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Research Article

Useful Medication

Development of a Useful Medication Package Insert for Patients: Sudan Intervention Study

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Objective: The study's main objective was the development of a model (intervention) medication package insert useful to patients. **Methods:** A control package insert which was randomly selected, was for a registered chlorpheneramine maleate tablets local brand, the experimental (intervention) one, for the same generic name, was articulately developed by the researchers. Together with two almost identical sets of questionnaires, composed of ten and eleven questions, were used as materials for the study. The two package inserts together with the two sets of questionnaires, were then handed over to (99) participants, who were randomly selected from the general public. **Results:** Result showed a (100%) literate participants' population, majority were young (75.8%), males (60 %), ten percent (10%) had basic schooling of eighth grade, (90%) had secondary, university and post graduate education. The intervention package insert developers used clear, easy lay native language (Arabic), minimum technical terms, short words, short sentences, alternating with longer ones, readable font size (11 points), leading (1.5 points), bullet points, section headings were in bold print, proper color background contrast (black and white), comprehensive and balanced informational contents under (20) medication information section headings. That greatly improved its readability, understandability, and usefulness to patients. As a result, the majority (81.82%) of participants preferred the intervention package insert to the control one. **Conclusion:** Useful package inserts shall target patients as main audience, provide sufficient, accurate, updated and balanced basically needed medication information, in simple, readable and understandable lay native language and terms.

Keywords: Sudanese, Patients, Package insert, Usefulness, Intervention

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Introduction

The importance and benefits of providing patients with written medication information is well documented in the literature. ([1], [2], [3] - [4]) Many authors pointed to the possibility of increased adherence following provision of appropriately designed written information. ([5], [2]) It is thought that written information may have negative consequences on the receiving patient. [6] However, many studies proved otherwise. ([7], [4]) The medication package insert, being the most available and easily accessible form of written medication information, is considered as the most important, easily accessible and frequently used source of written medication information for patients. [8] It usually is a small folded leaflet included by manufacturers in the small unit packs of pharmaceutical products to provide additional written information about medications to patients, and the prescribers, as per the Sudanese regulations requiring and controlling pharmaceuticals' legislations. [9] It is usually written in one or more languages including the official language(s) of the country concerned. Package inserts all over the world almost follow a standard format targeting specific type of information. This standard format is composed of informational section headings which may vary in number and wording, but ultimately gear towards the common goal of information about medications to patients, prescribers and the other health care team members. The regulatory authorities while defining or dictating the section headings of the package insert, do not usually give the due attention to the particulars of the informational contents, lay out and the overall design of the text conducive to easy reading and comprehension by patients. These are usually left to the manufactures, who usually and normally respect their business interest in what to be written. This is from where the disparities in package inserts' medication information quality and quantity in different parts of the world may ensue. Legibility readability and understandability and the particulars of the informational contents of such written information documents, which greatly affect their usefulness, should be of prime concern for the developers and writers, needless to say for the regulators. [2] The package inserts accordingly, must be written in the native language, of the targeted audience, that is easily readable and comprehensible even by Low literates and at the appropriate grade level of readability. [10] It must be written in simple plain language that avoids or at least minimizes and simplifies the technical terms, as advised by many researchers. ([10], [11], [12]) As medications themselves are required to be tested on the targeted population groups before being passed by the regulatory agencies, package inserts and other sources of written medication information have to be tested on selected groups of the targeted patients, prior to their approval and free circulation. ([13], [14])

Methods and Materials

Based on the above; two package inserts, the first being the (control) officially accepted by the Sudan medicines registration authorities (written in English) accompanying registered products randomly selected, and the second an experimental (intervention) one for the same generic name (Chlorpheneramine male ate tablets) articulately developed by the researchers (written in Arabic only) together with two almost identical sets of questionnaires, were used as materials for this study. The experimental (intervention) package insert was firstly piloted on (n=20) public individuals, to test and assess the design, readability and audience satisfaction with the text. The pilot study group was not included in the main study group. The piloting helped introduce some minor changes on the package inserts text and layout of the accompanying questionnaires. The potential participants (99) public individuals, who were purposively selected from the general public in both Khartoum and Gezira states (Sudan) on basis of non- probability sampling (limitless population) were verbally informed by the interviewers (three pharmacy students) of the nature and overall objectives of the questionnaire and were made aware that they are free to decide to participate or refrain ,and their highly needed and appreciated participation will be considered as a reliable form of free informed consent. They were allowed ample time to read the two leaflets and answer the two sets of questionnaires (almost identical safe for the eleventh question in the second one). The participant public individuals were assured that the two questionnaires and PIs were not meant to test their reading abilities and their identity will not be disclosed.

