Preference of Patient Information Leaflets over Standard Drug Monographs by Patients Prescribed Hydrochlorothiazide, Nifedipine and Enalapril

M Gossell-Williams[1], O Bennett[2], Y Dias[2], K Foster[2], M Houston[2], K Wright[2], Z Fairclough[2]

ABSTRACT

Standard drug monographs (SDMs) have been described as deficient in providing information in a manner simplified enough for patient reading. The aim of this study was to design patient information leaflets for hydrochlorothiazide, nifedipine and enalapril with content indicated by patients as relevant and to evaluate them against the SDM. Patient information leaflet (PIL) for each drug was designed to contain information on name, use of drug, how it works, how it is to be taken, common side effects, storage, missed dose action, things to avoid and when to contact the physician. Appropriateness was assessed by 10 practising pharmacists. For each drug, 40 patients were recruited, of which 20 were given SDM and 20 PIL. The knowledge of each participant was examined before and after exposure to SDM or PIL, as well as opinion on ease of reading and attractiveness using Pearson's Chi-square analysis. The results showed that both SDM and PIL improved knowledge of common side effects when compared with responses before exposure ($\chi^2 = 24.26$ for SDM and 27.64 for PIL, $p < 0.001$) with no difference between the groups. Respondents receiving PILs were better able to recall "things to avoid" after exposure to PIL ($\chi^2 = 10.85$, $p < 0.001$). After exposure to SDM or PIL, the respondents who received PIL were more aware of when to contact the physician, compared to the SDM group ($\chi^2 = 8.41$, $p < 0.01$). When compared with SDM, respondents receiving PIL were more likely to indicate that PIL was easy to read ($\chi^2 = 20.00$, $p < 0.001$), attractive ($\chi^2 = 12.45$, $p < 0.001$) and they were more likely to recommend distribution of their reading material to other patients ($\chi^2 = 22.11$, $p < 0.001$). We conclude that there is benefit in designing information leaflets that simplify language and medication information contained in SDMs, including better understanding of precautions to take while on medication and when to consult physicians.

Keywords: Antihypertensives, patient information leaflet, standard drug monograph

Preferencia por los Prospectos de Información al Paciente en Lugar de las Monografías Estándar sobre Medicamentos, por parte de los Pacientes a Quienes se les ha Prescrito Hidroclorotiazida, Nifedipina y Analapril

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RESUMEN

Las monografías de medicamentos estandarizadas se han considerado deficientes a la hora de proporcionar información de manera suficientemente simple para que el paciente pueda entenderlas. El objetivo de este estudio fue diseñar prospectos con información sobre la hidroclorotiazida, la nifedipina y el analapril con contenidos indicados como relevantes por los pacientes, y evaluarlos en comparación con las monografías estandarizadas de medicamentos (MEM). El prospecto de información para el paciente (PIP) fue diseñado de modo que apareciera información sobre el nombre del medicamento, su uso, modo de operar, manera de tomarse, efectos secundarios comunes, almacenamiento, qué hacer en caso de perder una dosis, cosas que deben evitarse, y cuando debe contactarse el médico. Se evaluó la adecuación por parte de 10 farmacéuticos practicantes. Para cada medicamento, se reclutaron 40 pacientes, a 20 de los cuales se les dio monografías (MEM), en tanto

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que a 20 se les ofreció prospectos (PIP). El conocimiento de cada participante se examinó antes y después de la exposición a MEM o PIP, así como la opinión en cuanto a facilidad de lectura y grado de atracción, usando el análisis del Chi-cuadrado de Pearson. Los resultados mostraron que tanto MEM como PIP mejoraron el conocimiento sobre los efectos secundarios comunes, cuando se hacía una comparación con las respuestas antes de la exposición (χ^2 = 24.26 para MEM y 27.64 para PIP, $p < 0.001$*) sin diferencia entre los grupos. Los encuestados que recibieron prospectos pudieron recordar mejor las "cosas a evitar" luego de la exposición a PIP (χ^2 =10.85,* $p < 0.001$*). Después de la exposición a MEM o PIP, los encuestados con PIP tenían mayor conciencia en cuanto a cuando contactar a un médico, en comparación con el grupo MEM (χ^2 = 8.41,* $p < 0.01$*). Cuando se les comparó con el grupo MEM, los encuestados que recibieron PIP mostraron por una parte mayor probabilidad de indicar que PIP era más fácil de leer (χ^2 = 20.00,* $p < 0.001$*) y atractivo (χ^2 = 12.45,* $p < 0.001$*), y por otra, una mayor tendencia a recomendar la distribución de su material de lectura a otros pacientes (χ^2 = 22.11,* $p < 0.001$*). Se llegó a la conclusión de que es beneficioso diseñar prospectos que simplifiquen el lenguaje y la información médica contenida en las monografías estándar del medicamento, incluyendo una mejor comprensión de las precauciones a tomar mientras se está bajo medicación, y sobre cuándo consultar al médico.*

