

Medicine labels incorporating pictograms: do they influence understanding and adherence?

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Abstract

The objective was to determine the influence of medicine labels incorporating pictograms on the understanding of instructions and on adherence. Eighty-seven Xhosa participants attending an outpatient clinic who had been prescribed a short course of antibiotics were randomly allocated to either a control group (41 participants given text-only labels), or an experimental group (46 participants given text + pictogram labels). All participants had a maximum of 10 years of formal schooling. Follow-up home visits were conducted after 3–5 days to assess understanding of instructions and to evaluate adherence. A high adherence of greater than 90% was found for 54% of the experimental group, compared with only 2% of the control group. Average percentages for understanding in the control and experimental groups were 70 and 95%, respectively, and average adherence was 72 and 90%, respectively. The presence of pictograms was found to contribute positively to both understanding of instructions and adherence.

Keywords: Medicine labels; Pictograms; Adherence; Low literacy; Understanding of instructions

1. Introduction

Poor adherence to prescribed therapy is regarded worldwide as a major public health problem, as it constitutes a significant barrier to the effective treatment of many acute and chronic diseases. The consequences of poor adherence are inadequate health outcomes and increased health care costs [1] and [2]. A study conducted in the United States showed that 5.5% of hospital admissions can be attributed to poor adherence [3] and this places a huge burden on national economic resources, e.g. the direct and indirect costs of poor adherence have been estimated to be \$ 100 billion per year in the United States [4]. Estimates of adherence range from 4 to 92%, with an average of 50% adherence to long-term therapy reported to occur in developed countries [1], [5] and [6]. Rates in developing countries have been found to be even lower than this, a finding partially attributable to the low levels of literacy in these countries [1].

Adherence to prescribed medication may be regarded as the extent to which a person's medication-taking behaviour corresponds with agreed recommendations from a health care provider [1]. This is an adaptation of the definition of adherence to long-term therapy adopted by the WHO adherence project. The phenomenon of adherence is a complex, multidimensional one influenced by a number of determinants which may be classified into five broad dimensions [1], [2], [7], [8], [9] and [10]: patient-related factors, characteristics of the disease, therapy-related factors, the health system and the health care team, and social and economic factors. In attempting to improve adherence and hence health outcomes, members of the health care team require adequate insight into all of these determinants in order to identify risk factors which may predispose the patient to poor adherence. Targeted interventions should then be developed in response to these identified risk factors and take into account the needs and illness-related demands of the patient [1].

Poor adherence may, in some cases, be intentional, where there is a conscious decision on the part of the patient not to take the medicine as prescribed, or it may be unintentional, where the patient wishes to take the medicine as prescribed but is prevented from doing so as a result of one or more barriers [7]. One such barrier is low

literacy which is directly correlated to poorer health and disease state outcomes. The prevalence and effects of inadequate health literacy have received increasing attention over the past few years, both by health researchers and by government agencies. Research has shown that patients with inadequate health literacy have a poorer health status, less knowledge about their disease and its treatment, fewer appropriate self-management skills, increased hospitalizations, increased health costs and poorer adherence rates [1], [2], [7], [11], [12], [13], [14], [15] and [16].

Functional health literacy is the ability to read, understand, and act on health information [15]. In order for a patient to adhere fully to the instructions for a prescribed medicine, it is essential that, at the very least, the instructions are understood, can be acted on and can be recalled. In many parts of the world, this basic ability to read and comprehend the instructions is assumed, and interventions to attempt to improve adherence have usually been directed at the other stages of medicine-taking behaviour. Relatively little research has addressed these basic cognitive issues in patients with limited reading skills.

A number of studies have assessed patient interpretation of medicine instructions [17], [18], [19], [20], [21] and [22]. Although these instructions are typically written in simple, basic language and appear to be easily understandable, results have consistently revealed an unacceptable degree of misinterpretation which is exacerbated when dealing with low-literate patients [17] and [22]. Despite an increasing awareness of the limitations and inadequacies of current labelling practices and written patient education materials, few efforts have been made to address the problem [16] and [23], particularly in countries with a high prevalence of low-literate patients.

