

# A randomised comparison of the effect of three patient information leaflet models on older patients' treatment intentions

S Whatley, M Mamdani and Ross EG Upshur

## SUMMARY

*One hundred and ninety-six patients over the age of 65 years suffering from joint pain were randomised to receive one of three patient information leaflets describing a hypothetical pain medication, a standard textual patient information leaflet (PIL) given out by a pharmaceutical chain, and two alternate forms depicting information with icons and graphs. The results showed that patients randomised to the traditional PIL were less likely to consider taking the hypothetical medication.*

**Keywords:** patient information leaflet; medication; acceptability; bias.

## Introduction

THE patient information leaflet (PIL) is a commonly used method to educate patients about prescription medications. In some jurisdictions PILs must accompany each prescription dispensed by a pharmacy. The Royal Pharmaceutical Society of Great Britain recommended research into how information in PILs could be best presented and how PILs influence beliefs about medicines and decision making.<sup>1</sup>

The most effective information format for enhancing patient knowledge and treatment adherence is not known, although framing effects exert a strong influence.<sup>2</sup> Prescription PILs use primarily textual information describing side effects, drug interactions, dosage, and storage, often providing little information about the likelihood or probability of harm versus benefit. Although various forms of textual information have been compared,<sup>3-5</sup> we are aware of no reported studies comparing PILs using an available PIL and real patients, employing numerical information or graphical representations of the relevant data to the standard textual PIL format. This report describes the results of a randomised comparison of three PILs.

## Method

One hundred and ninety-six competent, consenting patients over the age of 65 years with a history of osteoarthritis or joint pain were consecutively recruited to review a standard clinical scenario describing a common medical condition and randomised to receive one of three PILs. The drug was described as a therapy for osteoarthritis or joint pain and identified as 'medication X'. The information in the PIL was based on a non-steroidal antiinflammatory drug (NSAID), indomethacin.

Randomisation was achieved with a computerised random list generator. Patients were recruited from the Sunnybrook and Women's College Health Sciences Centre, Department of Community and Family Medicine Clinic. Research ethics board approval was obtained prior to participant enrolment.

Three PILs were used. Each PIL contained identical core textual information in identical font and script size. The standard PIL (Form I), given out with every prescription by a major pharmaceutical chain was a narrative leaflet that documents all potential adverse effects, but not the probability of such events occurring. The experimental forms contained additional numerical information on expected benefits and side effects. One experimental form presented side effect and benefit information with percentages and icons (Form II). The other experimental form contained a bar graph of the

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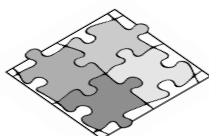
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**HOW THIS FITS IN***What do we know?*

How risks are framed exerts a powerful influence on patients' decision making regarding treatment acceptability. Patient information leaflets (PILs) are dispensed with each prescription

*What does this paper add?*

PILs that do not provide a context for the benefits and harms of medication may have a negative influence on patient adherence



statistical data (Form III). The likelihood of taking the medication was assessed on a seven-point Likert scale with likelihood ranging from 'will not take it' to 'will take it'.

The demographic characteristics of the study subjects between the three groups were assessed using analysis of variance for continuous parametric data, the Kruskal-Wallis H-statistic for continuous non-parametric data, and Pearson's  $\chi^2$  and Fisher's exact tests, where appropriate, for categorical data. Paired sample *t*-tests were used to assess differences between the pre- and post-acceptability scores for each of the study groups. The association of demographic factors with the difference in pre- and post-acceptability scores was assessed using multivariate regression analysis. Power was calculated to determine a one-point difference on a seven-point Likert scale. All data analyses were conducted using SPSS (Chicago, Ill). Statistical significance was set at *P* less than 0.05.

## Results

A total of 196 patients were randomised to three intervention groups. Randomisation achieved balanced groups and there were no statistically significant differences between the three groups in terms of age, sex, education level, medication use, experience of side effects, and co-morbidity. Table 1 shows the main results. There was a statistically significant decrease in acceptability for the standard PIL dispensed with prescriptions. (difference = -0.9, 95% CI = -0.44 to -1.3, *P* > 0.0001.) In contrast, no significant changes were observed for either of the two new forms. Multivariate analysis failed to demonstrate any independent variables that were associated with these results.

## Discussion

Participants who were presented with the standard text-only PIL (Form I) were less likely to take medication X than any medication. The shift is equivalent to making them on average more uncertain about taking the medication. The data for the other PILs (forms II and III) neither increased or

decreased the likelihood of taking the medication.

No independent variables were identified using regression analysis as being associated with this decreased likelihood except the form itself. Education was thought to play a role in PIL preference since education undoubtedly increases familiarity with graphical presentations. However, this was not the case. This study is potentially limited by a bias. Although randomised techniques were employed, the patient population, attending a family medicine practice in a tertiary care health sciences centre, may not reflect the broader Canadian population. Also the study population was older, so the results cannot be extrapolated to a younger population. Despite these limitations, we believe the results should stimulate further research on the appropriate format and content of patient information leaflets.

Is the difference reported clinically relevant? The results indicate that the standard PIL is associated with greater ambivalence and uncertainty about medication acceptability which may not be disclosed to physicians and thus thwart the attainment of therapeutic goals.<sup>6</sup> Physicians should inquire about patients' perceptions of medication acceptability and encourage open discussion about medication information received from various sources.

## References

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Table 1. Change in patients' willingness to take medication.

Form number	Any medication	Medication X	Change and 95% CI	<i>P</i> -value
I (standard)	4.8	3.9 –	0.9 (-0.44 to -1.3)	<0.001
II (iconic)	.7	4.4	-0.3 (-0.73 to 0.69)	0.11
III (graphical)	4.8	4.5	-0.4 (-0.69 to 0.77)	0.1