Written medicines information for South African HIV/AIDS patients: does it enhance understanding of co-trimoxazole therapy?

Leila Mansoor¹ and Ros Dowse¹,²

Abstract

Written information to promote patient education is being increasingly recognized as an integral part of quality health care. The main objective of this study was to evaluate the effect of distributing a patient information leaflet (PIL) on knowledge acquisition and recall. Two different PILs were designed for co-trimoxazole tablets: a simple, shorter PIL that incorporated pictograms and text and a text-only PIL that was longer and more complex. Human immunodeficiency virus-positive participants on chronic co-trimoxazole therapy were enrolled from five local primary health care clinics in Grahamstown, South Africa, and were randomly allocated to a Control Group (no PIL), Group A (text-only PIL) or Group B (simple PIL with pictograms). At the preliminary interview, demographic data were collected and the tablets dispensed according to normal clinic protocol. In a follow-up interview ~14 days later, participant medicines knowledge was investigated by asking a series of questions. The mean percentage for medicines knowledge was significantly higher in the group that received the simple PIL incorporating pictograms (76.3%), compared with both the Control Group (43.3%) and the group who received the longer, text-only PIL (50.9%). This study reinforces the value of providing patients with an appropriately designed PIL to inform appropriate medicine-taking behaviour.

Introduction

Human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) is the principal cause of death in sub-Saharan Africa and the fourth biggest killer worldwide [1]. With developing countries being the most affected, HIV/AIDS has become the most severe and overwhelming disease facing the world today [2]. In South Africa, 20.1% of the total population, ~5 million people, are infected making it the country with the largest number of people living with HIV/AIDS in the world [3]. Pneumocystis carinii pneumonia (PCP) is the most common, life-threatening opportunistic infection which can affect HIV-positive patients due to their weakened immune system. It presents itself as a lung infection, but can often spread to other organs. Co-trimoxazole is taken as an oral tablet and is used both for the prevention and the treatment of PCP.

Patients with HIV/AIDS are often on long term, multiple drug therapy [4] and as such it is crucial that such patients take charge of and responsibility for their health. Kitching [5] stated, ‘Lack of information has been identified as a major factor among 250 reasons why patients do not take their medicines as the prescriber intends’. The patient information leaflet (PIL) is one of the most widely used tools for patient education and health promotion [5, 6] and provides the patient with

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additional information about their medicines and/or disease state that does not appear on the medicine label.

A number of review articles have shown that many patients want to know more about their medicines [7–9], highlighting a definite need and expectation for information regarding the safe, effective use of medicines. Communication between health care professionals (HCPs) and patients often fails to inform patients effectively, as patients may not understand or do not remember what they have heard [5, 10], an issue that remains an ongoing challenge for HCP–patient relations [6, 11]. Health and medicine-related education often occurs during direct patient contact, sometimes supplemented by relevant reading material. In some instances, however, the only access to the relevant information is through written material [12]. The failure by HCPs to provide adequate information, coupled with the desire of patients for more information, and a frequent lack of understanding and recall of information presented orally, all point to the need to provide written information [5, 9, 13].

PILs can play a role in improving adherence in short-term therapy, satisfying patient information needs and educating patients on the correct use of their medicine [14–16]. They can also play an important role in creating a more health conscious patient who is an active participant in medical decisions [17]. The information contained in PILs should be patient orientated; it should also be relatively brief and concise, yet comprehensive enough to ensure that sufficient information is included [15, 18].

The argument that is used to explain an apparent underuse of PILs by the public is that many are poorly understood [6]. Drug information should be written in the simplest manner possible in order for it to be understood and be judged as understandable by patients [19, 20]. In addition to comprehensive content, PILs must be written at an appropriate reading skill or grade level for the intended audience [21]. One of the most frequently encountered problems with written health information is the use of language at a level greater than the reading skill level of the average patient [22]. Materials written at inappropriately high levels serve to depress understanding and transparency of information and increase confusion [19] thereby limiting their usefulness and preventing patients from becoming active, responsible partners and informed, conscious decision makers in their health care [23]. Overcoming this barrier requires both knowledge of the reading skills of the targeted patient population and the development and use of medicine information resources written at that skill level [21, 22].