One way of facilitating the communication of medicine information to patients with limited literacy is to incorporate visual aids such as pictograms on medicine labels and in patient information leaflets. Pictograms have been shown to enhance comprehension and recall of information when used both alone [24] and in combination with text [18], [25], [26], [27], [28] and [29]. However, it is generally acknowledged that pictograms should not be used as the sole source of communication as certain studies have shown that they convey insufficient detail for proper comprehension of medicine instructions [30] and [31]. Their use should always be accompanied by training and verbal reinforcement by the health care provider [30], [32], [33] and [34]. The interpretation of a wide range of pictograms has been assessed in participants from a number of different South African language groups all of whom displayed limited reading skills. These papers include comment on practical application as well as discussion on the misinterpretation of the pictograms [30], [35] and [36].

The objectives of this study were to design labels incorporating pictograms for selected medicines, to compare the understanding of these text + pictogram labels with conventional text-only labels, and to assess the influence of pictogram labels on adherence to therapy in patients with limited reading skills.

2. Methods

2.1. Selection of medicines

The study focused on adherence with short-term prescription of antibiotics as these drugs have a significant impact on preventable mortality in developing countries. Three antibiotics which appear in the local Essential Drugs List were chosen based on level of usage; amoxicillin (capsules and suspension), phenoxymethylpenicillin tablets and co-trimoxazole tablets.

2.2. Preparation of pictogram labels

Pictograms used on the labels had been previously developed locally and tested in the South African population [30]. The appropriate pictograms illustrating the instructions for use were identified and were printed on the reverse side of the standard resealable plastic packets which are routinely used in the public health sector in

South Africa when dispensing solid dosage forms. For the amoxicillin suspension, pictograms were printed on self-adhesive labels which could then be stuck on to the medicine bottle without obscuring any written information. All medicine labels incorporated blank clock faces. The specific times for administration were filled in after consultation with each patient. Examples of pictogram labels are shown in Fig. 1.

