Impact of Vietnamese written and verbal medicine information on Vietnamese-speaking Australians' knowledge and satisfaction

Anh Mai & Parisa Aslani

Faculty of Pharmacy, The University of Sydney, NSW, Australia

What is already known about this subject

- Written consumer medicine information has been associated with increased medicine knowledge, satisfaction and adherence to therapy, especially in combination with verbal counselling.
- Increasing internationally standardized and compulsory consumer medicine information leaflets are being prepared, primarily by pharmaceutical manufacturers.
- However, no studies have investigated the impact of Vietnamese standardized written information leaflets on consumers' medicine knowledge and satisfaction with information received.

What this study adds

- Vietnamese written medicine information was developed for three drug classes.
- There was an increase in consumers' medicine knowledge and satisfaction with the information received, after receiving written and verbal medicine information in Vietnamese (the consumers' native language).
- The increases in satisfaction and knowledge were maintained 2 months after receiving the information.

Correspondence

Dr Parisa Aslani, Faculty of Pharmacy, The University of Sydney, NSW 2006, Australia.

Tel: + 612 9036 6541

Fax: + 612 9351 4391

E-mail: parisa@pharm.usyd.edu.au

Keywords

consumer, pharmacist, Vietnamese, written medicine information

Aims

To develop three Vietnamese medicine information leaflets and to evaluate their impact in combination with verbal counselling (in Vietnamese) on consumers' medicine knowledge and satisfaction with the written information received.

Methods

Leaflets in Vietnamese were developed for three drug classes: biguanides, calcium channel blockers and HMG-CoA reductase inhibitors. A two-group (comparison and intervention), randomized, repeated measures design was used. The comparison group ($n = 51$) received routine verbal counselling in English. The intervention group ($n = 44$) received verbal and written information in Vietnamese. Australian Vietnamese-speaking consumers were recruited. Data on consumer knowledge and satisfaction were collected from both groups at three time points: baseline (prior to receiving leaflets and verbal counselling), at 1–2 weeks (first postintervention) and 8 weeks after receiving the information.

Results

All intervention group respondents were satisfied with the information. Mean medicine knowledge and satisfaction scores increased with time in the intervention group, and were significantly higher than in the comparison group (knowledge, $F = 18.5$, d.f. = 2, $P < 0.0001$; satisfaction, $F = 19.8$, d.f. = 2, $P < 0.0001$). The increases observed in the intervention group's mean knowledge and satisfaction scores at first postintervention were significantly higher compared with baseline for all drug classes.

Conclusions

Delivery of written and verbal medicine information in Vietnamese resulted in an increase in consumers' medicine knowledge and satisfaction with written information. This study highlights the importance of providing information in languages other than English and in consumers' native tongue to aid in the quality use of medicines.

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Introduction

Consumers have a right to evidence-based, consumer-centred, accurate and up-to-date medicine information [1], in particular written information. Written consumer medicine information has been associated with increased medicine knowledge [2–5], satisfaction with the information received [4–6] and adherence to therapy [7], especially in combination with verbal counselling [3]. However, written information can also lead to increased anxiety in some consumers [4, 8, 9], increased reporting of side-effects [4, 5, 10] and cessation of therapy [4, 9].

Healthcare professionals have a duty of care to provide information either verbally or in written format to ensure that consumers can take their medicines correctly. The challenge for healthcare professionals is to provide written information as part of their consultation process to equip consumers with the knowledge and skills not only to adhere to therapy, but also to address any issues arising from medicine taking, such as experiencing side-effects.

There is a plethora of research in the literature over the past 40 years, conducted mainly in the USA and Europe, investigating consumer use of a variety of different forms of written medicine information (ranging from medicine labels to structured and standardized leaflets). Increasing internationally standardized and compulsory consumer medicine information leaflets are being prepared [11–15], primarily by pharmaceutical manufacturers. However, no studies have investigated the impact of a Vietnamese standardized written information leaflet on consumers' medicine knowledge and satisfaction with information received.

In Australia, the Therapeutic Goods Regulations [14, 15] have required pharmaceutical manufacturers to produce Consumer Medicine Information (CMI) for prescription and pharmacist-only medicines since 1993 and 1995, respectively. CMI is brand-specific, standardized written information in English based on the medicine's approved Product Information. There are no CMI documents available in other languages, including Vietnamese, which is the fifth most commonly spoken language in Australia.