Palabras claves: antihipertensivos, prospecto de información al paciente, monografía estandarizada del medicamento

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INTRODUCTION

A drug monograph is a factual, scientific document on the drug that describes the properties, claims, indications and conditions of use for the drug. The standard format of a drug monograph consists of three distinct sections (1): *Section I* – health professional information which contains the information required for the safe and appropriate prescribing, dispensing and administering of the medication; *Section II* – scientific information which contains more in-depth and complete scientific/research information such as toxicology and data from animal studies and human clinical trials. It complements and extends the information contained in Section I; *Section III* – consumer information which helps the consumer understand what the medication is, how to use it and what the potential side effects are. It is also intended to serve as a guide for health professionals to easily identify the information needed for counselling patients.

Studies have confirmed that patients' inability to understand information provided is a barrier to compliance with medication (2). It has also been established in studies that the more patients know about their medications, the greater will be the compliance (3, 4). Therefore, providing patients with drug monographs should facilitate increased compliance. Consumer surveys done in Canada suggest that Canadian patients are routinely provided with drug monographs when filling prescription. While the participants acknowledged the benefits of the standard drug monograph (SDM) to compliance, they reported an overall dissatisfaction with font size, volume of the information, use of medical terminology and complicated language (5). The information participants in the Canadian survey identified as relevant included: the specific names of the drug (brand), the purpose of the medication, the ingredients, the dosage amounts, instructions on how to take the medication to maximize effectiveness, the potential side effects, how these side effects might be recognized, avoided and addressed. Studies done in the United Kingdom had similar findings (6). They also expressed a desire for clear, easy and concise information. With the challenges expressed and the information indicated by consumers as important for compliance, it would therefore by useful to design information leaflets that satisfy the patients identified needs. The first part of this study involved designing a "patient information leaflet" (PIL) for three commonly prescribed antihypertensive drugs: hydrochlorothiazide, nifedipine and enalapril. The second part aims to evaluate the knowledge of patients of their drugs before and after exposure to PIL and how it compares to exposure to SDM.

METHODS

Patient information leaflets were designed for hydrohlorothiazide, nifedipine and enalapril by a group of final year pharmacy students, using SDMs provided by the drug manufacturers: hydrochlorthiazide from Apotex Company in Canada, nifedipine from Bayer in Germany and enalapril from Dr Reddy's in India. The information included in the designed PIL was based on what Canadian consumers identified as important. Patient information leaflets contained drug name, available brands in Jamaica, uses, dosage range, how the drug works, when to take it, missed dose action, common side effects, storage information, precautions and when to consult a physician (Fig. 1). Information on brands available in Jamaica was obtained from local pharmacies.

In order to obtain a professional evaluation of the drug inserts, 10 practising community pharmacists were randomly selected using the list of all registered pharmacies within

HYDROCHLOROTHIAZIDE DRUG INSERT

Drug Name: Hydrochlorothiazide (HCTZ)

Brand Names: Apo Hydro®, Microzide®, Esidrex®

Main Uses: 1. Control of mild-moderate high blood pressure

2. Treatment of fluid build-up in heart failure

Dosage Ranges: 25 mg and 50 mg as scored tablets.

How drug works: Acts by preventing the re-uptake of sodium in the kidneys, causing a loss of this sodium along with water and potassium.

When/How to take: Take half (½) to two (2) tablets once daily, as is directed by your physician.
It may be taken with food or milk. Take early in day to avoid frequent urine at night. If you must take medication more than once, take last dose no later than 6 pm.

Missed dose: Take the missed dose as soon as you remember. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

Common Side Effects: A sudden fall in blood pressure when standing, sensitivity to light, a decrease in potassium levels in the body.