The use of pictograms in pharmacy has been receiving increased attention over the past few years, possibly due to an increased awareness of the specialized information needs of patient populations such as the low literate [24]. In order for pictograms to contribute meaningfully to the acquisition and understanding of information in PILs, they should clearly and unambiguously communicate a concept [13, 25]. They should be large enough to allow for easy identification of details but the final size should utilize space in the PIL efficiently. Although some research on the effectiveness of pictograms has not supported the hypothesis that pictograms are beneficial for the acquisition and comprehension of information [26, 27], most studies investigating health-related applications of pictograms have shown them to be of benefit in this regard [25, 28–31], as well as in enhancing the recall of instructions on prescription and over-the-counter medicines [28, 29, 32, 33]. Houts et al. [33] have stated, ‘...cued recall is far more effective than simple verbal instructions. By giving the patient a picture as a reminder, recall rates can go from 15% to 85%’.

The objectives of this study were to evaluate the influence of distributing a PIL on acquisition of knowledge and on recall of medicines information ~2 weeks later without referral to the written information, to compare two different PIL designs in order to assess the influence of complexity and extent of information on patient knowledge, and to investigate the association of demographic and other variables with patient knowledge.
Methods

Study site and study population

South Africa’s health care system consists of a large public sector and a smaller but fast-growing private sector. The public sector is underresourced and overused as it delivers services to ~80% of the population. The high incidence of poverty (71% in rural areas and 50% overall), and unemployment (at least 38%) make it almost impossible for the majority of people to pay for health services, which results in an immense strain on the public health sector [34].

This study was conducted in the largely rural Eastern Cape province, which is one of the poorest of the nine South African provinces with an exceptionally high unemployment rate. The majority of the local African population (83%) speak isiXhosa as their home language and form part of the Xhosa ethnic group [35]. Almost a quarter (23.3%) of the province’s black adult population (age ≥20 years) have had no schooling at all, a further 23.1% have had some primary school education and 9.2% have completed primary school education [35]. Inadequate literacy is therefore a serious problem, with a significant percentage of the population likely to encounter possible problems in reading and understanding written materials such as health care information.

Five local primary health care clinics in Grahamstown, a small town in the Eastern Cape, formed the study site for the interviews. Relevant health authorities provided us with written permission to conduct the research and consent forms were signed by the participants. Ethical approval for the study was obtained from the Rhodes University Ethical Standards Committee.

The participants in this study were HIV-positive out-patients on chronic co-trimoxazole therapy. None of the participants was on antiretroviral therapy. Additional inclusion criteria were stated ability to read and understand either English or isiXhosa, and participants had to be over the age of 16 years. Participants from all educational levels were included, provided they complied with all the inclusion criteria. Approximately 450 HIV-positive patients received co-trimoxazole therapy from these five clinics during 2004.

Research material

Two different PILs were designed for co-trimoxazole tablets. Their design features are described in Table I. The design and structure of the Australian consumer medicines information [36] was used as a guide to devise the ‘standard PIL’ (Fig. 1), which complied with all the specifications as stated by the South African Department of Health in Regulation 10 of the Medicines and Related Substances Act [37]. This PIL contained no pictograms and was a longer and more complicated PIL than the ‘simple text and pictogram PIL’ (Fig. 2), which was designed specially for the typical South African public sector patient who, commonly, is likely to have limited reading skills.

Simple, culturally acceptable pictograms which had been previously tested in the target population were included in the simple text and pictogram PIL [25, 38]. Particular attention was paid to ensuring the inclusion of uncomplicated words, translating medical jargon to commonly used plain language where possible, as well as using short sentences. Readability of the two English PILs was determined using Fry’s readability test [39].

The following information, as required by South African legislation [37], was deliberately excluded from this PIL: scheduling status, quantity of active ingredient/s, list of preservatives, presentation and

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<th>Table I. Design features of the PILs</th>
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<td>Pictograms</td>
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CO-TRIMOXAZOLE TABLETS

Trimethoprim and Sulphamethoxazole (S4)

Patient Information Leaflet

What co-trimoxazole is used for

Co-trimoxazole is a combination of two antibiotics used to prevent or treat various infections, including infections of the urinary tract, chest or lungs (pneumonia), ears and intestines. Its main use is to prevent or treat Pneumocystis Carinii pneumonia (PCP), which is more likely to occur as your HIV disease progresses.