They were also assured that the study has no other agenda than the objectives disclosed to them. This was meant to encourage them to secure their cooperation and participation, freely, willingly and comfortably. They were then handed over the official package insert accompanying the registered and available pharmaceutical product (control), branded generic chlorpheneramine, randomly selected (out of twelve registered brands of the same generic name, first to read at their ease and freedom and then answer the short open to answer questionnaire, consisting of ten questions and the second one consisting of eleven questions. The same subjects were then given the experimental (intervention) package insert about the same product to read and evaluate by answering the accompanying same questionnaire which consisted of eleven questions, ten of which were identical to those used in the evaluation of the control package insert and the eleventh was about the respondents' preference between the two package inserts.

Results

Table (1): Readability, understandability and satisfaction of respondent public individuals with the control Package Insert

Characteristic	Frequency	Percent	Valid Percent	Cumulative percent
Easily read PI Valid Yes No Total Missing Total	31 67 98 1 99	31.31 % 67.67 % 98.98 % 1.01 % 100.0 %	31.31 67.67 98.98 100.0	31.31 98.98 100.0
Text font size reasonable for reading Valid Yes No Total	37 62 99	37.37 % 62.63 % 100.0 %	37.37 62.63 100.0	37.37 100.0
Text language and terminology easy and conducive Valid Yes No Total	25 74 99	25.25 % 74.75 % 100.0 %	25.25 74.75 100.0	25.25 100.0
P.I. information useful , comprehensive about benefits and risks of medication Valid Yes No Total	26 73 99	26.26 % 73.74 % 100.0 %	26.26 73.74 100.0	26.26 100.0
Participants understood safe and correct use of medication Valid Yes No Total	35 64 99	35.35 % 64.65 % 100.0 %	35.35 64.65 100.0	35.35 100.0
P.I satisfactory and contains sufficient information Valid Yes No Total	25 74 99	25.25 % 74.5 % 100.0 %	25.25 74.5 100.0	25.25 100.0
P.I information help in correct use of medication Valid Yes No Total	34 65 99	34.34 % 65.60 % 100.0 %	34.34 100.0 100.0	34.34 100.0

The following results were obtained from the (99) respondent public individuals on the readability, understandability, satisfaction and usefulness of the medication information and the overall design of the control medication package inserts (Chlorpheneramine maleate) by the aid of a multi - variate questionnaire, which consisted of 10 questions. The age distribution of the respondent public individuals showed an overall young population, as 75 (75.8%) were below the age of 40 years. The gender distribution, from the other side, showed a majority (60%) of males, while females represented (40%). The educational level showed a 100% literate respondents population, of which (90%) had secondary, university and postgraduate education while those having primary school education were a minority (10%).It is worth mentioning that, the participant public individuals in the two parts of the intervention study were the same (control and experimental).

Results obtained on the readability ease, understandability, comprehensibility, satisfaction and useful medication information in both the control and experimental PIs were as per **Table (1)** Readability of the control PI text was easy for 31 (31.31%) of the participant public individuals, but was difficult for their majority (67.67%). The font size of the text of the control PI was conducive to easy reading for only 37 (37.4%) of the respondent public individuals, but was difficult to their majority 62 (62.6%). The language and terminology of the control PI (English only) were easy to understand and comprehend for only 25 (25.3%) of the respondents, but they were difficult for the majority74 (74.7%). The PI was supposed to provide the reader with the useful and comprehensive needed medications information as regards the benefits, risks and proper use of the medications.

The studied participant public individuals views about the control PI, were that it satisfied the above mentioned provision for only 26 (26.26%), while for the majority 73 (73.74%) it did not. On the same side the control PI was informative about the safe and correct use of the medication for only 35 (35.35%) of the participants' public individuals but for the majority 64 (64.65%) it was not. The control PI was also satisfactory and did contain sufficient information for 25 (25.25%) of the respondents but not for 74 (74.7%). The control PI medication informational contents helped only 34 (34.3%)

Of the respondents to use drugs safely, but it was not so for 65 (65.66%) of the participants. The experimental intervention PI **Table (2)** was found easy to read by 95 (95.95%) of the respondent public individuals while only 4 (4.05%) did not find it easy to read. The font size which if not reasonable for sight, would pose reading difficulty of written text, was found to be reasonable for reading the text of the experimental PI by 89 (89.9%) of the public individuals participants, while for a minority of 10 (10.1%) it was not reasonable.