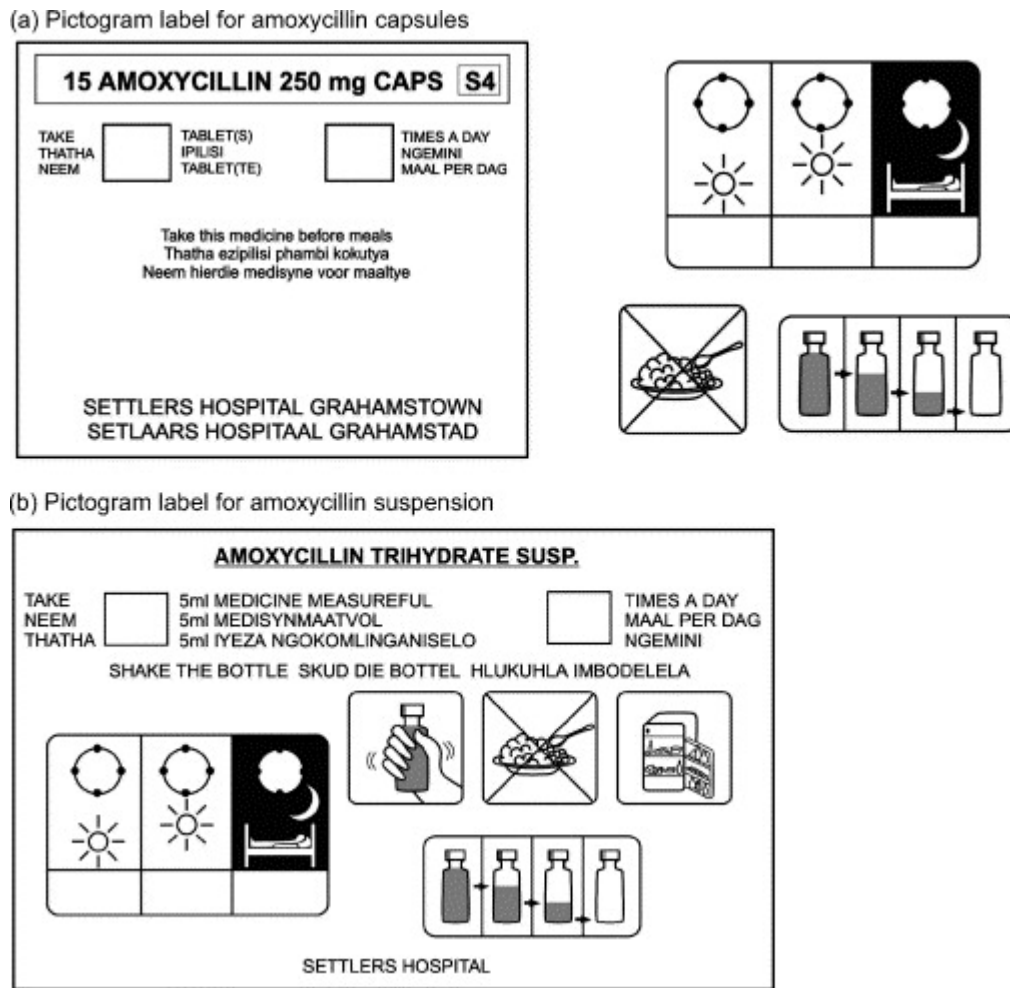


Fig. 1. Examples of labels incorporating pictograms.

2.3. Study site and study population

The study was conducted at the outpatient Day Hospital in Grahamstown, which is a small town in the largely rural Eastern Cape Province of South Africa. This province is one of the poorest, has an extremely high unemployment rate, and 20% of the adult population (20 years and older) in the province has had no formal education. The majority of the local African population (84%) belongs to the Xhosa ethnic group and have isiXhosa as their home language.

Participants were eligible for the study if they were from the Xhosa group, had completed between 0 and 10 years of formal schooling, and had been prescribed one of the antibiotics discussed in Section 2.1 or were caregivers who were responsible for the administration of one of these antibiotics. Participants were excluded if they had been prescribed or had been responsible for administering one of these antibiotics in the past 3 months. All participants were from the same socioeconomic group. Most of the participants were unemployed with a very low monthly income, they had no private health insurance and were indigent patients who obtained their health care from the public health sector. Permission to conduct the study was obtained from the Superintendent

of Settlers Hospital and the Matron of the Day Hospital. Approval for the study was obtained from the Rhodes University Ethical Standards Committee.

2.4. Interview process and data collection

A questionnaire for data collection was designed. A standardised approach was used for all contact with participants. Interviews were conducted by the research pharmacists with the aid of interpreters who had been specially trained. The interpreter approached potential participants, introduced him- or herself and elicited sufficient information to identify compliance with the inclusion criteria. Participants who complied with the criteria were invited to participate in the study. Eighteen potential participants were excluded as either they could not give a formal address for the follow-up interview or were unclear about their movements in the forthcoming week. A further five participants were excluded, as they appeared reluctant to participate. The remaining 87 study participants were randomly allocated to one of the two groups: a control group who received conventional text-only labels and an experimental group who received labels containing instructions in both the written and pictogram form (text + pictogram labels).

Participant contact details were recorded for the follow-up interview. Selected demographic information was collected (gender, age, educational level), and stated language proficiency in isiXhosa and English was recorded. Participants in both the control and experimental groups received their medicine from one of the research pharmacists, and were then counselled in a standardised manner. The time and date of the first dose of the medicine was noted.

