DESIGN AND EVALUATION OF A NEW PHARMACEUTICAL PICTOGRAM SEQUENCE TO CONVEY MEDICINE USAGE

L E Mansoor and R Dowse
Research Paper
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Leila E Mansoor, Bpharm, PhD Candidate (Rhodes University), Faculty of Pharmacy, Rhodes University, Grahamstown, P O Box 94, 6140, South Africa

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ABSTRACT

Pictorials may be used to augment textual instructions in the depiction of safety and warning information on medicines. The objective of this study was to design, develop and evaluate a simple and culturally appropriate pictogram sequence for using nystatin suspension, and to assess its understandability in low-literate Xhosa participants. A new pharmaceutical pictogram sequence was designed through focus group discussions and evaluated in a 2-phase process. The results of Phase 1 (30 participants) identified various problems associated with the new pictogram sequence. It was modified accordingly and re-evaluated in Phase 2 with 20 participants. All participants belonged to the Xhosa group, had between 0 and 7 years of formal schooling and had English as their second language. Acceptance of the new pictogram sequence was based on international standards (ANSI and ISO criterion) for evaluating the comprehensibility of pictograms. In Phase 1, the new pictogram sequence was correctly interpreted by 66.7% of the participants and this complied with the ISO criterion of 67% correct. In Phase 2, 95% of the participants were able to correctly interpret the new pictogram sequence. This result complied with the ANSI criterion of 85% correct, therefore, this new pictogram sequence was considered to be acceptable. This study has illustrated the success of using a consultative approach in the design of new pictograms.

Keywords: Pictogram, Design, Evaluation, Understandability and Culture

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INTRODUCTION

The use of warning signs and labels on consumer products is common in today's consumer market. Warning effectiveness may be influenced by the perception of the "hazards" or "danger" of the product: the greater the perceived danger of a product, the more cautious an individual will be in using it. Nonverbal symbols such as pictorials are increasingly being recommended and used to convey warnings and other safety-related information (Sojourner and Wogalter, 1998). Pictorials may be useful to persons who cannot read printed verbal messages because of inadequate reading skills or unfamiliarity with the language used in the message. One practical application of using pictorials to augment textual instructions is the depiction of safety and warning information on pharmaceutical products (Sojourner and Wogalter, 1997 and 1998).

While research into the effectiveness of pharmaceutical warnings is relatively limited, evidence to date indicates that people want to be informed of the benefits and the risks associated with medicines (Kalsher *et al.*, 1996). The effectiveness of good quality pharmaceutical labeling is crucial for the safe and effective use of medicines as most people are not aware of their appropriate use and their hazards. In many cases, the only printed information available to consumers at the time the product is consumed is usually the material found on the

product label. Unfortunately, for some consumers, this method of communicating instructions and potential hazards may be ineffective and potentially dangerous, particularly for the elderly and those persons lacking literacy or language proficiency. Difficulty is commonly experienced in reading the label itself owing to the small print size and the excessive amount of information compressed into a restricted area. This impacts negatively on the readability of medicine labels (Kalsher *et al.*, 1996; Dowse and Ehlers, 1998).

The limited literacy skills of a large proportion of the South African population present a significant barrier to accessing and understanding medicines information necessary for the degree of adherence required for a successful therapeutic outcome. The challenge facing health care professionals (HCPs) is to communicate this information in an appropriate, understandable form commensurate with the patient's literacy skills, and in addition, to ensure that it is acceptable in terms of the patient's culture, beliefs, attitudes and expectations. One way of addressing the low literacy problem is to use visual aids such as pictograms, which have been shown to enhance the comprehension and recall of information when used appropriately.

The United States Pharmacopoeial Convention (USPC) defined pharmaceutical pictograms as "*standardised graphic images that help convey medication instructions, precautions and/or warnings to patients and consumers"* (USP-DI, 1989). The design and evaluation of these pharmaceutical pictograms is a complex, multistage process. One of the main strategies to minimise problems in this process is to follow a basic ergonomic principle, which is to identify the target population and to involve that population in all stages of the design and evaluation process. The pictograms should firstly be tested in healthy participants from the target population, and only after the completion of this stage, should the successful designs be evaluated in a patient population to monitor for the effect of pictograms on the understanding of and adherence to medicine instructions (Dowse and Ehlers, 1998 and 2001).

