

**DOES THE PATIENT PACKAGE INSERT (PPI) IN SOUTH AFRICA SERVE
THE PURPOSE OF HEALTH COMMUNICATION?**

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ABSTRACT

The aim of this article is to reflect on the usefulness and efficacy of the patient package insert (PPI) from the perspective of health communication. From the literature it is clear that American and European PPIs suffer a host of communication problems. What is the standing of the South African PPI with regard to its communication efficacy? Up till now there has been no published research on this aspect. The South African PPI is investigated for communication barriers, keeping the profile of a developing country in mind. The present research has indicated that PPIs in South African medication packages do not fulfil their communication aim, due to barriers that can be traced mainly to document and reader variables, rendering the communication contained in the document less efficient. Additionally, in the case of the PPI, health communication efficacy is influenced by, amongst others, cultural competence and understandability; factors that have been neglected in the South African PPI. Finally this article proposes improvements in order to enhance the value of the PPI as a means of effective health communication.

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INTRODUCTION

Medication information, as a manifestation of health communication, is no new concept in South Africa. During the 19th century, amidst a host of epidemics and diseases such as leprosy, smallpox, cholera, syphilis and typhoid fever, pharmacists were expected to “educate an ignorant public in health matters” (Ryan 1986: 2). As a result of the isolation of the people living on farms and in small villages, a “Huis Apotheek” was their closest contact with medical care. This “apothek” was normally a tin container which contained medicines like *Versterk Droppels*, *Witte Dulcis*, *Rhubarber poeder* and *Jalappen poeder*. Although there was an instruction book on usage and dosages included in the medication container, many people were illiterate and/or ignorant, and rather used the medication according to a longstanding family tradition, and not according to the included written instructions (Ryan 1986: 2-3).

Nowadays, all medication (scheduled or over-the-counter (OTC)) includes a patient package insert (PPI) with important information, vital to the well-being and safety of the patient. Yet this vital document is hardly ever read and/or understood by patients taking the specific medication, as indicated in the literature (Doak, Doak, Friedell & Meade, as cited in Rudd & Colton 1998: 23; Rudd, Moeykens & Colton 1999: 10; McGinnis 2000: 5). Why has this not changed lately, given that standards of education have presumably improved and information is nowadays readily available everywhere? The problem may not be situated in the availability of the information, but rather in the accessibility of the information, amongst other complicating factors.

Although limited counselling is normally given by a health care provider when prescription medication is dispensed, it is not often the case with OTC medication, as certain OTC drugs are also available in supermarkets and chain stores. Given the socio-economic situation in South Africa, many people rely on over-the-counter medication, which is normally cheaper than prescription medication. (In 2005, 68% of the South African population could be classified in the Living Standards Measure (LSM) 2 – 6 grouping, having an average monthly household income of between R1 093 and R4 207 (SAARF, online)). Seen from this perspective, this document should contain information that is easily accessible and readable, otherwise it may have a negative impact on understanding of the message and this may ultimately negatively affect health outcomes.

The PPI within the context of health communication

Health communication can be seen as “the dissemination and interpretation of health-related messages” (Rensburg 1997: 212). Finnigan and Viswanath (in Freimuth, Edgar & Fitzpatrick 1993: 510) defined health communication as “the core of health promotion affecting individuals’ decisions or antecedent social and cultural conditions or public policy to make community environments supportive of healthier behaviours” (1993: 510), while Suggs stated it as follows: “Health communication efforts often are designed to improve lifestyle behaviors, reduce risk factors for disease, increase compliance with a medication or treatment plan, better self-manage a condition,

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provide social support, or provide help with making decisions about health” (2006: 62). From the above-mentioned definitions, it is clear that health communication has a serious responsibility, namely empowering patients with relevant health/medication knowledge to make informed decisions about their health behaviour. The PPI, through its health communication message, is especially indicated to increase medication compliance, empower self-management of medical conditions through self-medication, and to enlighten patients regarding health decisions where medication is involved.

However, the environment in which health communication functions, changes constantly with new technological advances, such as CD-ROM technology and Internet options, an increasingly great variety of health issues, as well as a consumer’s demand for high quality health communication information (*Medical Facilitation: A Communication-centred Healthcare Model* s.a.: online). It is thus clear that in such an ever-changing health communication environment, the patient/client would naturally select information purposefully to which he/she will pay attention, based on personal interests and preferences. Thus, the PPI has to meet the informational needs of patients in order to be an efficient health communication tool, as has been found through American research which indicated that the approach to health communication should reflect an audience-centred perspective, as well as the preferred channels, contexts and formats of the patients/clients (*Healthy people 2010* s.a.: online), if it is to achieve its aim.

Thus, if the PPI is to be a successful health communication tool, it is important to pay specific attention to the encoding of the health communication message, taking the message recipient and his/her needs and profile into consideration. However, not only formal relationships are included in the health communication contexts, but also the realities of everyday lifestyles, attitudes and beliefs, as expressed through the profile of the health communication audience: gender, age, education and income levels, ethnicity, cultural beliefs, primary language, physical and mental functioning, experience with the health care system, attitude and willingness towards different types of health communication (*Healthy people 2010* s.a.: online). In this regard, Murray-Johnson and Witte emphasised that a person’s motivation is central to the way a health message is processed and whether any action will result from the processed message (2003: 477). This emphasises once again the importance of accommodating patient needs in the health communication message and format.

Street also indicated the importance of linguistic resources in both the health care provider (be it the doctor/nurse/pharmacist, etc.) and patient/client as important factors to the success of health communication (2003: 65). However, the efficacy of health communication in a text is not only influenced by personal variables (age, psychological state, etc.), but also by variables intrinsic to the text (accuracy, balance, etc.) and the way that the message is conveyed (cultural competency, reach, repetition, etc.) (*Healthy people 2010* s.a.: online). From this it is clear that message presentation is as important as human factors at work in the health communication context.