Participants were followed up in their homes within 3–5 days after initiation of therapy. No indication had been given at the initial interview that this would occur. Recall and understanding of the medicine instructions was assessed using a series of structured questions. To try and assess depth of understanding and avoid biased results due to guessing the answers, some questions were asked more than once using different approaches, e.g. “Must you take all the capsules?” and “Will you keep any capsules to use when you get sick again?” A score for understanding was calculated based on the number of questions answered correctly.

Adherence was determined by self-reporting and by “pill count” and a score out of 10 was calculated which was then converted into a percentage. For the solid dosage forms, “pill count” accounted for eight of the 10 points and the remaining two points were allocated based on self-report of taking the medicine at the correct times and taking it on an empty stomach. The actions prior to use and the storage of the amoxicillin suspension add in additional variables which are essential in ensuring correct medicine-taking behaviour, therefore point allocation was as follows: six of the 10 points were allocated for volume of medicine remaining, two points for self-report as above, and the remaining two points for self-report were allocated for shaking the medicine before use and for appropriate storage.

A literacy test was administered to those participants who had stated they could read. Participants had a choice of completing the test in either isiXhosa or English. The participants were asked to read a short paragraph describing the instructions and precautions for taking a tetracycline antibiotic after which they were asked 16 comprehension questions. A literacy rating was calculated based on the number of questions answered correctly.

After informing the participant of the correct instructions, the following questions were asked to establish patient perception of the labelling practices and their opinion of pictograms on medicine labels:

- Do you feel that the instructions were clear and easily understood?
- Do you feel that you understood how to take the medicine?
- Do you think the pictograms helped/would help you to understand the instructions?

- Do you like having pictograms on the label?
- Do you think pictograms should be used on all medicine labels?

Those participants who had not received the pictogram labels were shown an example. At the end of the interview, participants were thanked for their participation and were given a small honorarium.

2.5. Statistical analysis

χ^2 -Tests were used to test for significant differences in demographic characteristics between the control and experimental groups, and to test for differences in the understanding of medicine instructions and adherence between the two groups. The influence of literacy on both understanding and adherence was investigated using correlation analysis. Level of significance was set at 1%.

3. Results

A total of 87 Xhosa participants were interviewed, 41 in the control group and 46 in the experimental group. Demographic characteristics are presented in Table 1. The overwhelming majority of female participants in this study (93%) can be attributed to two factors: firstly, females generally constitute the majority of patients at the clinics. Secondly, almost half the cases in this study involved the paediatric preparation of amoxicillin suspension, and the paediatric patients taking this medication were all accompanied by a female caregiver who became the study participant.

Table 1.

Demographic characteristics

	Control, <i>N</i> (%) (<i>N</i> = 41)	Experimental, <i>N</i> (%) (<i>N</i> = 46)
Gender		
Male	3 (7.3)	4 (8.7)
Female	38 (92.7)	42 (91.3)
Age (years)		
<21	3 (7.3)	5 (10.9)
21–40	25 (61.0)	21 (45.7)
41–65	12 (29.3)	13 (28.3)
>65	1 (2.4)	7 (15.2)
Education (years)		
0	11 (26.8)	6 (13.0)
1–4	4 (9.8)	10 (21.7)
5–7	15 (36.6)	19 (41.3)

	Control, N (%) (N = 41)	Experimental, N (%) (N = 46)
8–10	11 (26.8)	11 (23.9)
Stated ability to read		
English	14 (34.1)	9 (19.6)
isiXhosa	29 (70.7)	37 (80.4)

The majority of participants (82%) fell within the 21–65-year age group. Twenty-five percent of the participants had some high school education (8–10 years), whereas 36% had a maximum of only 4 years of schooling. A much higher proportion of participants claimed literacy in isiXhosa than in English. No significant differences in demographic characteristics were found between the control and experimental groups. The distribution of participants between the control and experimental groups for the four products is shown in Table 2.

Table 2.