The language and terminology in which the P.I text was written were known to be, strong predictors of the readability of written text. Ninety seven (98%) of the participant public individuals found both the language and terminology conducive to easy reading of the experimental PI, while for 2 (2%) they were not. Ninety eight (99%) of the participants asserted that the experimental P.I satisfied those provisions, while only 1 (1%) did not find it so.

The medication information in the PI was supposed to help the readers understand the correct use of the subject medication (Chlorpheneramine maleate), for an exclusive majority 97 (98%) of the participant public individuals, the experimental P.I was satisfactory, while for only one participant 1 (1%) it was not. It was planned and tailored that the written medication information in the experimental PI.

Should prove of help to the readers in the correct use of the subject medications. This was the case, as confirmed by 98 (99%) of the participants public individuals, while for only 1 (1%) it was not. When the participants were asked to give their free preference label for the first (control) PI or the second experimental (intervention), a casting majority of 81 (81.82%) of the respondents preferred the experimental PI.

The control PI was preferred by only 18 (18.18 **Table (3)** showed the descriptive analysis of the control and experimental package inserts detailed characteristics particulars, where the control was written in English only and the experimental PI. was written in Arabic only.

Table (2): Readability, Comprehensibility and satisfaction of the (n=99) public individuals participants by the Experimental Package Insert. (Intervention)

Characteristic	Frequency	Percent	Valid Percent	Cumulative percent
Easily read P I Valid Yes	95	95.95 %	95.95	95.95
No	4	4.05 %	4.05	4.05
Total	99	100.0 %	100.0	100.0
Text font size reasonable for reading Valid Yes	89	89.9 %	89.9	89.9
No	10	10.1 %	10.1	10.1
Total	99	100.0 %	100.0	100.0
Text language and terminology easy and conducive to understanding Valid Yes	97	98.0 %	98.0	98.0
No	02	2.0 %	2.0	2.0
Total	99	100.0 %	100.0	100.0
P.I. information useful , comprehensive and educative about benefits and risks of medication Valid Yes	98	99.0 %	99.0	99.0
No	1	1.0 %	1.0	1.0
Total	99	100.0 %	100.0	100.0
Participants understood safe and correct use of medication Valid Yes	97	98.0%	99.0	99.0
No	1	1.0 %	1.0	1.0
Total	98	99.0 %	100.0	100.0
Missing system	1	1.0 %		
Total	99	100.0 %		
P.I satisfactory and contains sufficient information Valid Yes	97	98.0 %	98.0	98.0
No	2	2.0 %	2.0	2.0
Total	99	100.0 %	100.0	100.0
P.I information help in correct use of medication Valid Yes	98	99.0%	99.0	99.0
No	1	1.0 %	1.0	1.0
Total	99	100.0 %	100.0	100.0
Participants prefer first (control) or second (experimental) Valid First	18	18.18 %	18.18	18.18
Second	81	81.82 %	81.82	81.82
Total	99	100.0 %	100.0	100.0

Table (3): Comparative description of the characteristics of the control and experimental Package Inserts