A comprehensive set of pharmaceutical pictograms first appeared in the United States Pharmacopoeia Dispensing Information (USP-DI, 2000). However, South African researchers (Dowse and Ehlers, 1998 and 2001) predicted that the local black, low-literate patients in South Africa would only poorly comprehend a number of the symbols and concepts used in these pictograms. Consequently, a set of country-specific, culturally appropriate pictorial material to relay information to this population group was designed and evaluated by these researchers. Many of these "modified" South African pictograms (hereafter referred to as SA pictograms) have been used in this study (Dowse and Ehlers, 1998 and 2001).

Confucius once said, "*A picture is worth a thousand words*". However, a better way of saying it for the purposes of patient education may be, "*The **appropriate** picture is worth a thousand words*" (Rohret and Ferguson, 1990). Inappropriate illustrations can confuse rather than help the learner if they are not linked to the educational purpose. Good illustrations, on the other hand, can make messages easier to grasp and recall (Rohret and Ferguson, 1990; van Hattum *et al.*, 1991). Styles of depiction are rooted in cultural milieus within which they have agreed-upon meanings. An image cannot be expected to convey the same information outside its milieu (Mangan, 1978) and must, therefore be acceptable and familiar to the target cultural group, and its message must be perceived as relevant, logical and attainable (Vincent, 1972; Doak *et al.*, 1996; Ngoh and Shepherd, 1997).

When artists from one culture design images indecipherable to representatives from another, the problem is more likely to be due to culture-based misinterpretation rather than cognitive difference. Awareness of cultural-based perception is imperative, precisely because these perceptions, incorporating individual proclivities, social factors and educational settings play a key role in the appropriateness of an individual's reaction to any situation within a particular environment (Scott and Charteris, 2004). "This is a fascinating area for continued research, for although we glibly talk of a "global village", the importance of understanding human variability and cultural influences is a challenge to all who strive for universal standards to ensure a smooth transfer of goods and information from one area to another in the global market place" commented Scott and Charteris (2004, p 237).

Research shows that, in order to be successful, visual aids should be designed considering four processes: they should connect to the learner's existing knowledge and interests, gain the attention of the learner, hold the learner's interest, and present the information in a way that helps the learner remember the information (Ngoh and Shepherd, 1997).

Several publications have included guidelines for designing pictograms (Hudson, 1967; Chaplin, 1971; Vincent, 1972; Mangan, 1978; Zimmerman and Perkin, 1982; Snow Docherty, 1983; Linney, 1985; Colle, 1986; Cairney and Sless, 1989; Rymes-Barley, 1989; Work, 1989; Rohret and Ferguson, 1990; van Hattum *et al.*, 1991; Wolff and Wogalter, 1993; Magumo *et al*., 1994; Ringseis and Caird, 1995; Sojourner and Wogalter, 1997). A summary of these guidelines is presented below:

- collaborate with the target population and gain insight into their knowledge, beliefs, attitudes and expectations
- use familiar objects and symbols
- design simple, realistic pictures with a limited content
- use the whole body image, as isolated organs may cause confusion. However, pictures showing the face and the hands are well interpreted
- use multiple-stage pictures with caution
- use abstract symbols, symbols depicting motion and symbols conveying perspective with caution
- use background space appropriately
- if used, colours should be as realistic as possible
- use the appropriate size and magnifications
- pre-test new pictograms in the target population

Given the potentially important role of pictorial symbols in communicating hazards, national and international standards have been established to evaluate their comprehensibility, including the American National Standard Institute's ANSI Z535.3 (ANSI, 1991) and the Organization for International Standardization's ISO 3864 (ISO, 1984). ANSI and ISO advise that, in a comprehension test, symbols must reach a criterion of at least 85% or 67% correct respectively, in order to be considered acceptable.