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THE PPI: ORIGIN, CONTENTS AND PRESENTATION

The PPI basically originated in the early 1960s, after the thalidomide tragedy in Belgium because it was realised that patients need full medication information to make an informed decision about benefits-to-risks of the medication. The PPIs (between 1963 and 1988) were no more than technical documents, laden with medical jargon and basically incomprehensible to the lay person, but distributed in the medication package and hence available to the patient (Vander Stichele 2004: 31). Gradually, over the years of its development, the document became more complete and scientific, yet also more difficult to be understood by the general public (Gosselinckx 1989: 49 - 50). Manufactured PPIs were first mentioned in European legislation in 1975. However, in the US, patient package inserts as a means of health communication, gradually came into existence from 1968 onwards. In 1979 the Food and Drug Administration (FDA) proposed patient package inserts for 10 drug classes (375 medications) (McGinnis 2000: 5). According to Basara and Juergens, an increasing demand for PPIs was sparked in the US at that time by the following factors:

- a growing interest by consumers in health information and self-medication;
- more direct-to-consumer advertising of prescription drugs; and
- laws requiring pharmacists to counsel patients (1994: 48).

Nowadays, PPIs are widely used throughout Europe (in the EU countries) for OTC and prescription drugs dispensed in their original packs (Amery & Van Winkel 1995: 52).

Basara and Juergens defined a PPI as follows: “a PPI is any document that describes the characteristics, dosing methods, and adverse effects of a specific prescription medication, is consistent with prescription drug labelling standards, and is written in consumer-oriented lay language” (1994: 48). According to Amery and Van Winkel, a PPI should be seen as a memory aid and should supplement information given by the health consultant (1995: 52), while Jones considered the PPI to be a small link between a huge body of drug information and the patient, where the function of the PPI depends on the specific uses ascribed to it by the users (1989: 185). The quality of the PPI is determined by the quality of the scientific data sheet, the communication skills of the responsible person in the pharmaceutical company (or other manufacturing body) and the national regulatory policies, rendering the PPI a document that has regulatory, legal and educational functions (Vander Stichele 2004: 31). According to Joossens, not only have patients the right to have a PPI, but it should provide information in clear language that is comprehensible to everyone, in an attempt to reduce the gap between health professionals and patients in order to promote drug compliance, and as a first step towards greater consumer participation in health care systems (1989: 20).

Contents of a PPI

Patients want to know what they are taking and what possible effects the medication could have, and prefer this information in a written format (McMahon, Clark & Bailie 1987: 356). From studies it was established that, first of all, patients want to know the

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name of the medication, what it is used for, common risks of normal use, risks of overdose and the risk of taking too little (Maes & Scholten 1989: 164). Other information seems to be superfluous, or at least not part of the patient's immediate communication needs. Vander Stichele pointed out that background information, such as medication composition and pharmacological action is not really wanted by patients (2004: 31-33).

Initially, drug manufacturers were obliged to list all actual and potential adverse drug reactions as part of "full disclosure" to patients. The implication is that the document became long and a skewed profile of benefits-to-risks resulted (Morris 1977: 424). Yet sub-minimum information is as dangerous (Williams-Deane & Potter 1992: 114) and a recommendation to include the most frequently experienced effects was made (Amery & Van Winkel 1995: 53). The recommendation included the following guideline for the contents of a PPI: it should be scientifically based, relevant and simply written, and based on a summary of the product characteristics, but without any pharmacological or technical information (Amery & Van Winkel 1995: 53). This applies also to OTC medication, where ethical pharmaceutical companies ought to provide patients with suitable and comprehensible information (Gruber *et al.* 1995: 248).

Presentation of the PPI

Research has indicated that PPIs in the US were prepared by private corporations, consumer groups, professional associations, governmental agencies and the pharmaceutical industry and therefore the content, style, level of readability and intended audience varied widely (Dolinsky & Sogol 1989: 29-30; Basara & Juergens 1994: 49). This resulted in a plea for standardisation of format and graphical style (Herxheimer 1989: 74) in order to enhance communication efficacy. Carter remarked that audiences have various linguistic, intellectual and educational backgrounds and these factors, together with the context in which the material is to be used, should be considered as preconditions for effective text design (1985: 148-149). In this regard, acceptance of the importance of the patient profile for text design of this health communication tool is realised. A logical structure to the presentation of information with clear headings was suggested by Fitzmaurice and Adams (2000: 260) to enhance communication efficacy. In 2004, Vander Stichele remarked that the lack of consistency in length, content and structure between PPIs of the same medicinal class was a technical weak spot of PPIs (2004: 131).

THE PPI: PROBLEMS

Readability of the PPI

It was found in research done in the US that patients' comprehension of their medication information was not satisfactory and that the readability of the PPI was a primary problem (Smith 2002: 1). A readability assessment of 63 nationally distributed PPIs in the US indicated that the readability of the texts was of the 8th to the 9th grade difficulty. The PPIs were written at a level that is above the average user's level of reading ability (which is the 5th to the 6th grade) (Basara & Juergens 1994: 49-51). In

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their readability assessment of PPIs designed for oral contraceptives, Williams-Deane and Potter referred to legibility as the ease with which the written information could be read and comprehended (1992: 114), a clear prerequisite for communication efficacy. Although Amery and Van Winkel suggested short sentences to improve readability (1995: 54), contrary results were obtained by other researchers: Riche *et al.* stated that the use of shorter sentences in order to make material more readable, often has the opposite effect, because meaningfulness might be sacrificed by such style condensation (1991: 288-290). These authors also found that shortening sentences does not improve readability and that people actually read at a lower level than their educational level (1991: 328). Similar results were obtained by Vander Stichele in a study about Belgian PPIs in which patients considered shorter sentences less interesting and childlike (2004: 124).

Riche *et al.* found that technical words, the use of passive voice and rare phraseology were confusing and negatively impacted on the readability of material. These researchers also found that readers preferred more meaningful words to less meaningful words, seen from the perspective of the patient; for example, they preferred “ongoing” to “chronic” (1991: 288-289). Similar results were obtained by Reid *et al.*, who have also found that technical words in PPIs caused comprehension problems and that people do not reread the PPI if at first they had not understood the terminology (1994: 332).