Storage: Store at room temperature, away from heat, moisture and light. Do not store in the bathroom. Keep HCTZ out of the reach of children and away from pets.

Precautions: Should not be taken if patient is pregnant, allergic to sulphonamide based drugs or any thiazides, has kidney disease, family history of gout, diabetes, (SLE)-Systemic Lupus Erythematosus.

Drugs that can prevent HCTZ from working properly:
Other water tablets eg Lasix, ACE inhibitors eg Enalapril, lithium, oral anti-diabetic drugs, anti-cholesterol drugs, pain killers, Digoxin, alcohol, garlic, ginseng and ephedrine.

Contact your doctor if you experience: nausea, vomiting, difficulty breathing, slow heartbeat.

NIFEDIPINE DRUG INSERT

Drug Name: Nifedipine

Brand Names: Adalat®, Adalat® CC, Nifedical® XL, Procardia®, Procardia XL®, Apo-Nifed®, Apo-Nifed PA®, Calcigard®

Main Uses: 1. High blood pressure

2. Chest pain (angina)

Dosage Range: Between 10 mg to 90 mg as capsules and extended-release (long-acting) tablets

How drug works: It lowers high blood pressure by relaxing blood vessels so the heart does not pump as hard. It also increases the supply of blood and oxygen to the heart to control chest pain (angina).

When/How to take: Taken once or three times daily. The long-acting tablet should be taken on an empty stomach, either 1 hour before or 2 hours after a meal, and should be swallowed whole. Do not chew, divide, or crush the tablet. If stomach upset occurs take it with food.

Missed dose: Take the missed dose as soon as you remember. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

Common Side Effects: Headache, dizziness when sitting or standing up, excessive tiredness, feeling of warmth, nausea and vomiting.

Storage: Store at room temperature, away from heat, moisture and light. Do not store in the bathroom. Keep Nifedipine in the container it came in, tightly closed and out of the reach of children and away from pets.

Precautions: Should not be taken if you are allergic to drug, have become pregnant, are breastfeeding, if you have or have ever had heart, liver, or kidney disease, or if taking certain other medications. Therefore inform your doctor about these things.

Drugs that can prevent Nifedipine from working properly: Digoxin, Cimetidine, Phenytoin, grapefruit juice, Warfarin, Quinidine, Ranitidine.

Contact your doctor if you experience: swelling (of the face, lips, tongue, eyes, arms and legs), skin rash, difficulty breathing or swallowing, fainting.

ENALAPRIL DRUG INSERT

Drug Name: Enalapril

Brand Names: Vasotec®, Enalapril (Health 2000), Enam®, Ednyt®, Las-Enalapril®, Apo-Enalapril®, Redopril®, BQL®, Invoril®

Main Uses: 1. High blood pressure

2. Heart failure

Dosage Range: Between 2.5 mg to 40 mg as tablets.

How drug works: Lowers blood pressure by preventing the production of certain substances in the body that would normally cause blood pressure to increase.

When/How to take: Taken once or twice daily with or without food as directed. If stomach upset occurs take it with food.

Missed dose: If you miss a dose take it as soon as you remember unless it is within 2 hours of the next dose. Do not take two doses at once.

Common Side Effects: Headache, dizziness when sitting or standing up, tiredness, dry cough, nausea and vomiting.

Storage: Store at room temperature, away from heat, moisture and light. Do not store in the bathroom. Keep out of the reach of children and away from pets. Do not use this medicine beyond the expiry date.