The HIV and AIDS crisis in South Africa dominates all health dialogues and makes headline news daily. With almost 20% of the population living with HIV, it is a significant developmental issue with far reaching social, political and economic implications. Drug therapy for HIV and AIDS, as well as related opportunistic infections,

usually involves polytherapy and complex regimens, both of which are risk factors for poor adherence to drug therapy. Successful therapy depends not only on taking the appropriate drug, but also on taking it in the appropriate way (Ringseis and Caird, 1995), but this can only be achieved if the patient can access and understand the information and then act upon it. Non-adherence with prescribed medicine is a significant health care problem, and in the low-literate patient this may be unintentional, owing to an inability to read and comprehend the medicine instructions.

Opportunistic infections such as Candidiasis are extremely common in HIV and AIDS patients, who have compromised immune systems. Candidiasis, better known as oral thrush, is an infection that is commonly treated with nystatin oral suspension. This liquid medicine should be taken into the mouth, swirled around in the mouth for a while and then swallowed. In order for the medicine to be effective in treating oral thrush, it is vital that it remain in contact with the fungus for as long as possible. It is therefore essential that the patient fully comprehend the instructions in order to promote efficacious medicine use. As no existing pictogram illustrating these instructions could be identified, a new pictogram had to be designed.

The objective of this study then was to design, develop and evaluate a simple and culturally appropriate pictogram sequence for nystatin oral suspension, and to assess its understandability in low-literate Xhosa participants.

METHODOLOGY

Early Stages of the New Pictogram Design

A workshop on the development of pharmaceutical pictograms was conducted with 40 students in their third year of study towards a pharmacy degree. Representatives from the target population culture were present in this class. The students were given some background information on pictograms, which included the history of pictogram development, the need for pictograms, particularly in target populations such as low literate or visually challenged individuals, as well as the use and application of pictograms in practice. Students were shown 23 USP-DI pictograms (USP-DI, 1989 and 2000) and the SA pictograms, and guidelines for designing effective, culturally sensitive pictograms for a target population were discussed.

Their task was to design a pictogram sequence intended for use by the local isiXhosa-speaking population, to convey the instruction "***place medicine into the mouth, swirl it around the mouth for a while, then swallow***". Using concepts and ideas from the USP-DI and SA pictograms, the students developed rough preliminary sketches. These were studied and a number of ideas, which incorporated promising design features, were used as a basis for the preparation of the new pictogram sequence.

In consultation with a graphic designer, three rounds of discussion sessions with focus groups from the target population were held, in which images were examined and modified with reference to the guidelines mentioned above. Special attention was paid to points regarding image design, concept familiarity and cultural relevance. The initial sketches were modified a number of times before the new pictogram sequence was produced. Figure 1 shows this initial design (Version 1) that was subsequently developed and tested.

Phase 1: Evaluation of Version 1

Study Site and Study Population

The study was conducted in Grahamstown, a small town in the largely rural Eastern Cape province. It is one of the poorest of the nine South African provinces with an extremely high unemployment rate. The majority of the local African population (84%) belongs to the Xhosa ethnic group and have isiXhosa as their home language.

Eighteen percent of the province's population aged 20 years and over have had no schooling at all, with only 8.4% holding a tertiary education qualification (Population census, 2001).

The target population was the low-literate isiXhosa-speaker. Literacy, or lack thereof, is difficult to quantify, but for the purpose of this study, any person with 7 years or less of formal education was categorized as being low-literate. All study participants were drawn from the Xhosa group, had educational backgrounds ranging from 0 to 7 years of schooling and had English as their second language. They were considered to be representative of the average South African patient who is likely to have problems accessing and understanding health care information. Relevant permission was obtained and the interviews were conducted in local primary health care clinics within Grahamstown. All patients attending the clinics and people accompanying the patients were approached and invited to participate in the project. Participants were also approached in their homes. The new pictogram sequence (Version 1) was assessed using 30 participants. Approval for the study was obtained from the Rhodes University Departmental Ethical Standards Committee.

Pharmaceutical Pictograms Tested

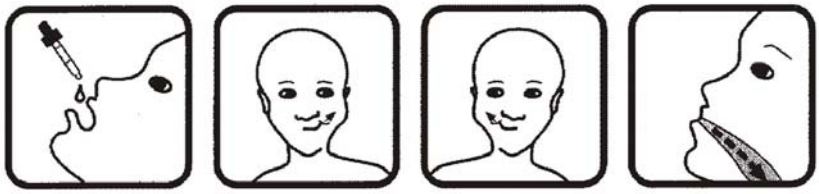
A total of 10 pharmaceutical pictograms, including Version 1, were evaluated. The other 9 were selected from the SA pictograms and ranged from being simple and easily understandable to more complex and difficult images, which demanded more advanced visual literacy skills (Figure 2). Two different examples of the SA pictograms were initially used to explain the concept of pharmaceutical pictograms to the participant. All the pictograms used were printed onto white card (11.5 x11.5 cm) with black ink and were numbered.