Before you take these tablets

Please consult your doctor, nurse or pharmacist for advice:
- if you are taking any other medicines on a regular basis
- if you have ever had any unusual or allergic reaction to co-trimoxazole
- if you are allergic to any other substance, such as foods, preservatives, or dyes
- if you are pregnant or breast feeding your baby
- if you have any other medical problems.

How to take these tablets

- These tablets are to be taken by mouth.
- Take one (1) tablet twice (2) a day, or as prescribed by your doctor, nurse or pharmacist.
- You should drink a full glass of water with each dose and at least eight (8) glasses of water during the day.
- These tablets can be taken with food or on an empty stomach. If it upsets your stomach, take it with food.
- These tablets must be taken every day for the rest of your life, even if you feel well.

If you forget to take your tablets

If you miss a dose take it as soon as possible. However, if it is time for your next dose, do not double the dose, just carry on with your regular dosing schedule.

Possible side effects

Although co-trimoxazole helps most people with their infections, and side effects are not common, they can occur. The following side effects may go away during treatment as your body gets used to the tablets. However, check with your doctor if any of the following side effects continue to worry you:
- diarrhoea
- dizziness
- headache
- tiredness
- loss of appetite
- nausea or vomiting
Not all side effects reported for these tablets are included in this leaflet. Make sure to check with your doctor, nurse or pharmacist as soon as possible if you do not feel well while taking these tablets.

While taking these tablets

- Co-trimoxazole can make your skin more sensitive to the sun than usual. Therefore try to keep out of the sun, wear protective clothing when outdoors and use a sunscreen with at least an SPF of 15 whenever you are exposed to the sun for long periods of time.
- These tablets may also cause people to become dizzy. Make sure you know how you react to this medicine before you drive a car, ride a bicycle, use machines or do anything else that could be dangerous if you are not alert.
- To help prevent and/or clear up your infection completely, keep taking these tablets for the full time of treatment, even if your condition has improved.
- Do not miss any doses.
- Do not share tablets prescribed for you with any other person.
- If you take too many tablets (overdose), consult your doctor, nurse or pharmacist immediately. If neither is available, contact the nearest hospital or poison control centre.

Storage

You should store these tablets at room temperature in a cool, dry place (15°–30°C), protected from light and well out of the reach of children.

Disposal

You should return all unused tablets to the clinic or to your pharmacist.

Product description

Each co-trimoxazole tablet contains 80 mg trimethoprim and 400 mg sulphamethoxazole. They are preserved with 0.025% m/m nipaastat and are sugar-free.

Co-trimoxazole tablets are white, round and flat, and are blistersed on one side. They are presented in bottles of 20, 100, 500, and 1000 tablets.

Registration number: 27/20.2/0302

Manufactured by: Micro Health
10 Lindley Street
Sefton
9701

Telephone no.: (068) 303 5476

Date Published: February 2004

Fig. 1. English version of co-trimoxazole standard PIL.
**CO-TRIMOXAZOLE TABLETS**

**Patient Information Leaflet**

- These tablets are often used for an infection (pneumonia) that starts as a problem in your lungs and can then spread to the rest of your body.
- They can also stop many other infections in your body.
- The information in this leaflet will help you take your tablets properly and stay as healthy as possible.

**Before using these tablets**

Tell your doctor, nurse or pharmacist if you...
- have any allergies
- are using any other medicines
- have anything else wrong with you

**How to use these tablets**

Take one (1) tablet twice (2) a day, or as your doctor, nurse or pharmacist told you to.

You must take these tablets every day for the rest of your life.

Take these tablets with a full glass of clean water.

You must try to drink at least eight (8) glasses of clean water a day.

You must take your tablets until they are all finished, even if you start feeling better.

**Problems you may have from using these tablets**

These tablets will help stop many infections in your body, but they may cause some other problems. These problems may go away as your body gets used to the tablets.

If you...
- get a runny tummy
- feel dizzy
- get headaches
- feel like being sick and vomiting
- feel tired
- don’t feel like eating

you MUST tell your doctor as soon as possible.