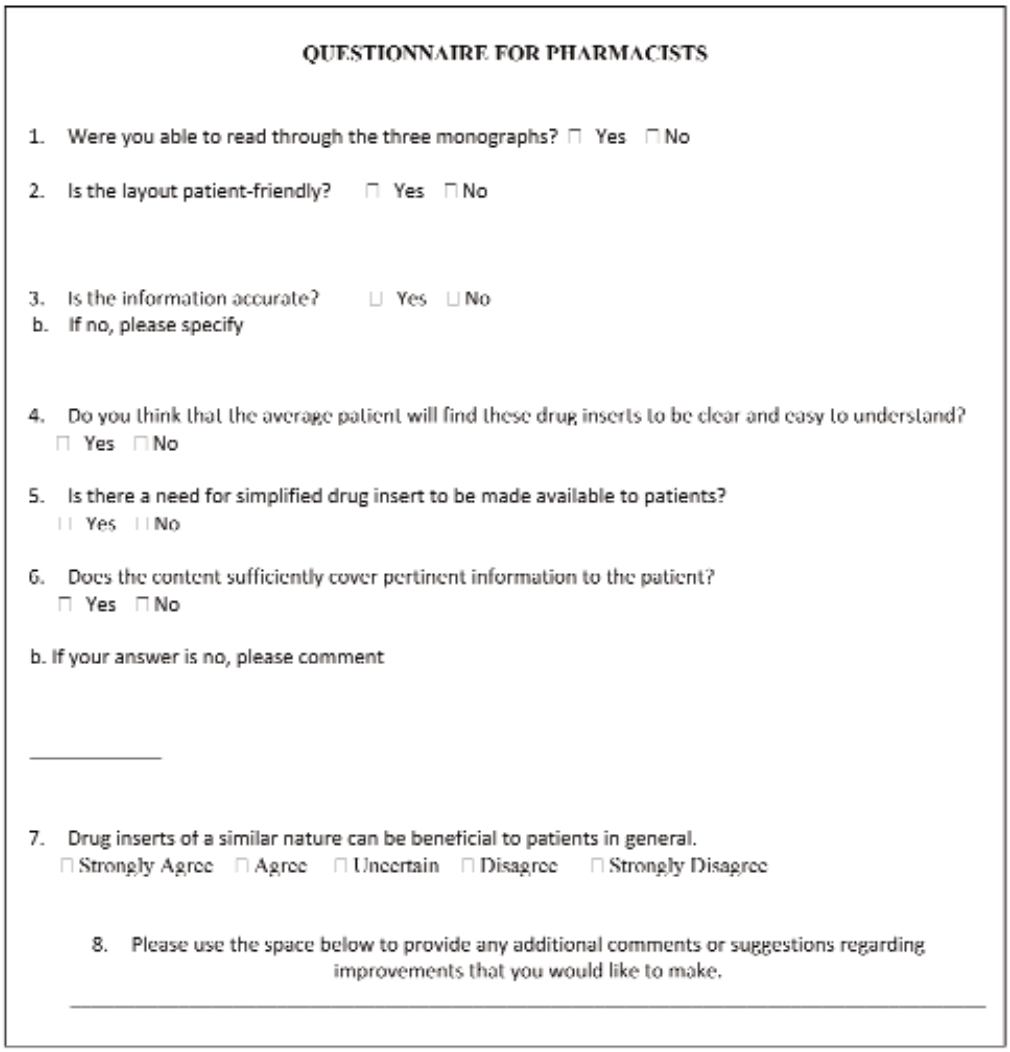
Precautions: Should not be taken if patient is allergic to drug, has become pregnant, is breastfeeding, is taking Dextran sulfate or potassium-sparing diuretics, have severe kidney or liver disease or are on dialysis. Never give this medication to anyone else, even if they have the same symptoms as you.

Drugs that can prevent Enalapril from working properly: Aspirin, Ibuprofen, Indomethacin, Dextran sulphate, Hydrochlorothiazide, Furosemide and medicines for diabetes and natural products such as garlic, ginseng, St John's wort and natural licorice.

Contact your doctor if you experience: swelling (of the face, tongue, lips or mouth), skin rash, difficulty breathing, slow heartbeat or abnormal stomach pain while taking Enalapril.

Fig. 1: Patient information leaflet designed for hydrochlorothiazide, nifedipine and enalapril.

Kingston (the capital city of Jamaica) and St Andrew obtained from the Pharmacy Council of Jamaica. Selected pharmacies were then telephoned to explain the purpose of the study, as well as to confirm the participation of the pharmacist in the study. Pharmacists who were not willing to participate in the study were removed from the list, and random selection continued until the target of 10 pharmacists was achieved. Participating pharmacists were given copies of each PIL and their assessment of it was evaluated using a questionnaire (Fig. 2). This aspect of the study was done during November 2007 to August 2008.