Interview Process and Data Collection

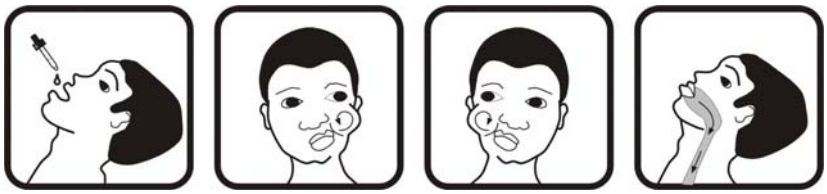
A questionnaire for data collection was designed. A standard approach was adopted for all interviews, which involved the interpreter introducing himself and the researcher, and explaining the purpose of the interview. These were the only two people who interacted with the participants. Participants were assured that this was not a "test" for them, but rather a test of whether the pictograms were successful in conveying their intended message.

Selected demographic data were collected (sex, race, age, home language and educational level) and the ability to tell time from either a clockface or a digital watch, or both, was also assessed, as selected pictograms incorporated clock-faces.

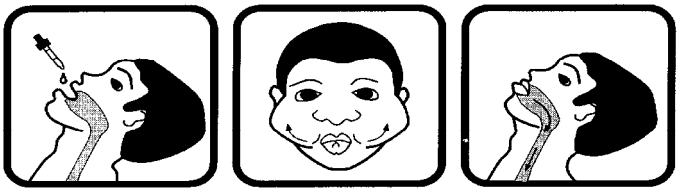
Instruction: Place medicine into the mouth, swirl it around the mouth for a while, then swallow.



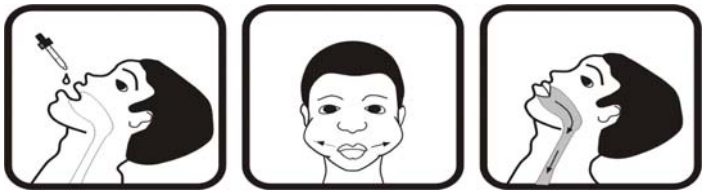
Version 1
(Phase 1 - 66.7%)



Version 2

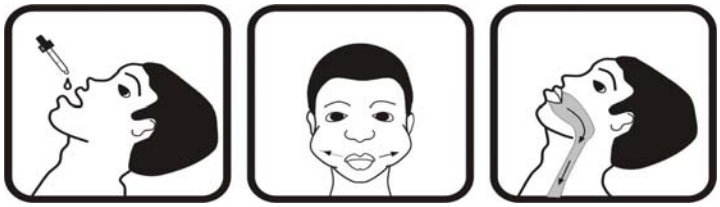


Version 3



Version 4(a)
(Phase 2 - 95.0%)

+



Version 4(b)
(Phase 2 - 95.0%)

Figure 1: **Modification process of new pictogram sequence**
(% of participants correctly interpreting the pictogram sequence is shown in parentheses)

After having the concept of using pharmaceutical pictograms explained, the participants were shown all 10 pictograms, one at a time, in random order with no previous explanation of the meaning of individual pictograms. The participant was asked to give his/her interpretation of each pictogram and any additional comments were recorded. During this phase of the interview, participants were encouraged to offer their opinion and to comment on the new pictogram sequence (Version 1). These additional comments were then recorded. This forms a crucial part of the design process, as it provides valuable feedback for subsequent modifications in order to enhance understanding.

The participant's opinion on the usefulness of incorporating pictograms on their medication labels was also recorded. This provides useful information on patient acceptability of and willingness to use pictograms. Participants were remunerated at the end of the interview and thanked for their time. Acceptance of the new pictogram sequence was based on international standards, i.e. the ANSI and ISO criterion.