**While using these tablets**

- Do not miss any doses...
- if you miss a tablet, take it as soon as you remember
- if you remember just before your next tablet, leave it out and continue as normal
- never take two doses at the same time
- Don’t stay out in the sun for too long as it might hurt your skin.
- Don’t do anything dangerous, like riding a bicycle or driving a car, while taking these tablets as you might get dizzy and hurt yourself.

**How to store these tablets**

Store these tablets in a cool, dry place, and out of the reach of children.

**How to dispose of these tablets**

You should return all unused tablets to the clinic or to your pharmacist.

If you need to know anything else about your tablets or your health, please speak to your doctor, nurse or pharmacist.

Published in February, 2004

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*Fig. 2. English version of co-trimoxazole simple text and pictogram PIL.*
description of packaging material, description of physical appearance of medicine, registration number of medicine and details of the holder of the certificate of registration. This information does not directly influence medicine-taking behaviour. We believe that the package insert should be the legal document containing all these details, whereas the PIL should be as succinct as possible and contain information that affords patients some insight into their disease state, together with information related to their therapy. The PILs were available in both English and isiXhosa.

**Interview process and data collection**

Nursing sisters at the five clinics recruited all HIV-positive patients presenting for a refill of their chronic co-trimoxazole therapy over a 2-week period in May 2004. A standard approach was used each time, with the same information being communicated to all patients. Patient permission to divulge their HIV-positive status to the interviewers was obtained and patients were guaranteed that all information would remain classified. On agreeing to participate, the consent form was then read and signed by the patient. The co-trimoxazole tablets were dispensed in a standard plastic medicine packet with a conventional medicine label, according to normal clinic protocol, by the clinic pharmacist. Participants were then directed to the research team. The interpreter introduced himself and used a standard approach for informing the participant about the study and ascertaining compliance with inclusion criteria.

Participants were randomly allocated to one of three groups: the Control Group who received their medicine and no PIL, Group A who were given their medicine and the standard PIL, and Group B who were given their medicine and the simple text and pictogram PIL. In the preliminary interview, demographic data including gender, age, home language, current employment and educational level were collected. The approximate date at which the participant was first diagnosed as being HIV positive was also recorded. Participants were questioned about their current medicine practices and their perceptions and expectations of their medicine in order to assess if these practices, perceptions and expectations had any influence on the extent of their medicine knowledge.

Participants allocated to Group A and Group B were given the appropriate PILs and were encouraged to refer to the PIL for any information that they may need regarding their co-trimoxazole therapy. All participants were counselled on the importance of taking their medicine as directed. To conclude this preliminary interview, participants were given a reminder note for the follow-up interview. In the public sector, patients are required to return to the clinic every 4 weeks for follow-up appointments and to obtain their medication. The follow-up interview for this project took place approximately halfway through this period and was conducted ~14 days after the initial interview either at the participant’s home or at the clinic.

At the follow-up interview, the depth of the participants’ knowledge of their co-trimoxazole therapy was investigated. A number of questions were asked to test insight into usage, side-effects, storage and actions to take in the event of missed doses. The participants who had received a PIL were asked not to refer to it when attempting to answer the questions as we were attempting to ascertain the role of the PIL in acquiring and recalling medicine knowledge. At the conclusion of the interview, participants were thanked for their time and offered a small honorarium.

**Data analysis**

Answers to the interviewer’s questions were recorded as being either correct or incorrect. An overall score for medicine knowledge based on these answers was calculated and expressed in the form of a percentage. Analysis of variance (ANOVA) was used to determine differences in knowledge among the three groups. The influence of demographic variables (gender, age, education, employment), duration of therapy and beliefs and perceptions relating to medicine-taking behaviour on participant knowledge of medicines information were investigated using ANOVA and the Tukey Honestly Significant Differences (HSD) test. The level of significance was set at 5%.
Sample size in each group was determined using the balanced one-way ANOVA power calculation. With three groups, medium effect size $f = 0.30$, significance level = 0.05 and power = 0.80, the calculated sample size was 34.43. We took a sample size of 40 in each group resulting in the power of the test to be 0.86.