According to Arndt and Janney, style is characterised by the choice of words and the arrangement of these words in a sentence (1987: 147) and these two elements have an impact on the accessibility and comprehensibility of the message. Amery and Van Winkel were of the opinion that personalisation of the text, through the use of personal pronouns, would enhance the relevance to the patient (1995: 54). This was also the viewpoint of Fitzmaurice and Adams, who suggested that the writing style used in PPIs should be personalised, unbiased and everyday; verbs should be in the active voice rather than passive voice and scientific jargon should be avoided in order to enhance readability (2000: 260).

The primary concern about communication effectiveness in PPIs, therefore, lies with text difficulty, expressed through style and word choice. Already in 1980 Morris, Myers and Thilman indicated that patient information should be “written for audience acceptance, rather than for favourable reading scores” (1980: 1504). Features other than word and sentence lengths also have an influence on reading ease, like sentence structure and the organisation of the information into logical units – perceived as the style of the document (Stevens 2000: online) – but also the physical aspects of the document, like style, layout, design and the use of graphics. All these factors should contribute to reading ease which also has an implication for communication efficiency and information comprehension.

Design factors

Design factors, like the manifestation of layout, typeface, style and size, use of white

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space, primary key information and active vs. passive voice have been studied by Rudd and Colton (1998: 23), and found to have, in some cases, negatively affected the accessibility of information presented in the PPIs. The design factors are, however, subject to the amount of information that has to be presented in the PPI, which has to be of such a format that it fits into the medication package (Basara & Juergens 1994: 52), a factor which could complicate design.

The following were quoted as important design factors that could inhibit the use of PPIs: a type size that is too small, paper that is too thin, or words that are too tightly spaced. Technical design variables, included in a study undertaken by Basara and Juergens, were pictograms/graphics, colour, type size, paper quality and white space; the research results indicated that the use of only one colour print, no pictograms/graphics, average use of white space, small print and paper of average quality did not enhance the use of the PPI as a source of health information (1994: 50-51).

The minimum font size required by the European consumer lobby is eight points (Amery & Van Winkel 1995: 56). When a PPI the length of one A4 page was tested, it was found to be too long. It was also found that comprehension of the information and willingness to take the drug were inversely related to the length of the provided text in the PPI and that itemised or summarised information aids comprehension (Amery & Van Winkel 1995: 54-55). From these findings the question can be raised whether all relevant information can be accommodated in a design that provides an easily readable text in a concise format.

Although PPIs are fairly standard regarding design factors, visual appeal of the PPI can be improved by using columns, itemising information, using headings and (sometimes) pictographs or graphics. Bullets, italics and bold print are useful decoration techniques (Amery & Van Winkel 1995: 52), while they also guide the reader through a text. A picture or illustration may activate background knowledge and may aid predictability of what to expect in the text (Fulcher 1997: 509). However, since pictograms have no universally agreed-on meaning, Amery and Van Winkel recommended their use simply as a guide through the text and not as an aid to vital information (1995: 54).

Already in 1985, Orna suggested the following presentation style to increase accessibility of information in the PPIs: clear signposting of headings, short sentences, lists, simple tables, codes to identify different types of information, and the standardisation of information elements and the sequence of information (1985: 30-31).

Communication barriers in PPIs

It is therefore clear that readability difficulty, design and message presentation problems can contribute to communication barriers in the health message.

Since noise is any stimulus that interferes either with the process of message transmission, or reception of a message (Hybels & Weaver 1992: 9; Lowe 1995: 52; Steinberg 1997: 16), it may limit or adversely affect communication efficacy. Usually

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noise exerts its influence on the communication message in one of the following ways: the message is affected in the transmission channel, through incomplete encoding, encoding ambiguity, by contextual ambiguity or often by a combination of these factors (Ritchie 1991: 57). Communication barriers can be classified as either of external, internal or semantic origin (Hybels & Weaver 1992: 9; Steinberg 1997: 16), and as such are situated either in the message sender, the message itself, the receiver, the channel or in a combination of these elements.

Especially relevant to PPIs, is the influence of semantic barriers. Meanings reside in people and not in words (Wood 2004: 79), as “language is a system of signs that express ideas” (Cobley 2005: 45). Therefore, to have mutual understanding of a concept implies that meanings between communication partners should overlap, otherwise “language becomes a barrier to effective communication” (Steinberg 1997: 49). Although language is an arbitrary code, depending on shared definitions, no two persons share exactly the same meaning for a given word (Hahn 2005: online). In order to identify communication barriers in patient package inserts, the technical quality of the document, as well as the contained message should be considered. Consumer organisations (in the US and Europe) had previously voiced concern about the standard of the PPI relating to the quality, availability and usefulness of PPIs, especially because medication non-compliance could lead to increased health care costs. Morris, as quoted in Williams-Deane and Potter (1992: 111), stated that in the evaluation of PPIs there are two matters of primary concern, the first being effective communication and the second, behavioural outcome. Communication efficacy refers to whether the PPI is readable and the message comprehensible, while the behavioural outcome is an indirect result of the communication efficacy of the PPI.

Research findings by Schaafsma regarding the information in PPIs indicated that: “Much of the information given on medicines is regarded by patients as too difficult, especially written information” (2003: online; Vander Stichele 1989: 4). Already in 1986 the difficulty in comprehending the contents of the PPI was recognised in Belgium and a second leaflet was dispatched with the PPI, in order to transpose technical language to the colloquial and to aid the patient to understand the instructions better (Laekeman & Geerts 1986: 93).

Patients make judgements on the content of messages, or evaluative inferences based on informativeness and coherence of a message. Informativeness is generally determined by only a small percentage of the available information. Concerning the coherence aspect of a message, Kellermann and Lim stated that coherence refers to the degree that the message meets message expectations. If the expectations about the message are met, the message will be judged as coherent (1989: 104-119).

Schaafsma pointed out that, due to low literacy and second or third language proficiency, users do not fully understand the information (2003: online). Vander Stichele identified the following further communication difficulties in medical information: the information is too complex, too extensive, not extensive enough,

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difficult to read, difficult to understand, difficult to remember, causing fear and/or causing confusion (2004: 124). The process of product registration is often complicating the process of message design in a PPI. The pressure to launch a new product on the market is huge, and few pharmaceutical companies can afford to lose time while discussing the wording of a PPI with the appropriate regulatory authority in Belgium (Vander Stichele 2004: 49). This often results in the launch of a product without any review of the PPI and in so doing, communication effectiveness is compromised.