Number of participants in each group for the four products

	Control	Experimental
Amoxicillin capsules	9	16
Amoxicillin suspension	22	20
Phenoxymethylpenicillin tablets	4	4
Co-trimoxazole tablets	6	6

Sixty-two of the 87 participants completed the literacy test in either English or isiXhosa. Combined results showed that just over a third (35%) obtained less than a 50% literacy rating, 21 participants (34%) achieved between 51 and 80%, and the remaining 19 participants (31%) scored above 80%. The content of the literacy test, which included both a medicine label and an auxiliary paragraph of medicine information, was more difficult than the labels used in this study.

Results from the four antibiotic labels used in this study highlighted significant differences between the two groups for both understanding of the instructions and for adherence (Table 3). A very poor understanding of instructions (<50%) was noted in nine participants (22%) in the control group. Pictograms appeared to contribute to improving comprehension as no participants in the experimental group obtained such a low score, and, in fact, the majority in this group (72%) displayed a high level of understanding (>90%). In contrast, only six participants (15%) in the control group achieved this high rating. The average score for understanding was significantly better in the experimental group (95.2%) than in the control group (69.5%).

Table 3

Percentages for understanding of label instructions and for adherence

Control, N (%) (N = 41) Experimental, N (%) (N = 46)

Understanding (%)

1–50 9 (22.0) 0 (0.0)

51–70 13 (31.7) 1 (2.2)

71–90 13 (31.7) 12 (26.1)

91–100 6 (14.6) 33 (71.7)

Average percentage for understanding 69.5 95.2*

Adherence (%)

1–50 8 (19.5) 0 (0.0)

51–70 8 (19.5) 3 (6.5)

71–90 24 (58.6) 18 (39.1)

91–100 1 (2.4) 25 (54.4)

Average percentage for adherence 71.5 89.6*

- Significant difference ($P < 0.01$).

A similar trend was noted in the results for adherence. Twenty percent of the control group displayed extremely poor adherence of less than 50%, whereas no one in the experimental group had such low adherence. This level of adherence would have placed these patients at high risk of therapy failure. The majority of participants in the control group (58.6%) achieved an average percentage adherence of between 71 and 90%. In comparison, the majority in the experimental group (54.4%) had a high percentage adherence of above 90%, a level of adherence that could be satisfactory for desired therapy outcomes. The experimental group who received labels with pictograms had an average percentage adherence of 89.6% compared with 71.5% achieved by the control group who received text-only labels. This significant improvement in adherence is supported by the difference in the scores for understanding attained by the two groups.

Results from the individual questions asked to ascertain understanding are presented in Table 4. In all but one question, pictogram labels were shown to be better understood than text-only labels. This improvement in understanding was particularly noticeable for the instructions specifying times of administration, taking the medicine on an empty stomach and finishing all the medicine.

Table 4.

Analysis of individual questions asked about medicine instructions, N (%)^a

	Control	Experimental
How many capsules/tablets/medicine must you take each time?	36 (87.8) (N = 41)	46 (100.0) (N = 46)
How many times a day must you take the capsules/tablets/medicine?	34 (82.9) (N = 41)	46 (100.0) (N = 46)
Give the actual times	23 (56.1) (N = 41)	44 (95.7) (N = 46)

	Control	Experimental
Must you take the capsules/tablets/medicine with food?	19 (46.3) (<i>N</i> = 41)	41 (89.1) (<i>N</i> = 46)
Must you take the capsules/tablets/medicine on an empty stomach?	18 (43.9) (<i>N</i> = 41)	40 (87.0) (<i>N</i> = 46)
Must you take all the capsules/tablets/medicine?	35 (85.4) (<i>N</i> = 41)	43 (93.5) (<i>N</i> = 46)
Will you keep any capsules/tablets/medicine to use next time you get sick?	24 (58.5) (<i>N</i> = 41)	41 (89.1) (<i>N</i> = 46)
Can you drink alcohol while taking this medicine?	1 (16.7) (<i>N</i> = 6)	6 (100.0) (<i>N</i> = 6)
What must you do to the bottle before pouring out the medicine?	22 (100.0) (<i>N</i> = 22)	19 (95.0) (<i>N</i> = 20)
Where must the medicine be stored?	22 (100.0) (<i>N</i> = 22)	20 (100.0) (<i>N</i> = 20)

^a Numbers vary as not all questions applied to all products.