QUESTIONNAIRE FOR PHARMACISTS

1. Were you able to read through the three monographs? ☐ Yes ☐ No

2. Is the layout patient-friendly? ☐ Yes ☐ No

3. Is the information accurate? ☐ Yes ☐ No
   b. If no, please specify

4. Do you think that the average patient will find these drug inserts to be clear and easy to understand?
   ☐ Yes ☐ No

5. Is there a need for simplified drug insert to be made available to patients?
   ☐ Yes ☐ No

6. Does the content sufficiently cover pertinent information to the patient?
   ☐ Yes ☐ No

b. If your answer is no, please comment

_____

7. Drug inserts of a similar nature can be beneficial to patients in general.
   ☐ Strongly Agree ☐ Agree ☐ Uncertain ☐ Disagree ☐ Strongly Disagree

8. Please use the space below to provide any additional comments or suggestions regarding improvements that you would like to make.

_____

Fig. 2: Questionnaire given to pharmacists to evaluate patient information leaflet for hydrochlorothiazide, nifedipine and enalapril.

The sample population was selected from two pharmacies in Kingston and St Andrew during the period September to November 2009. Persons included hypertensive patients over the age of 16 years and they had to be on the medications being evaluated. Persons who were on more than one of the three drugs were evaluated based on only one drug. This was done in order to increase patient cooperation, as well as to reduce any burden associated with reading more than one monograph and responding to the same questions more than once.

One interviewer was assigned to each drug with the responsibility of distributing SDM or PIL alternatively to patients agreeing to participate, until 20 PIL and 20 SDM for each drug was distributed; therefore a total of 120 monographs were distributed in the study. In order to make an accurate and unbiased comparison between the two sets of information leaflet, a standard questionnaire was developed. The questionnaire contained information based on the content of SDM and PIL to evaluate the respondents' knowledge before and after reading the information provided. Questions were used to determine knowledge related to common side effects, missed dose action, things to avoid while taking the drug and situations when patients should contact a doctor. The questionnaire had two parts (Fig. 3): Part A contained questions to evaluate prior knowledge before introducing SDM or PIL and Part B contained questions to evaluate knowledge after reading SDM or PIL, as well as to com-

Questionnaire for patients—Part A

Name: _____ Telephone Number: _____

Name of Drug:

Gender: Male [ ] female [ ] Age? _____

Are you employed? Yes [ ] No [ ] If yes state Occupation _____

How long have you been on this medication? Less than a year | | 1-5 years | | over 5 years | |

Have you ever been given a standard drug monograph before? Yes | | No | |

If yes, did you read it? Yes | | No | |

What are you taking this drug for? _____

What are the most common side effects of this drug? _____

What should you do if you miss a dose?

Is there anything you should avoid while on this drug? Yes | | No | |

If yes, please note comments here

_____

Part B

Did you read the information given to you? Yes | | No | |

How many times did you read it? Once | | 2-5 times | | over 5 times | |

Was it easy to read it? Yes [ ] No [ ] Did you find it attractive? Yes [ ] No [ ]

What are the most common side effects of this drug? _____

What should you do if you miss a dose?

Is there anything you should avoid while on this drug? Yes | | No | |

If yes state them _____

Are there any instances when you should contact your Doctor? _____

Are there any suggestions you would like to make about this monograph? _____

Do you have any questions about the information?

Would you recommend that every patient be given an information leaflet similar to this?

Fig. 3: Questionnaire used to evaluate patients' knowledge and opinions on reading material assigned (standard drug monograph or patient information leaflet).

pare them on preference by the respondents. Each participant was asked the questions in part A of the questionnaire and their responses were recorded by the interviewer. Interviewers were instructed to read through the information once with the participant. For the participants receiving SDM, only those sections that corresponded with the information in PIL were read. This was done to ensure consistency of presentation to participants and to remove bias associated with differences in content. Respondents were then given the respective reading material and told to read it when they got the chance, with the understanding that they would be called within two days of the initial meeting. Contact information was obtained from all respondents and they were contacted 2−3 days after to get their responses to the questions in Part B of the questionnaire. Patients who did not read the information given, at least once, when later contacted were eliminated and replaced. SPSS 17.0 was used to analyse the comparison between the responses for Part A and Part B of the questionnaire using descriptive statistics and Pearson's Chi-Square analysis with *p*-values less than 0.05 considered significant. Differences across the groups were also assessed.

RESULTS

Of the 10 practising community pharmacists involved in the assessment of PILs, eight agreed that the PILs were patient friendly (two did not agree) and 9 out of 10 agreed that the information was accurate. One pharmacist indicated that the dosing information for nifedipine needed to be checked. Most of the pharmacists (9 out of 10) agreed that the information was clear and easy to understand by patients and that the content sufficiently covered pertinent information for the patient. The majority (7 out of 10) were supportive of the general idea of PILs for use in the future being of similar format to the ones involved in this study. Three pharmacists suggested a need for an increase in the font size.