Comprehensibility

Readability of the text is the first step to the comprehension of the information contained in the PPI. Eaton and Holloway concluded that comprehension depends on reading skill and that comprehensibility can be improved by adjusting the readability level of PPIs (1980: 242). Patients' literacy levels also influence their ability to comprehend information. However, readability assessments do not give an indication of the patient's familiarity with medical terminology, or previous experience with similar documents (Rudd, Moeykens & Colton 1999: online), and as such are not clear indicators of the comprehensibility of the information.

According to Reid *et al.* factors affecting the text are meaningfulness, organisation and syntax, and these factors are not evaluated by means of readability assessments. Reader characteristics can also influence message comprehension (1994: 328). Studies conducted by Fleckenstein *et al.*, Liguori, Benson *et al.* and Morris *et al.* indicated that the reading ability of the patient on its own, as well as the readability of the material on its own, had an influence on the patient's perception of how comprehensible the material was (Eaton & Holloway 1980: 240). It was further found that incomprehensibility of the information affected health status, service utilisation and behaviour of the patients (Basara & Juergens 1994: 49; Rudd, Moeykens & Colton 1999: 10). Comprehension is therefore the result of the process of interaction between the reader and the text. Based on their research findings, Riche *et al.* concluded that reader variables, such as interest, prior knowledge of the topic and reading proficiency, also play an important part in the comprehension of patient literature (1991: 287-288).

Since communication interactions take place in a complex field of forces, which include contextual, psychological, social and cultural forces, social and cultural beliefs or values and individual feelings can create an atmosphere in which there is a prospective uncertainty about the outcome of a given communicative interaction, not less so in health communication (*Medical Facilitation: A Communication-centred Healthcare Model* s.a.: online). Hahn felt that differences in background could be one of the most difficult communication barriers to overcome. Under "background" is included: age, education level, gender, social status, economic position, cultural background, temperament, health status, political and religious orientation (2005: online). Jones named the following influencing factors on comprehension of the message: demographic variables, education level (also recognised by Reid *et al.* 1994: 333), and the state of wellness or illness of the patient (1989: 186).

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It has already been seen that human variables and interest factors are important in the accessibility of health information. Health literacy is defined as the ability to read, understand and act on health information (*What is health literacy* s.a.: online). This implies that the comprehension of health information is necessary to lead to behaviour modification. According to McCray, the problem lies in the difference between the basic literacy level of the patient and the readability of the health-related materials that the patient is expected to read, and the frequent mismatch between the two (2005: online). Yet a patient's reading ability does not always reflect accurately how well the material is understood (Estey, Musseau & Keehn 1991: 166-168). The result of low health literacy is normally lower rates of adherence to recommended treatments, more medication errors and poor health outcomes (Quyen Ngo-Metzger *et al.* 2006: online). Herxheimer and Davies stated that the fact that a PPI contains full information does not imply that the patient will be able to assimilate and use it, since effective transmission relies on both the transmitter and the recipient (1982: 94; Gibbs, Waters & George 1987: 24).

The patient has to understand the purpose of the message in order to benefit from it and to facilitate comprehension (Herxheimer & Davies 1982: 94-95). This viewpoint was confirmed by research done by Amery and Van Winkel, who found that the right information presented in the right way could improve comprehension, and therefore health outcomes (1995: 53). Yet not only is comprehension of the purpose of the message important, but also the level of complexity of the information (Pyrzczak & Roth, as quoted in Spadaro, Robinson & Smith (1980: 215).

The pure reduction of the readability level of health material, as expressed by readability assessments, is not an appropriate solution for comprehensibility, as this benefits those with higher health literacy skills more than those at the lower end of health literacy, since the information becomes even more accessible to them (Rudd, Moeykens & Colton 1999: online). In order to enhance health literacy, it would be beneficial to write in a conversational style and adapt the content to be culturally relevant.

From the above-mentioned literature it is clear that the PPI (in Europe and America) may not be fulfilling its potential as health communication tool, due to various communication barriers originating in text design and/or message presentation. What is the situation in South Africa?

CONSIDERATIONS FOR A DEVELOPING COUNTRY

Already in 1978 Hermann, Herxheimer and Lionel suggested that each country should produce its own sets of minimum information for patients, as the extent of information needs may vary (1978: 1135). Yet, according to Amery and Van Winkel, it is time to ask whether the Western approach is also applicable to Third World countries and it was suggested to identify specific problems with the use of PPIs in these countries (1995: 57).

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The effectiveness of PPIs as a source of health communication is negatively affected by medication distribution problems in the Third World. The reasons supplied by Amery and Van Winkel include: availability of medicine on the “black market”, where no PPI is available, as well as the illegal dispensing of scheduled drugs without any prescription. Additional factors include counterfeiting of medicines and importing from manufacturers who do not uphold World Health Organisation (WHO) standards, and therefore also do not pay attention to the supply of applicable health information to the patient (1995: 59). At a Drug Information Association (DIA) meeting in 1999, hosted in Gauteng, it was stated that less expensive drugs are being used without adequate patient information (Barnes *et al.* 2001: online).

A complicating factor to the distribution and standards of drug information is the fact that in a country like South Africa there are 11 official languages, which would have to be taken into account when composing and designing PPIs. This could imply huge financial and practical implications for drug manufacturers, should they decide to accommodate linguistic diversity. Linked to the problem of multiple languages, is the problem of literacy and reading skills. From demographic and English language proficiency studies undertaken in the US, it was found that patients with poor reading skills included, amongst others, the poor, minorities, the unemployed, patients older than 60 years and those who had not completed their high school education (Jackson *et al.* 1991: 1172). In developing countries, of which South Africa is partially an example, unemployment and limited schooling are also problems that often reflect in language proficiency. Thus socio-economic factors play a role in language proficiency, and by implication, in access to and comprehensibility of health messages.