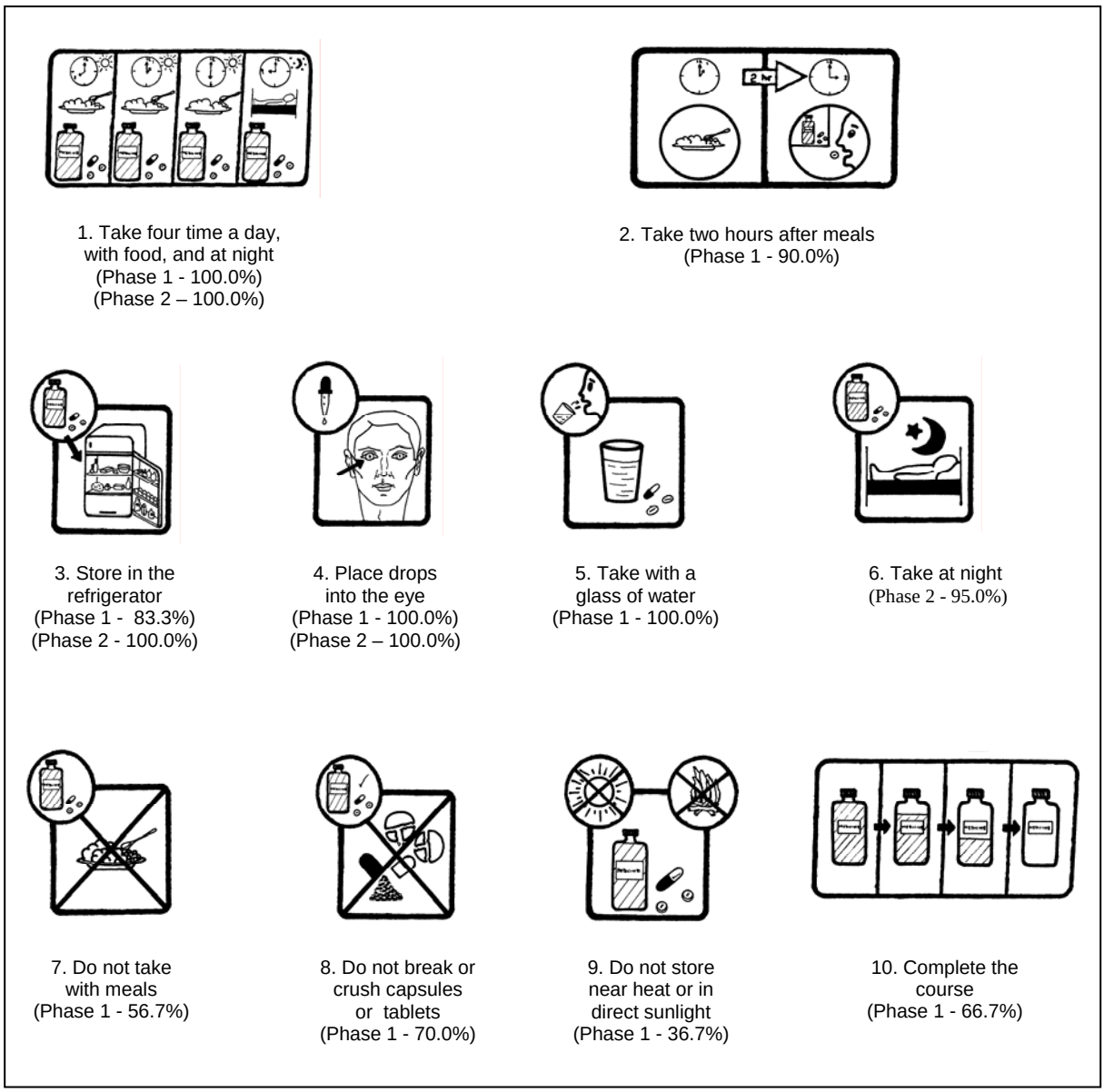


Figure 2: **SA pictograms included for evaluation**
(% of participants correctly interpreting the pictogram is shown in parentheses)

Modification of Version 1

The following problems associated with Version 1 were identified:

- The patient had no hair. Participants assumed that the medication would make you lose your hair.
- The swirling action, represented by the two small arrows, was not clear enough, as the arrows were taken to be part of a smile.
- The throat was not shown clearly. Many participants thought that the medication should be spat out rather than being swallowed.
- The pictures were too small. Many participants had difficulty in seeing the details of the pictures.