Description		
Characteristic	Control (official) leaflet	Experimental leaflet
Language	English only	Arabic only
Paper texture: matt non- glossy and non – transparent surface.	Yes	Yes
Area of leaflet to the nearest cm²	73.7 cm² (One page)	1247.4 cm² (TwoA4 pages)
Colors used	Blue , brown and white	White and black only
Total number of words in PI.	171	767
Average words / cm²	2.32 words / cm²	0.614 words / cm²
Empty white space	Little	Quite ample white space
Total number of lines	38	78
Average number of words / line	4.5	9.83
Average letters/ line	40	47
Total No of sentences	14	48
Average words / sentence	12.8	16
Random sentence length sequence (based on number of words)	15-1-11-17-12-12-21-18-21-10-11-21-18-1-15.	12-6-9-12-8-2-15-14-4-20-3-19-2-17-17.
Text font size in points	6	11
Leading (vertical space between lines)	1	1.5
Headings in bold print	No	Yes
Capitals and italics use.	Capitals used in brand and company's names only. No italics.	No capitals or italics used.
Number of available section headings	7	20
Tables	None	None
Pictograms	None	None
Justification of text	Justified left hand side	Justified right hand side
Bullet points	None	20(including sub-headings)
Technical terms in text	33 (19.29 % of total words)	10 (1.3 % of total words)
Active voice used to address readers	No	Yes.
Missing section headings and subheadings	• Side effects reporting and management. (only some side effects were mentioned) • Contraindications. • Drug interactions. • Missed dose management. • Overdose and it's management • Handling of unused portion of medicament. •Don't use medication after expiration date, and disposal of unused portion. • Use by special population groups (Pregnancy, hepatic ,renal etc • Storage conditions. • Keep out of the sight and reach of children and the mentally handicapped • Date of last revision of leaflet. • Request to keep leaflet for future reference. • Do not advise others to use same medication based on information you had from PI.	• All were available.

The control PI was composed of one a matt, non glossy and non transparent small paper while the experimental one consisted of two (n=2) A4 pages of the same texture as that of the control. The area (in cm²) of the control PI was 73.7 cm² while area of the two pages of the experimental PI was 1247.4 cm² in area? The total number of words of the control PI was 171 and the experimental had 767 words in 38 and 78 lines respectively. The total numbers of sentences were 14 for the control and 48 for the experimental PI. The text font size of the control PI was 6 points while that of the experimental was 11 points. Headings were written in bold in the experimental PI, but not in the control PI. There were no tables or pictogram in both the control and experimental PI. The active voice was used in the experimental PI to address the reader, but not in the control. Justification was used for the left side of the control PI but right side justification was used for the experimental because it was written in Arabic. Most importantly, the control PI had only seven medication's information section headings, while the experimental one had twenty (n=20) section headings. Compared to the experimental PI the control PI was missing in thirteen section headings and subheadings.

Discussion

Table (3) showed the characteristics of the control and experimental (intervention) package insert which was mainly developed by the researchers to secure a readable, understandable and satisfactory information documents for the readers. The experimental PI, was intended, written and designed on the basis of clear writing, [15] those bases were broadly defined as a way of presenting information so that it is easy for everyone to read and understand. Many package inserts are poorly read and understood because their design and complex informational contents texts lead to problems even to literate readers. ([13], [16]) The various design characteristics of a readable, understandable and satisfactory P.I were respected by the researchers

While developing the experimental PI. Thus, lay Arabic language was used as it is the official national (native) language of Sudan which is spoken and understood by almost all the population. This choice of the native language was in line with the recommendations of a group of researchers. ([12], [17], [18]) The second factor considered in the development of the experimental package insert, was the minimization of the technical terms to the extreme possible limit (1.32% of the total number of words of the PI. text) as per the recommendations of many authors. ([19], [20], [18]) It was reported by some researchers that, technical legal language and Jargon might exclude readers who are not familiar with these terms. [15] The respondents in one study in Saudi Arabia recommended that the PI be written in simple Arabic. [21] That was because the classical Arabic in which the PIs were written was difficult to comprehend by the ordinary citizens. There was no use in the experimental PI of any terms or expressions that demonstrated cultural, gender or class bias. The experimental package insert text used the active voice to address readers to attract and motivate them and create a conversational lively text that helps to create a warm relation with readers. [20] In contrast, the control package insert was in English only (highly limited use in Sudan, contained a lot of technical terms (19.29 % of total text's words) and did not at all use the active conversational voice or tone, this might had created a certain degree of intimidation to readers, which limited their understanding to and satisfaction with its written text. The researchers gave quite much attention to the medication informational needs of the readers in the experimental medication package insert. Almost (n = 21), section headings and subheadings embraced = the information which was intended to cover all the aspects of risks and benefits of the subject medication (Chlorpheneramine Maleate). Those headings and subheadings were put in the text according to their perceived importance to readers. The contraindications were put among the top headings as that aids memorization and reduces intimidation of readers. [4] The developers intended to give detailed medication information as that what the patients always needed. [22] Those headings and subheadings which followed the Sudanese Pharmacy and Poisons Act, [9] were respected but relocated. As advised by other researchers, [23] some side effects were reported numerically.