Linked to language barriers are cultural differences (attitudes, norms and values), which affect health beliefs, including the utilisation of health information. Cultural factors may cause problems with the interpretation of pictographs and as Twyman warned: “If cultures are different, then picture conventions are also likely to be different; and if picture conventions are different, then so too will be the ways in which people interpret them” (1985: 301). Schaafsma expressed the problem as follows: “... so simply translating information in a ‘technical manner’ does not account for such differences in beliefs and attitudes. If no ‘cultural’ translation is done, the information is not tailored to the patient.” “Cultural” translation in this sense refers to adapting the message to the profile of the message recipient. In a country like South Africa, with its diverse cultural component, it is especially important to adapt texts culturally to accommodate the socio-economic and educational variations in an effort to increase comprehensibility. Other intercultural translation problems may also occur, for example, some words do not exist or have different meanings in other languages (Schaafsma, Raynor & De Jong-van den Berg 2003: online). Added to the problem is the presence of culture-specific language and medical bias (Schaafsma, Raynor & De Jong-van den Berg 2003: online) aspects of which the South African context is not free of.

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In South Africa, package inserts, produced by the pharmaceutical industry, have texts in English and Afrikaans. In April 2005 the South African Medicines Control Council (MCC) published a set of guidelines which should be followed for these inserts. In these guidelines, exact instructions are outlined about headings, subheadings and the type of information that has to be presented under each heading or subheading. A proposed chronological order of information is also given, starting with scheduling status, followed by scientific pharmacological information. Only under heading number 11 will the patient read about the dosage which means that he/she has to search in the document for relevant (wanted) information (MCC 2005: online). It is notable that in this outline provided by the MCC, product information enjoys higher priority than patient-preferred sections. Yet, as indicated by several European studies, if the PPI is to fulfil its health communication goals, it should be written with the patient's needs in mind. It is certainly important that full and objective information is presented, also to exempt the pharmaceutical companies from legal responsibility in the case of an adverse event, but it must also be kept in mind that the public receiving the PPI varies widely regarding educational, intellectual and socio-economic factors and therefore have varied medication information needs.

Concerning the translation of texts, Schaafsma was of the opinion that translation is not a solution if the translation is done in another language than the patient's first language, as this will not enhance comprehensibility of the message (2003: online). This has to be seen against the background of South African patients who often only have a basic knowledge of either English or Afrikaans. In addition to language proficiency, education levels have a real impact on accessibility of health communication in the South African context. It was found from research done on health communication by Tichenor, Donohue and Olien, as cited in Freimuth, Edgar and Fitzpatrick (1993: 513), that patients with higher education levels acquire knowledge faster than those with relatively less education, resulting in even bigger disparities between groups of higher education and those with less education. This disparity will reflect in the ability to access health information, as well as the comprehension of the information contained in a PPI.

According to Rudd, Moeykens and Colton (1999: online), socio-economic status is expressed by education, occupation and income, and these factors are strongly correlate with health. In diverse socio-economic and educational circumstances, health communication has an added responsibility to ensure that health communication messages are accessible and that communication barriers are limited, in order to improve the state of health awareness of the patient. The DIA, at their meeting in 1999, expressed it as follows: "Although it is generally accepted that a medicine comprises a drug and drug information, limited provision is made to ensure adequacy of patient information. High levels of illiteracy, confusing package inserts and labels, and limited availability of patient information leaflets and other appropriate patient information are widespread problems in Africa" (Barnes *et al.* 2001: online).

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From the above-mentioned it is clear that, although the package insert has a responsibility to communicate effectively with a diverse health audience, there are barriers to this aim, as has also been noted in the literature. Up to the present, in order to accommodate the low literate patient/client, there has not been an expert decision on whether health information should be written at such a level that will accommodate the low health literate, or whether there should be two versions of the material – one for the health literate and one for the low health literate (Bernhardt & Cameron 2003: 595). In the South African context, this could have huge financial implications, as it would mean that all PPIs have to be produced in 11 languages, and possibly in two versions, in order to accommodate diverse health literacy levels. Not only will this cause logistical problems, but it could lead to more intolerance towards the PPI, as an element of exclusiveness might arise regarding the more “difficult” of the two texts.

The South African MMC has in its concept document (MCC 2005: online) standardised the information elements and sequence of information in the South African PPI, yet other design factors have not been dealt with in the document. The print size and the layout certainly influence the accessibility of the information. No recommendation is given in the official guideline of the South African Medicines Control Council (MCC 2005: online) regarding font size.

Communication efficiency of the South African PPI

An empirical study was recently undertaken to investigate communication barriers in the South African PPI, making use of readability assessments (quantitative) and sample testing through interviews and focus groups (qualitative). Sixty PPIs (30 from over the counter (OTC) medication and 30 from prescription medication) were subjected to a readability assessment. These PPIs represent most regularly used medication (five drug classes, respectively). Next, in-depth interviews were conducted and the constructs identified from these interviews were tested in focus group discussions. Sample selection for the focus groups was done according to the following criteria: language preference (Afrikaans or English), age group (younger than 40 years and older than 40 years) and LSM classification (according to the Universal LSM classification determined in November 2006 by the South African Advertising Research Foundation (SAARF)) (SAARF online). The LSM grouping was done as follows: LSM 1 – 4 (basic lifestyles), LSM 5 – 7 (average lifestyles) and LSM 8 – 10 (above-average lifestyles). As a measure of triangulation, structured interviews were also conducted with pharmacists. Participants were informed of their right to withdraw at any moment without penalty, of the confidentiality of their identities and responses and they were debriefed after the interview sessions.

The results obtained from this study indicated that, based on semantic variables, the readability of the PPI texts of some English and Afrikaans examples could be considered “very difficult” or “difficult”, causing communication impediments. None were considered to be “easy”. From unstructured interviews it became clear that the communication barriers in the PPIs are contained in aspects related to the PPI itself, the information contained in the PPI, and the use of language in the PPI. These aspects

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were confirmed by focus group results, selected according to language preference, age and LSM classification. Sub-group analyses were also performed on these three classifications: LSM groupings, language preference (English or Afrikaans, since the texts are only available in these two languages) and age grouping.

The study results indicated that, in addition to technical aspects and information overload, the biggest problem was situated in language usage and style. It was stated that:

- the included terminology hampered comprehension;
- a very formal style is unfriendly and not accessible to all;
- there was a want for laymen's terms and simplified language usage;
- long sentences and "big words" excluded readers with little schooling; and
- there is a demand to supply the PPI in more indigenous languages.