**Results**

**Demographic characteristics**

A total of 138 participants were approached to participate in the study. Out of which 11 participants declined for various reasons and a further seven were lost during the study. A final total of 120 participants were enlisted and interviewed, and their demographic characteristics are presented in Table II. No significant differences in demographic characteristics were found among the three groups.

Participants were all black, isiXhosa speaking and HIV positive with co-trimoxazole tablets being part of their current drug regimen. All participants were able to read isiXhosa, but only 44 (36.7%) were able to read English fluently. This did not hinder the study in any way, as the PILs were available in both English and isiXhosa in compliance with South African legislation [37]. More than two-thirds (73.3%) of the participants were female and the majority (60.8%) was between the ages of 26 and 40 years. Seven (5.8%) participants had never attended school, 44 (36.7%) had between 5 and 7 years of formal education and 44.2% had been to school for between 8 and 12 years. Our participants were from a socio-economically disadvantaged population and this was confirmed by the unemployment figures as only 11 (9.2%) participants were employed at the time of the study. All participants could interpret a digital clock face, with five (4.2%) being unable to tell the time from an ordinary clock face.

Time since being diagnosed as HIV positive ranged from nine (7.5%) participants who had been newly diagnosed within the last 3 months, 45 (37.5%) between 3 months and 1 year, 45 (37.5%) between 1 and 4 years and 21 (17.5%) for >4 years. Twenty-one participants (17.5%) were receiving co-trimoxazole tablets for the first time, seven (5.8%) had been taking co-trimoxazole for <3 months, 15 (12.5%) between 3 and 6 months, 35

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<th>Table II. Demographic characteristics ($n = 120$)</th>
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<td>Sex$^a$</td>
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<td>&lt;18</td>
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<td>26–40</td>
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<td>&gt;40</td>
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<tr>
<td>Highest qualification$^a$</td>
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<tr>
<td>None</td>
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<td>Grade 1–4</td>
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<td>Grade 5–7</td>
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<td>Grade 8–12</td>
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<td>Currently employed$^a$</td>
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$^a$No significant differences among the three groups.
(29.2%) between 6 months and 1 year and 42 (35.0%) for >1 year. The incidence of concomitant chronic medicine use was high, with 113 (94.2%) participants taking chronic medications such as vitamins, folic acid and ferrous sulphate and 14 (11.7%) taking additional medication for a variety of chronic diseases.

**Participant knowledge of information pertaining to co-trimoxazole therapy**

The questions used to assess depth of knowledge were asked during the follow-up interview, without referral to a PIL if one had been received. The mean percentage score for knowledge of medicines information pertaining to co-trimoxazole tablets was significantly higher in Group B, who received the simple, pictogram PIL (76.3%), compared with both the Control Group, who received no PIL (43.3%) and Group A, who received the more complex PIL without pictograms (50.9%) (Table III). Although in general, the results from Group A appeared to be better than those of the Control Group, these differences were not significant.

Looking at individual questions (Table III), significantly more correct answers were noted from participants who received the simple text and pictogram PIL (Group B) compared with the other two groups. Significant discrepancies in knowledge were noted for all questions except Q10 (complete the course), which was answered correctly by all but two participants.

Questions 1, 3, 6, 7 and 8 were poorly answered by all groups. Even when given additional written information in the form of a PIL, many participants still did not know why they were taking co-trimoxazole, what actions to take in the event of a missed dose or when left with leftover tablets, or the significance of certain side-effects. However, it