Investigation into the relationship between literacy and both understanding and adherence yielded interesting results (Table 5). As anticipated, when looking at the pooled results from the 62 participants who completed the literacy test, a significant correlation was found between literacy and understanding ($r = 0.5595$, $P = 0.00$). This strong association was noted in the control group but, interestingly, the association was much weaker and was not significant in the experimental group. This may suggest that the presence of pictograms reduces the reliance on literacy skills in order to comprehend medicine instructions. These findings are similar to those generated from the regression analysis between literacy and adherence. The association between literacy and adherence was a highly significant one in the control group ($r = 0.6155$, $P = 0.001$), but was weaker and not significant in the experimental group ($r = 0.3393$, $P = 0.05$). Pooling the results indicated that literacy has a significant effect on adherence ($r = 0.5782$, $P = 0.00$).

Table 5.

Regression analysis between literacy and the variables of understanding and adherence

	Control (<i>N</i> = 28)		Experimental (<i>N</i> = 34)		Total (<i>N</i> = 62)	
	Correlation coefficient, r^a	<i>P</i>-value	Correlation coefficient, r^a	<i>P</i>-value	Correlation coefficient, r^a	<i>P</i>-value
Understanding	0.5623	0.002	0.3746	0.03	0.5595	0.00
Adherence	0.6155	0.001	0.3393	0.05	0.5782	0.00

The opinion of the majority of participants in both groups was that the instructions were clear, despite the fact that many obviously had not understood aspects of the written instructions. However, virtually all participants, irrespective of their literacy level, were very positive about the pictograms, they liked the idea of having pictograms on the labels and felt that they would be a valuable aid in recalling the instructions.

4. Discussion and conclusion

4.1. Discussion

This study indicates that the presence of pictograms on medicine labels had a significantly positive influence on both understanding of instructions and on adherence. These findings support those of Ngoh and Shepherd [37] who reported significantly higher comprehension and adherence measures in the patient group that received visual aids.

Much of the research into adherence originates from the USA and the UK whereas only a relative paucity of information is available from developing countries with their unique patient populations. A selection of South African studies has estimated medicine nonadherence rates ranging from 38 to 69% [38], [39], [40], [41] and [42]. The mean adherence rate found in this study was 81%. This higher rate may be partially explained by the fact that the study only included participants on short-term therapy, and they received more attention and counselling than they normally would have in a standard public health outpatient clinic. In a similar study conducted in rural Cameroon on low-literate patients, the mean adherence rate to a short course of antibiotics was found to be even higher at 87% [37].

Adherence of 100% with all medicines is clearly neither necessary nor realistically attainable under normal circumstances, so ideally, desired levels of adherence should be specified for each disease and treatment. This issue is addressed by Urquhart in his paper entitled "Ascertaining how much compliance is enough with outpatient antibiotic regimens" [43]. Although he does not specify the level of adherence necessary for the effective use of antibiotics, he does emphasize that the important errors to avoid are prolonged intervals between doses and early cessation of treatment. The importance of these factors was emphasized when counselling both groups of participants participating in this study. An analysis of the questions asked about medicine instructions revealed that pictograms were particularly valuable in communicating the information needed to avoid these errors.