From structured interviews with pharmacists it was confirmed that the value of the PPI in improving health literacy depends upon reading and understanding of the document, criteria not met by the present format, information and language usage in the PPI.

This study further indicated that:

- PPIs in South African medication packages do not fulfil their communication aim, due to barriers that can be traced mainly to document and reader variables, rendering the communication contained in the document less efficient; and
- Health communication efficacy is influenced by, amongst others, cultural competence and understandability; factors that have been neglected in the present PPI.

CONCLUSIONS

In diverse socio-economic, cultural and educational circumstances, health communication has an increased responsibility to disseminate linguistically accessible and comprehensible health information messages to facilitate an informed health decision. At present, the PPI included in the medication packet is subjected to various communication barriers, as has been from research findings. These barriers are of text and/or reader variable origin, which reflect negatively on the readability of the document and therefore, on medication information access via the package insert. Reader variables complicate text wording and design – a fact that was emphasised by Gillam and Levenson, who said that "effective communication in health care relies on a common language, but also on culture, class, beliefs, trust, and many other factors" (1999: online). It is therefore necessary that adaptation of the message should take these reader-based variables into consideration.

There is a definite need for a PPI as was indicated by research findings in 1987, which showed that between 55% and 69% more information is given and between 62% and

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68% of patients' informational needs are being met by means of written information (Ascione *et al.* 1987: 59). A study conducted in 1996 by the World Health Organisation has indicated that "there is a well evidenced and compelling need for public education in the appropriate use of drugs, with potential benefits for the individual, the community and the policymakers" (Vander Stichele 2004: 135). Although new technologies allow for the delivery of health communication messages by means of telephone, video and other electronic means (Suggs 2006: 62), the educational role of written patient information should not be overlooked, especially in the South African context where there are many people without access to electronic resources. This is mainly where an insert into the medication package should fulfil an important health communication role, provided that it communicates its message clearly (*Patient education s.a.*: online).

Health communication efficacy is influenced by accuracy, availability, balance, consistency and cultural competence; it should be evidence-based and it should reach the target population repeatedly and timely in a format and text that is comprehensible (*Healthy people 2010 s.a.*: online). It seems that especially the latter is at present a problem in the South African PPI. The above-mentioned South African research study has indicated that, in addition to readability difficulty, reader variables (including perceptions) contribute to barriers in South African PPIs. It is necessary to realise that "effective communication in health care relies on a common language, but also on culture, class, beliefs, trust, and many other factors" (Gillam & Levenson 1999: online). From the above-mentioned results it is therefore apparent that adaptation of the message should take these variables into consideration.

The two most neglected aspects in the PPI at present are *cultural competency* and *understandability*. *Understandability* refers to the reading and language levels which should be fitting to the audience, while *cultural competency* refers to allowing for various population groups, language preference and linguistic and educational levels. It seems therefore that all the problems identified in the European and American PPIs are also present in the South African equivalents. It is therefore also time for a re-thinking of the South African PPI, as it is at present not meeting its aim and not satisfying patients' needs.

Thus, a document that will render effective medication information will have to satisfy document technical demands, as well as informational and linguistic demands. The document should be about the size of an A5 page, printed in letters of at least a 10-point print size. Headings should be distinct and sufficient white space should separate different text sections. More than one colour printing will enhance the look and layout of the document, a method that can also be used to indicate more important sections, e.g. "Warnings". Where possible, use should be made of pictograms/diagrams that are culturally sensitive. This will also accommodate readers of low literacy. The desired (reduced) informational sections should be presented in the preferred patient order, in order to enhance readability and perceived utility of the document. The information should be presented in everyday language without any scientific terminology or jargon.

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Texts should also be produced in various indigenous languages to accommodate readers not fluent in either English or Afrikaans. Yet, as appropriate translations from the present English or Afrikaans terminology to the indigenous languages may not exist, this objective might be fairly difficult to attain, apart from the other logistical and financial implications of such translations. It is, however, imperative if cultural competence of the document is to be attained.

The PPI, in its aim to disseminate comprehensible health communication messages, should aim at fulfilling all the communication efficacy demands to prove itself a valuable health communication tool, accessible to all. Through achieving this aim, the health literacy of even the least educated members of society will be improved and in so-doing, it will render an incontestable health communication service to the South African patient.

REFERENCES

- Amery, W.K. & Van Winkel, M. 1995. Patient package inserts for prescription drugs in an international pharmaceutical company. *Drug information Journal* 29: 51-60.
- Arndt, H. & Janney, R.W. 1987. *Intergrammar. Toward an integrative model of verbal, prosodic and kinesic choices in speech*. Berlin: Mouton de Gruyter.
- Ascione, F.J., Kirking, D.M., Wenzloff, N.J., Foley, T.A. & Kwok, D.K. 1987. Effect of innovation characteristics on pharmacists' use of written patient medication information. *Patient education and counselling* 9: 53-64.
- Barnes, K., Gunston, G., Edwards, R. & Mehta, U. 2001. Drug safety: A shared responsibility. Proceedings of the DIA meeting held in Gauteng, South Africa, September 1999. *Drug Information Journal* July – September 2001. [Online]. Available at: http://findarticles.com/p/articles/mi_qa3899/is_200107/ai_n895550. [Accessed on 10/02/2007].
- Basara, L.R. & Juergens, J.P. 1994. Patient package insert readability and design. *American Pharmacy* 34 (8): 48-53.
- Bernhardt, J.M. & Cameron, K.A. 2003. Accessing, understanding, and applying health communication messages: The challenge of health literacy. In Thompson, T., Dorsey, A., Miller, K. & Parrott, R. (eds.) *Handbook of health communication*. Mahaw: Lawrence Erlbaum.
- Carter, J.F. 1985. Lessons in text design from an instructional design perspective. In Duffy, T.M. & Waller, R. (eds.) *Designing usable texts*. Florida: Academic Press.
- Cobley, P. 2005. The object of linguistics. In Cobley, P. (ed.) *The communication theory reader*. Oxon: Routledge.
- Dolinsky, D. & Sogol, E. 1989. The patient package insert and the pharmacist's role. In Bogaert, M., Vander Stichele, R., Kaufman, J.M. & Lefebvre, R. (eds.) *Excerpta Medica (International Congress Series 853). Patient Package insert as a source of drug information 27-37*. Amsterdam: Elsevier Science Publishers B.V.
- Eaton, M.L. & Holloway, R.L. 1980. Patient comprehension of written drug information. *American Journal of Hospital Pharmacy* 37(2): 240-243.
- Estey, A., Musseau, A. & Keehn, L. 1991. Comprehension levels of patients reading health information. *Patient Education and Counseling* 18: 165-169.
- Fitzmaurice, D.A. & Adams, J.L. 2000. A systematic review of patient information leaflets for hypertension. *Journal of Human Hypertension* 14: 259-262.
- Freimuth, V.S., Edgar, T. & Fitzpatrick, M.A. 1993. The role of communication in health promotion. *Communication Research* 20(4): 509-516.
- Fulcher, G. 1997. Text difficulty and accessibility: reading formulas and expert judgement. *System* 25(4): 497-513.