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<th>Questions</th>
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<td>Control</td>
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<td></td>
<td>No PIL</td>
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<td>n = 40</td>
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<tr>
<td>1. Do you know what your co-trimoxazole tablets are used to treat?</td>
<td>4 (10.0)</td>
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<tr>
<td>2. If you have been given any other medicines or buy some medicines,</td>
<td>26 (65.0)</td>
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<tr>
<td>what should you do before taking them?</td>
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<tr>
<td>3. What should you do if you miss a dose of your tablets?</td>
<td>9 (22.5)</td>
</tr>
<tr>
<td>4. Where should you store these tablets?</td>
<td>11 (27.5)</td>
</tr>
<tr>
<td>5. If you feel like being sick and vomiting, or you get headaches</td>
<td>24 (60.0)</td>
</tr>
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<td>while taking these tablets, what should you do?</td>
<td></td>
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<tr>
<td>6. Can these tablets make you dizzy?</td>
<td>2 (5.0)</td>
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<tr>
<td>7. What should you do with any of your tablets that may be left over?</td>
<td>7 (17.5)</td>
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<tr>
<td>8. Do you think the tablets will affect you if you spend a lot of time</td>
<td>5 (12.5)</td>
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<td>in the sun?</td>
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<tr>
<td>9. Do you know that you have to drink lots of water during the day,</td>
<td>27 (67.5)</td>
</tr>
<tr>
<td>while taking these tablets?</td>
<td></td>
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<tr>
<td>10. If you’ve been taking these tablets for a week and you start feeling</td>
<td>39 (97.5)</td>
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<td>better, what should you do?</td>
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<tr>
<td>11. If you have any questions regarding your tablets or your disease</td>
<td>37 (92.5)</td>
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<td>state, who should you talk to?</td>
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<tr>
<td>Mean rating (%)</td>
<td>43.3</td>
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aSignificant difference between Group B and other two groups (P < 0.05).
bSignificant difference between Group B and Group A (P < 0.05).
must be borne in mind that participants had to rely on memory alone as they had been asked not to refer to the PILs.

Application of Fry’s readability test found the standard PIL to be suitable for Grade 7 readers and the simple text and pictogram PIL to be suitable for Grade 4 readers. Although an overwhelming majority of 118 (98.3%) participants claimed to know how to take their tablets correctly (number of tablets and how often), 31 (25.8%) were actually taking them incorrectly. Forty-two (35.0%) participants believed that the co-trimoxazole tablets would cure their HIV/AIDS, 54 (45.0%) believed that they would improve their general health, 18 (15.0%) believed that they would decrease their tiredness and increase their energy levels, four (3.3%) believed that they would increase their lifespan and two (1.7%) were of the opinion that the tablets would do nothing for them. Bearing in mind the importance of this type of prophylactic therapy in maintaining health in the absence of antiretroviral therapy, it was noted with concern that only 45 (37.5%) participants knew that these tablets constituted chronic, lifelong therapy.

**Influence of variables on extent of medicine knowledge**

Both age and level of education were significantly associated with knowledge of medicine information. Increasing age was associated with a decrease in patient knowledge, and increasing levels of education had a significantly positive effect on patient knowledge. Lack of any significant association with patient knowledge was found for a number of other factors; these included gender, employment, time since a positive HIV diagnosis, time since initiation of co-trimoxazole therapy and beliefs about the usefulness of co-trimoxazole therapy in treating HIV/AIDS and associated conditions.

**Discussion**

This study illustrates some value in providing patients with written medicines information to educate them about their medicines and medication-taking behaviour, with the greatest benefit being associated with a simple PIL incorporating pictograms. A significant improvement in medicine knowledge was found after participants received this PIL compared with receiving a longer, more complex PIL or receiving no PIL at all. These findings support those of Winfield and Owen [40], who showed that simple PILs given with dispensed medicines provided a significant improvement in patient knowledge of their medicines. They also concluded that no matter how simple, PILs can improve medicine knowledge, an opinion supported in a recent review by Johnson and Stanford [41].

The problem of written medicines information using language at a level greater than the reading skill level of the typical patient is well documented [19, 21–23]. Materials that are difficult to read may be comparable to receiving no medicines information at all and may even increase confusion, suggestions which are supported in this study by the lack of any significant difference in results between the participants who received the more complex standard PIL and those who received no written information. In fact, two of the 11 questions were answered correctly by more in the latter-mentioned group compared with those who received the standard PIL.

A number of participants in this study had received only limited formal schooling and they obviously had difficulty in reading and comprehending all the information. Poor readers tend to obtain much less from health care information [42]. Even if they read all the words, they may miss the context and fail to extract the exact meaning from the sentence. Poor readers tend to read slowly and tire quickly, therefore making the design and layout of written information of vital importance in ensuring acceptability and readability. It was apparent in this study that participants struggled to explain what the co-trimoxazole tablets were used for. This may have been due to the use of unfamiliar medical terms such as ‘infection’ and ‘pneumonia’. The fact that this is prophylactic therapy and not for an identifiable symptom may also have contributed to the confusion.
Certain types of information are difficult to communicate simply, and it was noted that information in the PIL that contained subordinate clauses was generally not well understood. For example, the concept of missed doses is a multifaceted one and the information requires the reader to identify a situation and choose the appropriate action. This more complex information is challenging for the poorer reader to comprehend and translate into action. Clerehan *et al.* [43] suggested that a multidisciplinary approach to writing patient information materials that includes proficiency in applied linguistics might improve the quality and effectiveness of these materials. These points emphasize the need for simple, understandable medicines information in order to help patients become informed, conscious decision makers in health care issues.