These comments were taken into account in producing Version 2 (Figure 1). In this version hair was included, the entire neck and throat were shown and the oesophagus in the final frame was shaded to indicate the presence of suspension being swallowed and moving down the oesophagus.

Further focus group discussion identified the arrows in the two central frames of Version 2 as being a source of confusion and these frames were amalgamated into a single frame. In order to establish consistency with the picture in the final frame, an oesophagus outline was drawn into the first frame (Version 3, Figure 1).

In discussion with the graphic designer, research colleagues and pharmacy students, the face in the middle frame was further modified as it was clearly out of proportion with the other facial images and it generated an amused response. The final versions (Version 4(a) and 4(b), Figure 1) were then assessed during Phase 2 of this study.

Phase 2: Evaluation of Version 4(a) and 4(b)

The study site, study population and interview process were the same as previously described. Twenty participants were interviewed and a total of 6 pharmaceutical pictograms were evaluated, including Versions 4(a) and 4(b), as well as 4 SA pictograms. Method of data collection was consistent with that described in Phase 1.

At the end of these interviews, participants were shown Versions 4(a) and 4(b) together and were asked to identify the difference between the two pictogram sequences. They were quizzed on their awareness of what the lines (demarcating the oesophagus) represented and which part of the body this “pipe” led to. Finally, they were asked to decide which version was clearer in communicating the intended medicine-taking instructions. Participants were remunerated at the end of the interview and thanked for their time.

RESULTS AND DISCUSSION

Demographic Characteristics

Participants were all black isiXhosa-speaking adults and their demographic details are presented in Table I. Females constituted the majority (70%) of the participants. More than 90% of the participants were between the ages of 21 and 65 years old. All the Phase 2 participants had attended school for a maximum of 7 years, whereas 30% of Phase 1 participants had no schooling at all.

Table I: Demographic characteristics

Demographic Parameters		Participants **N (%)**	
		Phase 1 **N = 30**	Phase 2 **N = 20**
Sex	**Male**	9 (30.0)	5 (25.0)
	Female	21 (70.0)	15 (75.0)
Age	< 21	1 (3.3)	1 (5.0)
	21 - 40	10 (33.3)	13 (65.0)
	41 - 65	18 (60.0)	6 (30.0)
	> 65	1 (3.3)	0 (0.0)
Highest Qualification	None	9 (30.0)	0 (0.0)
	Grade 1 - 4	9 (30.0)	4 (20.0)
	Grade 5 - 7	12 (40.0)	16 (80.0)

During Phase 1, in ascertaining competence with telling the time from a clock face, the majority (70.0%) indicated that they could do so, whereas 20.0% of the participants were only able to read digital time. Only 3 participants, none of whom had attended school, were unable to tell the time at all.

Interpretation of Pictograms

The SA pictograms have been extensively evaluated in the South African population and problems with their interpretation identified and discussed (Dowse and Ehlers, 1998 and 2001). Similar findings were noted for the SA pictograms evaluated in this study.

The percentage of correct interpretation for individual pictograms (Figure 2) on testing during Phase 1 ranged from 37% to 100%. Of the total of 9 SA pictograms evaluated, 5 exceeded the 85% ANSI criterion and 7 complied with the 67% criterion. These pictograms had been modified for use in a low-literate Xhosa population, the same population as in the present study, therefore, they already incorporated familiar culturally acceptable symbols. This is evident from the results obtained in Phase 2 of this study in which 4 SA pictograms were evaluated, with 3 of these being correctly interpreted by 100% of the participants (Figure 2).