Does the patient package insert (PPI) in South Africa serve the purpose of health communication?

- Gibbs, S., Waters, W.E. & George, C.F. 1987. The design of prescription information leaflets and feasibility of their use in general practice. *Pharmaceutical Medicine* 2: 23-33.
- Gillam, S. & Levenson, R. 1999. Linkworkers in primary care, an untapped resource. *British Medical Journal* 319: 1215-1215. [Online]. Available at: <http://www.bmj.com/cgi/content/full/319/7219/1215>. [Accessed on 11/04/2007].
- Gosselinckx, F. 1989. The Belgian patient package insert. In Bogaert, M., Vander Stichele, R., Kaufman, J.M., & Lefebvre, R. (eds.) Excerpta Medica (International Congress Series 853). *Patient Package insert as a source of drug information* 49-52. Amsterdam: Elsevier Science Publishers B.V.
- Gruber, W., Llewelyn, J., Arras, C. & Lion, S. 1995. The role of the pharmaceutical industry in promoting patient education. *Patient education and counseling* 26(1-3): 245-249.
- Hahn, M. 2005. *Overcoming communication barriers between people*. [Online]. Available at: http://ezinearticles.com/?Overcoming-Communication-Barriers-Between_People&id=119628. [Accessed on 16/02/2007].
- Healthy people 2010*. [Online]. Available at: <http://www.healthypeople.gov/Document/HTML/volume1/11HealthCom.htm>. [Accessed on 03/02/2007].
- Hermann, F., Herxheimer, A. & Lionel, N.D.W. 1978. Package inserts for prescribed medicines: What minimum information do patients need? *British Medical Journal* 2: 1132-1135.
- Herxheimer, A. & Davies, C. 1982. Drug information for patients: Bringing together the message from prescriber, pharmacist and manufacturer. *Journal of the Royal College of General Practitioners* February: 93 – 97.
- Herxheimer, A. 1989. Regulatory approaches: The consumer viewpoint. In Bogaert, M., Vander Stichele, R., Kaufman, J.M. & Lefebvre, R. (eds.) Excerpta Medica (International Congress Series 853). *Patient package insert as a source of drug information* 73-76. Amsterdam: Elsevier Science Publishers B.V.
- Hybels, S. & Weaver II, R.L. 1992. *Communicating effectively*. New York: McGraw-Hill.
- Jackson, R.H., Davis, T.C., Bairnsfather, L.E., George, R.B., Crouch, M.A. & Gault, H. 1991. Patient reading ability: An overlooked problem in healthcare. *Southern Medical Journal* 84(10): 1172-1175.
- Jones, J.K. 1989. The 1988 patient package insert symposium. In Bogaert, M., Vander Stichele, R., Kaufman, J.M. & Lefebvre, R. (eds.) Excerpta Medica (International Congress Series 853). *Patient package insert as a source of drug information* 181-187. Amsterdam: Elsevier Science Publishers B.V.

Does the patient package insert (PPI) in South Africa serve the purpose of health communication?

Joossens, L. 1989. Why patient package inserts: A consumer view. In Bogaert, M., Vander Stichele, R., Kaufman, J.M. & Lefebvre, R. (eds.) *Excerpta Medica (International Congress Series 853). Patient package insert as a source of drug information 19-25*. Amsterdam: Elsevier Science Publishers B.V.

Kellermann, K. & Lim, T-S. 1989. Inference-generating knowledge structures in message processing. In Bradac, J.J. (ed.) *Message effects in communication science*. Newbury Park: Sage.

Laekeman, G.M. & Geerts, W. 1986. The pharmacist and written patient information. Results of an inquiry among Belgian pharmacists. *Journal of social and administrative pharmacy* 3: 92-97.

Lowe, G. 1995. *Communication Science*. Pretoria: Kagiso Publishers.

Maes, S. & Scholten, H. 1989. Can patient package inserts harm patients? In Bogaert, M., Vander Stichele, R., Kaufman, J.M. & Lefebvre, R. (eds.) *Excerpta Medica (International Congress Series 853). Patient package insert as a source of drug information 163-170*. Amsterdam: Elsevier Science Publishers B.V.

McCray, A.T. 2005. Promoting health literacy. *J. Am Med Inform Assoc.* 2005 March – April, 12 (2): 152 – 163. [Online]. Available at: <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=551547>. [Accessed on 10/02/2007].

McMahon, T., Clark, C.M. & Bailie, G.R. 1987. Who provides patients with drug information? *British Medical Journal* 294: 355-356.

Medical facilitation: A communication-centered healthcare model .s.a. [Online]. Available at: <http://www.creativehealing.org/Medical%20Facilitation.doc>. [Accessed on 03/02/2007].

Medicines Control Council 2005. *Proposed guideline on information of package inserts for human medicines (orthodox)*. [Online]. Available: <http://www.mccza.com/documents/9.13%20USRN%20May06%20v1.doc>. [Accessed on 10/02/2007].

McGinnis, T.J. 2000. Why we are here. In *Current status of useful written prescription drug information for patients*. Transcript of a Public Meeting by the Department of Health and Human Services, Food and Drug Administration. [Online]. Available at: <http://www.fda.gov/cder/ddmac/tranvol1.htm> [Accessed on 22/04/2002].