There were forty respondents for each antihypertensive drug; 20 were given the SDM, while the other 20 were given the PIL; this gave a total of 60 respondents receiving SDM and 60 receiving PIL. There were 66 females and 54 males with no difference in gender distribution between the groups. There was no difference in the mean age between the groups (55.6 ± 13.8 for SDM *versus* 56.1 ± 13.3 for PIL), nor in the number of unemployed respondents (19 for SDM *versus* 25 for PIL). Except for one respondent that indicated an enlarged heart as reason for which the medication was prescribed, the other respondents indicated hypertension. Most of the respondents were on their prescribed medication for more than one year (83 respondents); 37 respondents were on prescribed medication for one year or less.

Most of the respondents (91) could not recall ever been given an SDM. Of the respondents in the SDM group, only 12 indicated ever receiving a drug monograph prior to this study and seven recalled reading it. Of the respondents in the PIL group, only 17 indicated receiving a drug monograph prior to this study and 12 recalled reading it.

Most of the respondents indicated that they had read the information given to them independent of the initial contact only once in the two to three days allowed (52 of SDM and 44 of PIL). Respondents were asked to recall at least one common side effect that they know could occur with the use of their prescribed antihypertensive (hydrocholorthiazide, nifedipine or enalapril). Before exposure to either SDM or PIL, most of the respondents did not know any common side effect associated with their prescribed medication (72 did not know *versus* 48 knowing at least one). However, after exposure to either the SDM or PIL, there was a significant improvement in knowledge of common side effects when compared to before exposure response (χ^2 for SDM = 24.26, $p < 0.001$; χ^2 for PIL = 27.64, $p < 0.001$) and there was no difference in the impact made when between groups comparison was assessed (Fig. 4).

Before exposure to either SDM or PIL, most of the responders could not recall any precaution while on their medication, with no difference between the groups. However, after exposure, only respondents receiving PIL showed a significant improvement in knowledge of things to avoid when compared to before exposure response ($\chi^2 = 10.85$, $p < 0.001$, Fig. 5). This was not the case for those in the SDM group.

Prior to exposure to SDM or PIL, respondents were asked what they would do if they forgot to take their medication. About half were partially correct, indicating that they should take it as soon as they remember or skip the dose (55 for SDM and 50 for PIL). Only two respondents in PIL noted the importance of time for next dose as a consideration (none for SDM). After reading either SDM or PIL, there was no significant influence on the response to this question, as the majority of the respondents remained partially correct, again not recognizing the importance of time between dosing (60 partial correct for SDM and 57 for PIL) .

After exposure to SDM or PIL, respondents were asked to indicate reasons to contact the physician; respondents in the group receiving PIL were significantly more likely than those receiving SDM to know at least one valid reason to make contact (44 of SDM *versus* 55 of PIL; $\chi^2 = 8.41$, $p < 0.01$). Significantly more of the respondents who were given PIL indicated that they found it easy to read ($\chi^2 = 20.00$; $p < 0.001$) and attractive ($\chi^2 = 12.45$, $p < 0.001$, Fig. 6)

When respondents were asked if they had any suggestions to make, 61 provided one to three suggestions. This gave a total of 97 suggestions and the suggestions were more represented in the group receiving SDM ($\chi^2 = 5.06$, $p < 0.05$, Table).

The respondents were asked if they would recommend the reading material given to them to other patients. Most of the respondents (missing responses = 1) from both groups indicated yes, but the PIL group showed a greater willingness

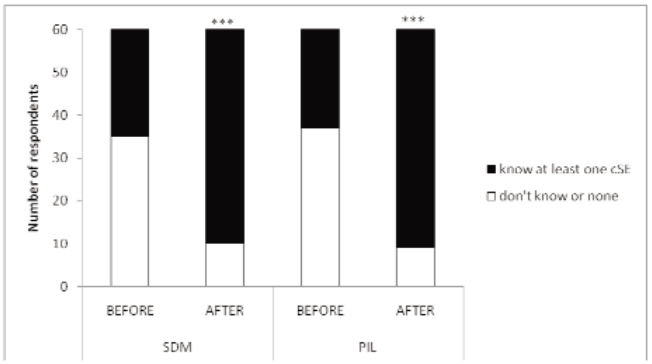


Fig. 4: Common side effects (cSE) knowledge before and after exposure to standard drug monograph (SDM) or patient information leaflet (PIL). Both groups showed an improvement in knowledge of at least one side effect after exposure (χ^2 for SDM = 24.26; χ^2 for PIL= 27.64) with no between group difference.
*** indicates $p < 0.001$ comparing before and after exposure to reading material.