However, it is apparent that further modifications are required for the 4 SA pictograms that did not achieve the 85% ANSI criterion. Pictogram no. 9 (do not store near heat or in direct sunlight) was correctly interpreted by only 37% of the participants. The symbolism used in this pictogram was far too abstract for the majority of our participants. Many thought the sun was a watch and some had difficulty recognizing the fire. Another pictogram, which was poorly interpreted, was pictogram no. 7 (do not take with meals). Many participants were able to recognize the food being eaten in a shallow bowl with a spoon, but the cross, signifying negation was often totally ignored. Some participants interpreted this pictogram to mean that the medicine should be taken using a spoon. Pictogram no. 10 (complete the course) often confused participants due to its 4 segments and they responded by saying that the medicine should be taken 4 times a day. Many participants had problems recognizing the open capsules and broken tablets in pictogram no. 8 (do not break or crush capsules or tablets) and they thought that it represented a pile of sand, or a loaf of bread.

Version 1 of the new pictogram sequence (Figure 1) was correctly interpreted by 20 (66.7%) of the 30 participants and although this result just complied with the ISO criterion of 67% correct, it was far below the ANSI criterion of 85% correct.

Considering the importance of understanding the correct medicine instruction in order to use a medicine safely, it was felt that the comprehension should be above the 85% level if possible. This necessitated modifying Version 1 as described previously. The final version, as tested in Phase 2, proved to be much more successful, resulting in 95% of the participants being able to interpret correctly both Version 4(a) and 4(b). This result exceeded compliance with the ANSI criterion of 85% correct, therefore these pictogram sequences were considered to be acceptable.

Acceptability of Pictograms

In testing new pictograms, assessing patient acceptability is as important as establishing patient understanding, as it provides us with a convenient and powerful tool for identifying problem areas and improving consumer ability to use the information effectively.

During both phases of the study, every participant reacted positively to the idea of having pictograms on their medicine and they all felt that pictograms could play a valuable role in helping them remember how to take their medicine.

During Phase 2, patient acceptability was assessed by asking the participants to choose between Version 4(a) and 4(b). Every participant was able to identify the difference between Version 4(a) and 4(b) and all were aware that the “pipe” represented the oesophagus, which led to the stomach. The most interesting result was that 100% of the participants preferred Version 4(a), which included the outline of the oesophagus drawn into the first frame, as they said it was clearer in showing them how to take their medicine correctly. This pictogram sequence would, therefore, be better suited for use on a medicine label.

The design and evaluation of pharmaceutical pictograms has not been extensively investigated and reported. Researchers have expressed surprise and alarm at some of the gross errors in interpretation of pictograms, which could have potentially serious effects on health outcomes (Hanson and Hartzema, 1995). Further concerns are the publication of pictograms which have not been adequately tested before their adoption for public use, as well as the assumption that the intended meaning can be conveyed to all groups, irrespective of linguistic or cultural background (Sojourner and Wogalter, 1997; Dowse and Ehlers, 1998). The importance of using country-specific, culturally appropriate pictorial material to relay information, particularly to the low-literate populations, has been well documented (Hudson, 1960; Zimmerman and Perkin, 1982; Linney 1985; Adams, 1991; Ngoh and Shepherd, 1997; Dowse and Ehlers, 1998 and 2001).

Results from this study together with the research mentioned above communicates a clear message to anyone developing visual aids for use on medicine labels, in patient information leaflets or on health posters, that they should develop such material in collaboration with representatives of the target culture, as this affords valuable insight into the most appropriate, culturally acceptable images to use. The success of this approach is illustrated in this study, which resulted in the development of a successful new pharmaceutical pictogram sequence.

STUDY LIMITATIONS

In this study, the same researcher designed and evaluated the new pictogram sequence. This introduces a potential weakness in the research methodology, as the evaluation process could potentially have been influenced by bias. However, all communication with the participant was via an interpreter, therefore, direct communication between the researcher and the participant was minimal. The interpreter, who had no vested interest in the outcome of the project, was therefore the person responsible for communicating the interpretation of the pictogram, a process that obviated any possible direct influence the researcher may have unwittingly exerted over the participant.

CONCLUSION

A major focus of this research was to design a pictogram sequence for use in the local ethnic culture, which incorporated clear, simple, culturally appropriate images. It was, therefore, essential to involve representatives of the target population in all aspects of the multiple stage, iterative design process. This was achieved by using a combination of focus group discussions and formal quantitative assessment in the target population. The modifying, re-testing and refining process, although costly, time-consuming and labour-intensive, is unavoidable if a favourable outcome is desired. This study has illustrated the success of using a consultative approach in the design of new pictograms.

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