Instructions that require new or different behaviour are not as easily communicated and comprehended as those that reinforce known information, e.g. the majority of participants appeared to be confused about the link between taking medicine and exercising caution when exposed to sunlight. It is possible that practising sun-protection behaviour is not as familiar to this darker-skinned population as it would be to fairer-skinned people. Participants were also unaware that they should return their leftover tablets to the clinic as they typically disposed of them in the toilet. Problems were encountered with the question concerning the possible side-effect of dizziness. Participants appeared to take this as a direct inquiry about personally experiencing dizziness and although the interpreter tried to clarify the question numerous times, misinterpretations still occurred and influenced responses. This emphasizes the importance of framing questions appropriately in order to avoid confusion and elicit the desired feedback.

A further factor that may have contributed to improved acquisition and recall of information in the group receiving the simple pictogram PIL is the presence of pictograms. Bernadini *et al.* [17] evaluated the attitude of 1004 patients towards PILs provided with symbols or pictograms and found that patients usually read the PILs but few understood them or readily found the needed information. However, they considered the use of symbols and pictograms helpful in locating the needed information. Text accompanied by pictograms has been shown to be the preferred format for the presentation of medicine instructions [20, 30]. Improved recall was found for pictures followed by a descriptive sentence, compared with pictures presented alone [44]. It was also found that participants preferred a fully redundant (combined) text and pictorials format, rating it more effective and easier to understand and remember [20, 30]. From this study, for example, the question relating to storage of the medicine was answered correctly by an overwhelming majority (82.5%) of those who received the simple text and pictogram PIL, whereas this was very poorly answered by the other participants. This instruction was illustrated using a previously tested pictogram [38].

Correct responses to certain questions may not always be indicative of the successful communication of that information (verbal or written form) during the encounter under study. Participants were eager to respond appropriately and give the answer they thought was the ‘right’ one (i.e. to try and ‘please the researcher’). For example, the concept of continuing with therapy despite an improvement in their health is one that is continually emphasized by all HCPs, especially in HIV-positive patients. We felt that participants responded instinctively to this question in offering the correct answer, but it is highly debatable whether this information would be translated into appropriate medicine-taking behaviour over a long period of time, a point raised by other researchers [45].

The poor results obtained for certain questions indicate lack of recall of pertinent information and also highlights the lack of appropriate counselling at the point of dispensing. In the underresourced South African public health sector, pharmacists often practice under stressful, adverse conditions and insufficient time is available for detailed counselling, which makes the availability of information in the written form all the more important. South African legislation [37] has mandated the provision of PILs with all dispensed medicines,
although this is not yet standard practice. The PIL that was designed in accordance with the legislated guidelines was generally not favourably received and had no significant effect on the depth of patient knowledge concerning co-trimoxazole therapy. It was regarded as being too long and complicated, containing unnecessary information and was generally poorly understood, whereas the PIL incorporating simple text and pictograms was considered to be preferable. This finding highlights the need to establish guidelines on the design, development and assessment of PILs to ensure that the final product is of value to the target population. Such materials should not be regarded as satisfactory if they merely comply with a legal requirement.

In conclusion, a label alone cannot communicate all the information needed to promote appropriate medicine-taking behaviour. It is essential that verbal counselling and detailed written information should accompany a medicine with its label when provided to the patient. PILs are a convenient, valuable way of addressing this need, but they will only be effective if they are memorable, understandable and acceptable. However, this is unlikely to be the complete answer because of limitations in literacy, motivation and cognitive ability of patients. Further research on the application of simple, basic language to all labelled instructions and PILs should be a priority for all medicine regulatory authorities.

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Conflict of interest statement

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