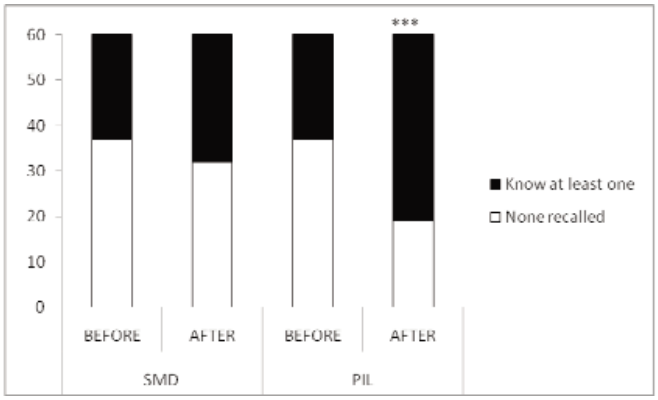


Fig. 5: Respondents recall of things to avoid knowledge before and after exposure to standard drug monograph (SDM) or patient information leaflet (PIL). Only respondents receiving PILs showed significant improvement in knowledge of things to avoid when compared to before exposure response ($\chi^2 = 10.85$).
*** indicates $p < 0.001$ when compared with before exposure to reading material.

than SDM (26 out of 60 for SDM and 50 out of 59 for PIL, $\chi^2 = 22.11$, $p < 0.001$).

DISCUSSION

This study was done because of a need expressed by patients from previous surveys (5, 6) for alternative reading material to standard drug monographs that are short, easy to read and provide information relevant to improving compliance. Previous studies have confirmed the benefit of simplified information leaflets to improve patient's knowledge (4, 7−10); however, assessments to compare such information leaflets against the standard monograph are limited. While PILs serve the purpose of providing information to patients that have been identified as relevant for facilitating compliance, it is also important to ensure accuracy and avoid inconsistency

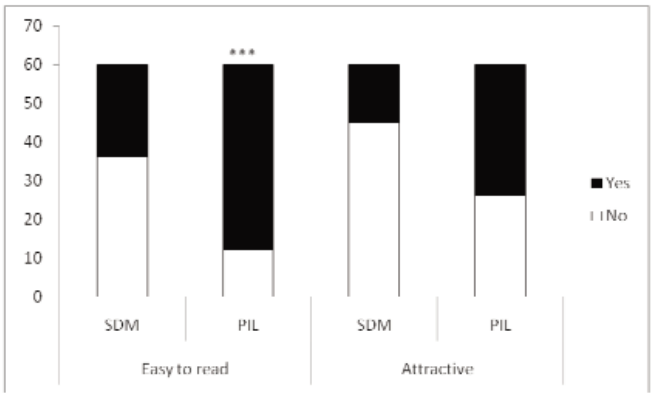


Fig. 6: Respondents view on ease of reading and attractiveness. When compared with the standard drug monograph (SDM) respondents, significantly more of the patient information leaflet (PIL) respondents indicated that the reading material was easy to read ($\chi^2 = 20$) and attractive ($\chi^2 = 12.45$).
*** indicates $p < 0.001$ when comparison was made between groups.

Table: Total number of suggestions provided by respondents in standard drug monograph [SDM] (n = 31) and patient information leaflet [PIL] (n = 30). Each respondent was allowed to provide more than one suggestion.

Suggestions	SDM	PIL
Increase font size	22	16
Jargon needs simplification	20	7[a]
Shorten content	20	7[a]
Needs graphics/colour	1	3
Give to all patients	1	0
Total suggestions	**64**	**33[a]**

[a] Significant difference when compared with respondents receiving SDM ($\chi^2 = 5.06$, $p < 0.05$)

between SDMs and PILs, as this can negate the benefits of PILs (11).