A further finding in this study is that the literacy rating was found to be associated with both understanding and adherence. The inadequate literacy skills in this patient population are highlighted by results from the literacy test that was attempted by 71% of the participants. Only a third of the participants who had stated that they could read managed to score above 80% and this figure does not take into account the 25 participants (of a total of 87) who did not even attempt the literacy test. When evaluating overall comprehension of the labels used in this study from pooled data, only 45% of participants achieved a high level of understanding of greater than 90%.

In a study conducted in Malaysia in which 52% of the patient population had a primary level of education, only 21% of participants were able to fully comprehend the entire antibiotic label [17]. However, the problem is not restricted to only developing countries. Williams et al. [13], in a study conducted at two public hospitals in the US, expressed great concern that between 24 and 58% of patients did not understand directions to take a medicine on an empty stomach. Unless patients such as these are intensively counselled when they receive their medicines, and have some means of recalling the instructions after leaving the clinic, appropriate medicine-taking behaviour is highly unlikely.

The significantly improved comprehension of instructions by participants in the experimental group illustrates the valuable role played by the pictograms in enhancing understanding in low-literate patients. It is widely accepted that knowledge does not necessarily influence behaviour, particularly with chronic therapy. However, many of the factors influencing chronic medicine-taking behaviour are less applicable to short-term therapy, whereas the more basic cognitive aspects assume a much greater importance. In this study, the improvement in comprehension complements the higher adherence rate observed in the experimental group. A contributing factor to this enhanced adherence could be the success of pictograms in stimulating the memory and aiding

recall of information over a prolonged period of time. A previous study conducted in a low-literate South African population demonstrated the value of pictograms in this role [30].

The inclusion of pictograms on the labels was found to be particularly valuable in communicating instructions for taking the medicine on an empty stomach, and for emphasizing the necessity of completing the course. The actual times of administration were drawn in for each individual patient on the clock faces and this feature was extremely successful in avoiding prolonged intervals between doses. Patients actively welcomed this pictogram as they found it to be extremely useful in clarifying one of the most difficult features of taking multiple daily doses. Contrary to a widely-held perception of literate people that low-literate people would not be able to tell the time, we found that a high proportion of people in South Africa, regardless of their literacy level, were able to tell the time from a clock face. In a study of 304 South African participants who had a maximum of 7 years of schooling, 82% could read the time correctly [36].

4.2. Study limitations

The intervention being tested in this study was a visual one (i.e. different labels), so neither the patients nor the researchers were blinded to the conditions as it was overtly apparent merely by observing the label on the medicine to which group the patient was allocated. However, a standard interview protocol was followed for both groups, and all communication with patients was conducted through interpreters who were totally objective intermediaries as they had no vested interest in the final outcome of the study. This mimics practice in the public health sector, where many pharmacists are unable to counsel patients directly due to language barriers and therefore have to work through interpreters.

4.3. Conclusions

In a population with limited reading skills, the inclusion of pictograms on medicine labels was found to positively influence understanding of instructions and adherence to short-term antibiotic therapy. This study isolated and investigated merely one narrow aspect of the multidimensional problem of poor adherence to prescribed medicine and did not take into account the possible influence of any other factors. In people with limited literacy, lack of cognitive skills is undoubtedly a contributory factor to nonadherence. However, it must be acknowledged that this finding is but one small piece of the complicated puzzle that represents adherence to prescribed medicine.

4.4. Practice implications

Using visual aids to facilitate the communication of medicine information to low-literate patients requires extra time for explanation and places additional demands on health professionals, as pictograms should not be used as the sole communication source. Given the negative health outcomes and unfavourable economic consequences of poor adherence to drug therapy, policy makers and regulatory bodies in countries with a high incidence of inadequate literacy skills should pay particular attention to improving labelling practices and to considering the inclusion of pictograms on selected medicine labels.

Acknowledgements

Financial assistance for this study was provided by Rhodes University and by Roche Products. Pictogram labels were printed by Stripform Packaging. Our thanks to Professor Radloff for statistical assistance, the interpreters for their assistance, and the patients who willingly participated and offered their valuable opinions.

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