently accompanying the USPC pictorials. Inter-observer agreement (number of times the two judges agree / number of opportunities to agree) was .95.

The standard used by the International Standards Institute (ISO) of at least 85% correct was invoked as a cutoff for evaluating correct comprehension. All but five of the pictorials reached or surpassed this criterion. The five pictorials that failed are shown in Figure 1.

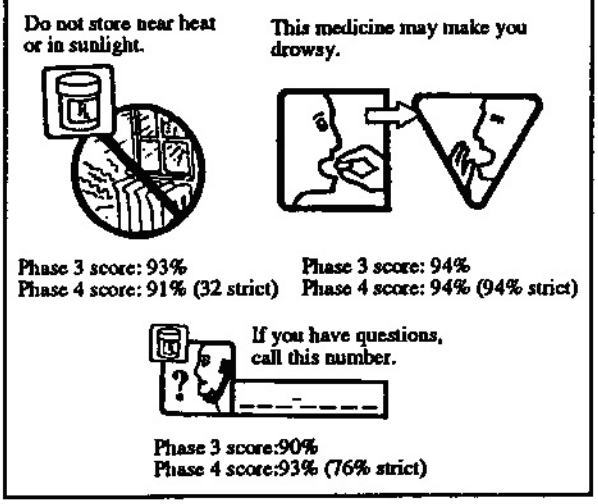
## PHASE 2
## Error Analysis and Redesign of Pictorials

The written responses for all of the pictorials were analyzed to identify why and how errors were made. Particular attention was directed to the five pictorials that failed to reach criterion. The error analysis suggested ways that some of the pictorials could be improved. The problems fell into three general categories: (a) poor depictions, (b) ambiguous language, and (c) difficulty conveying the passage of time. Examples are described below.

- The pictorial "Do not store near heat or in sunlight" produced numerous answers related to flammability. The frequency of these responses suggests that the depiction of flames is not a good indicator of the intended concept. This pictorial was redesigned to depict a common heat and light source, a radiator below a window with the sun shining through it (as shown in Figure 2).

- The pictorials "This medication may make you drowsy" and "Take medicine before you go to bed" were frequently confused. These pictorials were redesigned to illustrate effects across time (e.g., taking the medicine and then drowsiness). Generally, standards and guidelines of pictorial design recommend against multiple images, but this kind of depiction seemed necessary. The revised "drowsy" pictorial is shown in Figure 2. The "Take at bedtime" pictorial barely exceeded the 85% criterion (88%). A revision was made as an attempt to increase its understandability and distinguish it from the "drowsy" pictorial. The original and the Phase 2 revision are shown in Figure 3.

**FIGURE 2**
**Successful Revisions in Phase 3**




- The pictorial "Do not break or crush tablets or open capsules" (i.e., take whole) failed to reach criterion. Considered in the redesign was the possibility that a prohibited action may be confusing, because people may recognize the action, but fail to recognize that it is prohibited. The pictorial was redesigned to show both the positive event of taking whole pills and the prohibited event of not taking broken pills (as shown in Figure 4).

- The pictorial "Take until gone" is an example of the problem of respondents taking a pictorial too literally. Some participants incorrectly answered that one should consume half of the bottle's contents at one time. Three revisions were developed to depict consumption across a series of times. These pictorials are shown in the top section of Figure 5.

- The pictorial "If you have questions, call this number" just missed the 85% criterion. Error analysis indicated that several participants thought the number was only for emergencies. The revision in Figure 2 shows a calmer person.

## PHASE 3
## Testing Revised Pictorials

The pictorials that were designed or redesigned in Phase 2 were tested.

**FIGURE 3**
**The "Take at Bedtime" Pictorial**

ORIGINAL USPC
Phase 1 score: 88%

PHASE 2 REVISION

Phase 3 score: 57%
Phase 4 score: 56% (56% strict)

PHASE 6 REVISION

not yet evaluated

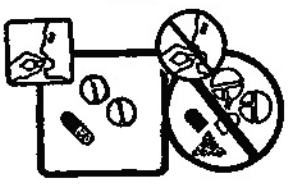
*Method*

*Participants.* One hundred twelve participants (85 males, 27 females) ranging in age from 18 to 48 (M=21.8, STD=5.4) from Rensselaer Polytechnic Institute and the Troy, NY community were tested.