Like other developing countries, cardiovascular diseases comprise a significant proportion of the population with non-communicable diseases in Jamaica (12, 13) and compliance with therapy is a known concern among this population (14−16). Thus it is important to explore methods known to improve patient compliance. Improving patient knowledge is one method that has been successful (3, 4). To explore the potential of this method, this study focussed on drugs that are known to be very commonly chosen to manage hypertension, namely, hydrochlorothiazide, nifedipine and enalapril.

The first activity was to design PILs; this was done by extracting content from SDM that was specifically identified by Health Canada survey, as being important for compliance, as well as ensuring the information was simple and easy to read. The ability to meet these needs was first assessed by practising community pharmacists. This group was considered appropriate, as they dispensed these drugs on a daily

basis and are responsible for consulting with patients on similar content during dispensing. Most of the pharmacists involved in this evaluation expressed a need for PILs and indicated an overall satisfaction with the products.

Focus was then aimed at evaluating PIL against SDM. To do this, respondents were asked questions based on information contained in the PIL or SDM in order to assess knowledge and to evaluate respondents' personal views on ease of reading, attractiveness and usefulness. They were also invited to offer suggestions.

An assessment was first made of their knowledge of the drugs before exposing them to either type of reading material. It was clear that although the majority indicated never reading an SDM despite being on the drug for a long time, they were at least familiar with why they were taking the drug. They, however, could not correctly articulate what needed to be done if they missed a dose. In a study by Almas *et al* (17), patients on antihypertensive drugs who were non-compliant with therapy had more elevated blood pressures and reported forgetting to take medication as the main factor for missing dose. Thus improving compliance among hypertensive patients should involve ensuring patients are aware of how to handle missed dose issues. For all the drugs involved in this study, action to be taken when a dose is missed was time dependent. The PIL designed for each drug in the study stated that a missed dose should be taken as soon as remembered, unless it is within two hours of the next dose. The information provided by both SDM and PIL did not, however, make an impact on the respondents, as they still neglected to mention the importance of the time in determining action. This suggests that there was lack of understanding of what was stated in both types of reading materials and that attention should be given to paraphrasing this section of each PIL. Manufactures of SDMs should also consider rephrasing their instructions.

Ensuring drug benefits outweigh risks requires monitoring not only efficacy, but the presenting side effects. It has been suggested that the involvement of patients in reporting their experience with side effects can make a valuable contribution to the process (18−20), thus some emphasis should be given to making patient aware of risk associated with use of their medication. Exposure to either SDM or PIL did improve the respondents' knowledge of common side effects with no difference between the groups, suggesting that exposure to both types of the reading material was similar in effectiveness in this regard.

Prior to exposure to reading materials, respondents were unable to recall things to avoid. Exposure to SDMs failed to improve this; PILs were superior in this regard, as the respondents receiving PILs showed significant improvement of precaution knowledge base. Both SDMs and PILs listed reasons when patients should contact their physicians. Respondents receiving PILs were better able to answer this question; however, as this question was only asked after exposure to SDM or PIL, no conclusion can be drawn on whether the difference was as a result of PIL exposure. It should be noted that a comprehensive review by Kenny *et al* confirmed the benefits information leaflets have in improving patient doctor relationships (21).

There were more complaints about the length of the reading material and the need for simplification of the jargon from respondents in the SDM group. Few of the PIL respondents did have difficulty with the font size, as could be seen in the suggestions that were made and this complaint was similar for those exposed to SDM. While this deficiency of the PIL has been recognized, respondents in the PIL group were more likely to find the jargon simpler and the presentation attractive. They were also more likely to recommend giving this reading material to other patients. Future use of PILs designed in this study should review the font size.

This study did not assess compliance and therefore cannot evaluate whether any impact was made on this aspect of patient management. As this is a major aim of increasing knowledge, future assessment of PILs should also assess whether the benefits translate to greater compliance.

CONCLUSIONS

This study clearly showed that the simplified format designed was able to improve patients' awareness of information identified as relevant, without impacting negatively on the content provided by the standard drug monographs. It was also the preferred format by patients and seemed to have a greater influence on knowledge of precautions, as well as when there may be a need to consult physicians. Although regulations governing drugs require manufactures' use of the standard format for providing information about the drugs, more consideration needs to be given to designing simplified reading material to facilitate patients' desire to better understand drug benefits.

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