In comparison to the experimental PI, the control PI, was completely missing thirteen (n = 13) sections and subsections headings. That indicated a less rich medication informational contents .That comprehensiveness of the experimental PI necessitated the use of two A4 pages (Area of 1247.4 cm^2) compared to one small page for the control PI. (Area 73.3 cm^2). The total number of words used for the experimental PI. Were 767 compared to only 171 words for the control PI? Which used only 38 lines as compared to 78 lines for the experimental package insert? To ease readability of the text, very strong consideration was given to the typography of the experimental PI. Thus the text was written in a font size of eleven points as recommended by a big group of researchers. ([15], [24]) All headings were written in 13 points font with bullets, as that made the text easy to navigate, facilitated reading and captured attention. Moreover, an extra white space was left before the headings which were all written in bold point's typeface. [25] Plenty of white space was also left around the text and between the paragraphs and in the margins of the experimental PI, as this is known to provide a strong contrast and give the readers the feeling that the text was not dense. [13] In contrast the control P.I text was written in 6 points font size and 8 points for the headings which were not written in bold, but capitals were used in them. To further ease readings, the leading used in experimental P.I was 1.5 points compared to only one (1) in the control PI. Plenty of white space between lines was secured to help separating one line from another. [13] Leading used in the experimental package insert was recommended to be 1.5 points [26] both the control and experimental P.I were one side justified (left and right for the control and experimental PIs respectively. As recommended by other researchers, [15] one side justification of text was used in the experimental PI, as it aided easy location of the start of the lines of its text. Both the control and experimental package inserts did not contain medication pictograms. Though advocated by many authors, medication pictograms were not proven to be of great value for the understandability of the PI [1], and their meaning might, as well, be poorly interpreted [27] even after verbal explanation to patients. The overall syntax of the experimental package insert followed the ideal possible pattern, thus using short words, [28] and shorter sentences (16 words / sentence in

Average). It was recommended that a maximum of 20 words / sentence should be used. As could be seen from the random sentence length sequence based on number of words, short and long sentences were used alternatively [29] as glossy papers make reading difficult since they reflect light. And transparent paper texture, from the other side, makes letters and words difficult to distinguish, the type of paper texture used in the experimental PI, was matt, non – glossy and non – transparent. [13] Black ink on a white background was used in the experimental PI. As it gave the best color contrast and enhanced readability, [20] in comparison the controls PI used blue ink on white paper and brown color as a background for their brand name which appeared in white. By observing all above much recommended points when developing the experimental PI, the developers, were able to produce an easily readable, understandable satisfactory and useful PI which won the bless of the participants as it was matching to recommendations of ([13], [26], [16], [30]) reported that well designed and easily readable drug information leaflets will help patients gain significant amounts of knowledge from them. [30] This successful end was possible when the developers respected the various comments of the target audience as the experimental package insert was first piloted (before arriving at the final manuscript) on twenty public individuals randomly selected, whose various comments were sufficiently considered as advised by many authors, ([31],[13],[20]) when the researchers felt comfortable with the overall contents, layout and design of the experimental package insert, they then sought the final evaluation of the control and experimental PI. From the (n = 99) selected public individuals' participants by the aid of a structured questionnaire. The questionnaire was composed of 10 identical questions for both PIS but the one related to the experimental had one extra question more (the eleventh) in which the participants were requested to point to their preference choice for the best PI, between the control PI, (First one handled to them) and the experimental one. Results (Table1,and 2) of the readability of control P.I rating was consistent with the opinion of other researchers [32] who reported that the readability level of much of the written health and medicine information was beyond the reading abilities of many of the readers who have limited literacy. The high rate of the easy readability of the experimental PI Text compared to that of the control PI, might probably be due to the easy lay Arabic language, appropriate font size and minimum technical terms used. That was evident from the results of the answers given for the same questions that followed where the font size of the control PI. Was not reasonable for reading for 67 (65.4%) compared to only 10 (10.1%) of participants who found font size of the experimental PI. not reasonable for reading. Moreover, the language and terminology in which the control P.I was written were not found to be conducive to ease of understanding. In comparison (98 %) of the participants found the language and terminology in which the experimental PI. text was written, easy and conducive for understanding. The experimental PI with its easy readability, understandability, satisfaction and usefulness to the participants was crowned with their preference over the control PI by a casting vote of (81.82%) to the control, which won only (18.18%).

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