*Materials and procedure.* Sixteen concepts were tested. Included were revisions of the five concepts that failed to reach the 85% criterion and six pictorials that reached the criterion, but had responses that indicated serious confusions or other problems. Also included were two original pictorials which had not been tested in Phase 1 and three additional pictorials were included as fillers. Up to three revisions per concept were evaluated. The pictorials were randomly assigned to a set of groupings and assembled into booklets, with the constraint that only one pictorial for a given concept was assigned to a grouping to avoid assisting subjects on subsequently answered versions. Thus, any one pictorial was seen only by a subsample of 28-66 participants. Otherwise the procedure was identical to Phase 1.

**FIGURE 4**
**Revisions of "Do not break or crush tablets or open capsules"**

PHASE 2



Phase 3 score: 58%
Phase 4 score: 68% (62% strict)

PHASE 6

not yet evaluated

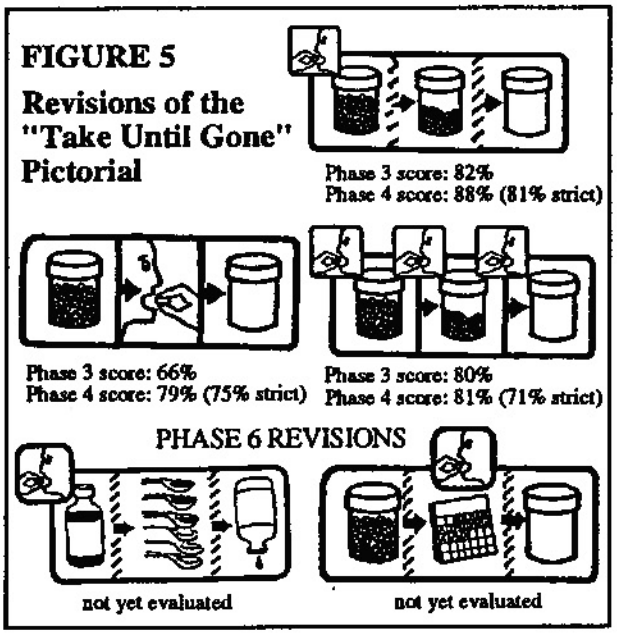
*Results and Discussion*

Scoring of pictorials was identical to Phase 1. Inter-observer agreement was .91. Percentage correct scores are shown below the revised pictorials in Figures 2-5. Two concepts failed to show a successful revision of 85% correct: "Do not break or crush tablets or open capsules" (Figure 4) and "Take until gone" (Figure 5). In addition, several other pictorials barely met the 85% criterion. Successful revisions are shown in Figure 2.

## PHASE 4
## Re-examination of Concepts and Scoring

Several scoring difficulties became apparent in Phase 3. Up to this point, a lenient criterion had been used to determine a passing score. While judges tended to agree using this criterion, when a stricter criterion was attempted, the judges had difficulties determining the correctness of the responses. An expert in pharmaceuticals from the Albany College of Pharmacy was contacted to help resolve some of the difficulties and establish better scoring criteria.

Booklets from Phase 3 were re-scored by three students of the pharmacy college according to both lenient and strict (i.e., its actual intended meaning) criteria. Averages of their scores (Phase 4) are shown below the earlier Phase 3 scores. In general, the Phase 3 scores and the pharmacy students' lenient scores tended to agree. However, the strict scores were lower and less consistent.




Some pictorials which initially passed using the earlier lenient criterion, now showed difficulties, indicating that the need for further work. Some of these cases are described below.

- Several pictorials and their associated verbal labels had unclear meanings. For example, most participants produced the correct verbal label for the pictorial "Wash hands." However, error analysis revealed that some participants gave answers of the need to wash hands *before* whereas other participants responded with an answer to wash hands *after*.

- For the pictorial "This medication may make you drowsy" (in Figures 1 and 2), several participants indicated that the medication was to be taken as a sleeping aid.

- For the pictorial "Do not break or crush tablets or open capsules," certain responses such as "take whole dose" imply that one can break the tablet as long as all of the broken pill is consumed. Pills with a coating or time-release must sometimes be swallowed whole to prevent improper short-term absorption or damage to the stomach lining. Therefore, under a more strict criterion the correct answer should be something more akin to "Swallow pill whole." It is unclear whether participants possibly understood this while writing something different.