Morris, L.A. 1977. Patient package inserts, a new tool for patient education. *Public Health reports* 92(5): 421-424.

Morris, L.A., Myers, A. & Thilman, D.G. 1980. Application of the readability concept to patient-oriented drug information. *American Journal of Hospital Pharmacy* 37: 1504-1509.

Does the patient package insert (PPI) in South Africa serve the purpose of health communication?

Murray-Johnson, L. & Witte, K. 2003. Looking toward the future: Health message design strategies. In Thompson, T., Dorsey, A., Miller, K. & Parrott, R. (eds.) *Handbook of health communication*. Mahaw: Lawrence Erlbaum.

Orna, E. 1985. The author: Help or stumbling block on the road to design usable texts. In Duffy, T.M. & Waller, R. (eds.) *Designing usable texts*. Orlando: Academic Press.

Patient education. [Online]. Available at:

<http://igitur-archive.library.uu.nl/dissertations/01797903/c1.pdf>. [Accessed on 18/02/2007].

Quyen Ngo-Metzger, Q., Telfair, J., Sorkin, D.H., Weidmer, B., Maldonado, R.W., Hurtado, M. & Hays, D. 2006. Cultural competency and quality of care: Obtaining the patient's perspective. In *The Commonwealth Fund Report, Oct 2006*. [Online]. Available at:

http://www.cmwf.org/usr_doc/Ngo-Metzger_culturalcompqualitycare_963.pdf. [Accessed on 18/02/2007].

Reid, J.C., Kardash, C.M., Robinson, R.D. & Scholes, R. 1994. Comprehension in patient literature: The importance of text and reader characteristics. *Health Communication* 6(4): 327-335.

Rensburg, R.S. 1997. Health communication. In Rensburg R.S. (ed.) *Introduction to communication. Course Book 4: Communication Planning and Management*. Cape Town: Juta.

Riche, J.M., Reid, J.C., Robinson, R.D. & Kardash, C.M. 1991. Text and reader characteristics affecting the readability of patient literature. *Reading Improvement* 28: 287-292.

Ritchie, L.D. 1991. *Communication concepts 2: Information*. California: Sage.

Rudd, R.E., Moeykens, B.A. & Colton, T.C. 1999. A review of medical and public health literature. In Comings, J., Garners, B. & Smith, C. (eds.) *Annual review of adult learning and literacy*. New York: Jossey-Bass. [Online]. Available at: http://www.hsph.harvard.edu/healthliteracy/litreview_final.pdf. [Accessed on 18/02/2007].

Rudd, R.E. & Colton, T.C. 1998. An overview of medical and public health literature addressing literacy issues: An annotated bibliography. In *The National Centre for the Study of Adult Learning and Literacy Report # 7*. Cambridge: Harvard University Press.

Ryan, M. 1986. *A history of organised pharmacy in South Africa 1885 – 1950*. Cape Town: Creda Press.

SAARF. *The SAARF universal LSM*. [Online]. Available at: <http://www.saarf.co.za>. [Accessed on 23/01/2007].

Schaafsma, E.S., Raynor, D.K. & De Jong-van den Berg, L.T.W. 2003. Accessing medication information by ethnic minorities: barriers and possible solutions. In

Does the patient package insert (PPI) in South Africa serve the purpose of health communication?

- Pharm World Sci* 2003, 25 (5): 185 – 190. [Online]. Available at: <http://genesmiddelen.wewi.eldoc.ub.rug.nl/FILES/root/artikelen/2003/FIPminorities/2003PWS185Schaafsmaea.pdf>. [Accessed on 18/02/2007].
- Smith, S. 2002. Readability testing, health information. *Beginnings*. Electronic newsletter. [Online]. Available at: <http://www.prenataled.com/story9.htm>. [Accessed on 19/03/2007].
- Spadaro, D.C., Robinson, L.A. & Smith, L.T. 1980. Assessing readability of patient information materials. *American Journal of Hospital pharmacy* 37: 215-221.
- Steinberg, S. 1997. *Introduction to communication. Course book 1: The basics*. Cape Town: Juta.
- Stevens, C. 2000. *All about readability*. [Online]. Available at: <http://plainlanguage.com/newreadability.html>. [Accessed on 07/02/2007].
- Street, R.L. 2003. Communication in medical encounters: An ecological perspective. In Thompson, T., Dorsey, A., Miller, K. & Parrott, R. (eds.) *Handbook of health communication*. Mahaw: Lawrence Erlbaum.
- Suggs, L.S. 2006. A 10-year retrospective of research in new technologies for health communication. *Journal of Health Communication* 11: 61 – 74. [Online]. Available at: <http://www.ingentaconnect.com/content/tandf/uhcm/2006/00000011/00000001/art00007>. [Accessed on 02/04/2007].
- Twyman, M. 1985. Using pictorial language: A discussion of the dimensions of the problem. In Duffy, T.M. & Waller, R. (eds.) *Designing usable texts*. Orlando: Academic Press.
- Vander Stichele, R. 1989. Patient package insert as a source of drug information: Review of the literature. In Bogaert, M., Vander Stichele, R., Kaufman, J.M. & Lefebvre, R. (eds.) *Excerpta Medica (International Congress Series 853). Patient package insert as a source of drug information* 3-11). Amsterdam: Elsevier Science Publishers B.V.
- Vander Stichele, R.H. 2004. Impact of written drug information in patient package inserts: Acceptance and impact on benefit/risk perception. Unpublished doctoral thesis. Ghent: Ghent University. [Online]. Available at: http://users.ugent.be/~rvdstich/thesis/written_drug_information_screen.pdf. [Accessed on 18/02/2007].
- What is health literacy?* s.a. [Online]. Available at: www.pfizerhealthliteracy.com/public-policy-researchers/what-is-health-literacy.html. [Accessed on 03/02/2007].
- Williams-Deane, M. & Potter, L.S. 1992. Current oral contraceptive use instructions: An analysis of patient package inserts. *Family Planning Perspectives* 24(3): 111-115.
- Wood, J.T. 2004. *Communication theories in action*. Belmont: Wadsworth.

Does the patient package insert (PPI) in South Africa serve the purpose of health communication?