The aim of this study was to develop three Vietnamese medicine information leaflets and to evaluate their impact, in combination with verbal counselling, on Vietnamese speaking Australian consumers' medicine knowledge and satisfaction with the written medicine information received.

Methods

A two-group, randomized, comparative, repeated measures study design was used to evaluate the impact of the

Vietnamese written medicine information leaflets and verbal counselling. The null hypotheses tested were, that there were no statistically significant differences (at the $P = 0.05$ level) in consumers' medicine knowledge and satisfaction with the written information received between the two groups over the study period; and before and after receiving the written information and verbal counselling (medicine knowledge only). Approval for conducting the study was granted from the Human Research Ethics Committee of the University of Sydney.

Preparation and pretesting of written medicine information leaflets

The following medicines were selected because they were the most commonly dispensed medications in the study community pharmacy (based on the pharmacy's monthly dispensing records):

- Calcium channel blocking agents: nifedipine, felodipine, verapamil, amlodipine, diltiazem.
- 3-Hydroxy-3-methyl-glutaryl-coenzyme A (HMG-CoA) reductase inhibitors: atorvastatin, simvastatin, pravastatin.
- Biguanides: metformin.

A general medicine information leaflet was written for each specific medicine class using the approved Product Information and Consumer Medicine Information of each product. The same headings as in a CMI were used in these leaflets: what is in this leaflet; what the medicine is for; before you take/use the medicine; how to take/use the medicine; while you are using the medicine; side-effects; after using the medicine; and product description. The leaflets were translated into Vietnamese and verified by an accredited translator. Two-column and one-column versions of each leaflet were prepared initially for pretesting.

The leaflets were pretested with a convenience sample of Vietnamese-speaking consumers ($n = 64$). The consumers were provided with one to three written medicine information leaflets to read and evaluate in terms of readability, layout and information content, using the Consumer Information Rating Form [16] in English. The majority of respondents preferred the two-column leaflets as they were easier to read. Overall, the respondents commented that the leaflets were easy to understand, were useful, and contained the right amount of information. Minor changes were made to the content of the written information leaflets based on the comments received.

Sample

A community pharmacy located in Marrickville (New South Wales, Australia) was selected as the study pharmacy. This pharmacy was selected as Marrickville is a suburb containing a high population of Vietnamese-speaking Australians [17].

Consumers were recruited in the study pharmacy based on the following inclusion criteria: (i) ≥ 18 years old; (ii) speaking Vietnamese as their primary language; (iii) collecting one or more of the study prescription medications for themselves or for a person (e.g. parent) in their care; (iv) having taken at least one of the study prescription medications (or the person under their care having taken at least one of the study prescription medications) for at least 1 month prior to participation.

Sample size

The sample size was calculated based on the results of a similar research study which evaluated the impact of an educational intervention (receiving written information in the form of package inserts, plus verbal counselling) delivered by pharmacists on patients' medicine knowledge [18]. The authors demonstrated that the proportion of patients giving correct responses in the intervention group was 89% compared with 33% in the control group. Thus, based on the above findings and using the POWER[®] program [19] for comparison of proportions for sample size calculation, the number of subjects to be recruited into the study was calculated as 14 per group, per drug class ($P = 0.05$, 80% power), or a total of 84 subjects in the study.

Sample recruitment

The pharmacist, who is fluent in Vietnamese, approached all Vietnamese-speaking consumers attending the study pharmacy who met the study inclusion criteria over a 3-month period. The subjects were provided with the study Subject Information Sheet and additional verbal information if required (all in Vietnamese). Consenting subjects were requested to sign a consent form. Eligible patients within a drug group were randomly allocated to either the intervention or comparison group. This allocation involved placing the first recruited subject in the intervention group, the second in the control group, the third in the intervention, and so on.

Research instrument

A structured questionnaire was developed, translated into Vietnamese and used for data collection by the pharmacist. Data were collected on knowledge (17 questions) and satisfaction (two questions) with the information received, as well as readership of the leaflets,

opinions about the information content, preferred language and timing of receiving the leaflets. Knowledge questions were developed based on the written medicine information leaflets prepared. The questionnaire was pretested with a convenience sample of researchers and Vietnamese-speaking consumers, to test for face and content validity, exploring the subjects' understanding of the questions and what the questions purported to measure. Some items were modified as a result of the feedback received.