- Another problem of language was identified in scoring the pictorial "Do not drink alcohol while taking this medication." The judges had difficulty determining from participants' brief verbal answers whether they understood the intended concept. For example, did the participants realize that one should not drink alcohol at any point (within some unstated time period) before and after consuming the medicine—not just at the point in time of actually consuming the medication?

## PHASE 5
## Visual Concepts from Focus Groups

Having identified several difficulties with some of the pictorials in Phases 3 and 4, additional data was collected on ten "problem" concepts in order to generate more ideas on how these concepts might be depicted in alternative ways. Interviews were held individually or in small groups with participants who were asked to draw pictures of these concepts.

### *Method*

*Participants.* A diverse group of 34 individuals (ranging in age from 10 to 80) with ethnic backgrounds including African-Americans, Asians, Hispanics, and Whites were tested and interviewed.

*Materials and procedure.* Test booklets contained short descriptive paragraphs of each concept at the top of otherwise blank pages. Participants were told to imagine the concept and then draw a picture as best they could. They were told drawing skill was unimportant and to label the components to help clarify meaning.

### *Results and Discussion*

The drawings were collated by concept. Consistent recurring images, if any, were counted, including whether the images showed a negative prohibition or a positive action, how the images were grouped, what kind of action was shown, etc. One example image that was suggested from the focus group data is the pictorial showing the knife cutting the pills in Figure 4.

## PHASE 6
## A Second Set of Alternative Designs

A second set of alternative pictorials were designed from ideas identified in the earlier phases including information from focus group drawings, expert advice, and error analyses. Examples of the newest pictorials are shown in Figures 2, 3, and 5. These pictorials have not yet been tested.

## General Discussion

This present research is part of a continuing study of pharmaceutical pictorials. Several basic points are demonstrated. First, preliminary testing of pictorials using readily available participants is a way of determining which pictorials are deficient (without the expense) before formal testing of representative groups of the target populations.

Second, it became clear that additional pictorials for the concepts are needed. This relates to the varied kinds of drug preparations and how they must be consumed (e.g., tablets, capsules, liquid, patches, injection). Visually depicting each of these methods of consumption would require a prohibitive number of pictorial labels if they aredesigned like most of the original USPC pictorials (with the inset image on the upper left corner showing the drug being taken by mouth). Use of oral consumption as the standard method of communicating consumption could potentially confuse the user to perform the wrong activity. This suggests the need for customized pictorials. For example, for a given prescribed regimen, the appropriate pictorial components could be selected and combined by a computer with graphics capabilities and then printed as part of the accompanying verbal label.

Third, several strategies of pictorial design were identified. Some are listed below:

(a) Low comprehension by participants as well as low reliability by judges are indications that the pictorial or the concept is not well understood.

(b) The kinds of errors made to the pictorials should be identified to provide information for their redesign. Particular attention should be given to critical confusion errors where the pictorial is interpreted in the completely wrong way.

(c) Another source of design ideas can be rough drawings of images from focus group subjects.

(d) The meaning of the concept and verbal message of the intended pictorial should be clarified. The verbal message associated with the pictorial may be incorrect or unclear.

(e) An expert in the subject domain may need to be consulted to clarify issues relating to the intended concepts. Expert information will help establish the criteria for scoring the comprehension tests.

(f) Although the original pictorials followed a pleasing and consistent visual pattern, this pattern may not be adequate to indicate certain concepts such as the passage of different periods of time. The pictorial grammar needs to be flexible to represent and distinguish between the concepts.

Finally, it should be mentioned that the present article only describes the initial phases of the project. A later phase will test the existing USPC pictorials and several of the redesigned pictorials representative, random samples of participants, stratified according to age, language skills and cultural background.

## Acknowledgements

Copyrights for the orignial pictorials are owned by U.S. Pharmacopoeia Convention (USPC). Appreciation is extended to USPC for giving permission to test them. Thanks to Professor Gary D. Hall of the Albany College of Pharmacy for his valuable input and to his students, Maria DeCroce, Melanie LeClau and Joe Bayne for scoring the pictorials. The authors also appreciate the help of Richard R. Duffy and Shin-Ju Chen of Rensselaer Polytechnic Institute for helping in the early stages of the study.

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