Study design

Baseline data were collected from consumers in both groups using the study questionnaire prior to dispensing a 1-month supply of their prescription medication (Figure 1). This was followed by delivery of the intervention (see below) to the intervention group. Follow-up data were collected using the study questionnaire at 1–2 weeks, and 8 weeks after receiving the intervention. The subjects attended the pharmacy at the two postintervention time points for the data collection. The intervention consisted of:

- 1 Provision and discussion of the Vietnamese written medicine information leaflet (for the consumers' prescription medication), highlighting salient points and encouraging respondents to read the leaflet.
- 2 Provision of verbal counselling in Vietnamese about the prescription medication.

The comparison group did not receive any written information, but received routine verbal counselling only, in English. Routine counselling was defined as information provided on the name of the medicine, the indication and dosage regimen. Furthermore, at the time of dispensing, the pharmacist responded to any questions raised by consumers about their medications in either group. To ensure consistency in the information given to the subjects in each group, and to avoid contamination between the groups, the pharmacist kept a record of the verbal information provided to all subjects. These data were continuously monitored.

Several steps were taken to minimize bias. One pharmacist was used to recruit subjects, deliver the intervention and collect data from both the intervention and comparison groups. Every consumer who met the inclusion criteria was approached and invited to participate. Participating consumers were randomly allocated to the two study groups. The study pharmacist recorded the verbal interaction with all participants (in both groups) to ensure that additional verbal information (other than routine verbal counselling) was not provided to the subjects in the comparison group.

Figure 1
Study design

Data analysis

All data were coded and entered into a database in the Statistical Package for the Social Sciences (SPSS; SPSS Inc., Chicago, IL, USA). Frequency distributions were compiled and examined for the responses to each question. Knowledge and satisfaction scores were calculated for each respondent at the three data collection times. The knowledge score was calculated by giving a score of 1 to each correct response (and 0 to the incorrect responses) to the 17 knowledge questions and summing the scores. The final knowledge score was calculated as a proportion of the total score for each respondent, where the minimum score was 0 (did not know any medication information) and the maximum score was 1 (gave a correct response to all knowledge questions). The satisfaction score was calculated by giving 0 to 'not at all satisfied' and 4 to 'very satisfied' to the two satisfaction questions, and summing the scores. The final satisfaction score was calculated as a proportion of the total score for each respondent, where the minimum score was 0 (not at all satisfied) and the maximum score was 1 (very satisfied).

Repeated measures analysis of variance (ANOVA) was used to investigate the effect of the intervention on the two outcome variables: consumers' medicine knowledge and satisfaction, at all three data collection times.

Response rate

A total of 110 consumers were invited to participate in the study. A total of 101 consented to participate, a response rate of 91.8%. Six consumers dropped out of the study due to various reasons (e.g. loss of contact, illness), giving a completion rate of 94.0%. The distribution of the sample with respect to the drug classes is illustrated in Table 1.

Results

Sample demographics

Of the 95 consumers, 37 were male (38.9%) and 58 (61.1%) female. The respondents' ages ranged from 28 to 89 years, with a mean value of 60.6 years (SD 11.6 years).

Table 1

Sample distribution by drug class

Drug classes	Intervention group	Comparison group	Total
Calcium channel blockers	14	17	31
HMG-CoA reductase inhibitors	19	19	38
Biguanides (metformin)	11	15	26
Total (n)	44	51	95

A total of 47 subjects (49.5%) had migrated to Australia in the period 1978–1988 and a similar number in the period 1989–1999. The majority of respondents were married (83%) and most (89.5%) were not working, with only a small proportion (9.5%) in full time employment.

Readership of Vietnamese written medicine information leaflets

All 44 consumers in the intervention group received written information leaflets. A total of 100%, 91.4% and 77.3% of the consumers reported reading the written medicine information leaflets for the calcium channel blocking agents, HMG-CoA reductase inhibitors and biguanides, respectively. The remaining consumers, who did not read their leaflets, stated that another person had read the leaflet for them. The specific items of information which the consumers read are reported in Table 2. The most popular item of information read was the indication of the medicine. Forty-two respondents (95.5%) reported that they filed their leaflets away for future reference. Two respondents (4.5%) reported that the leaflets were damaged unintentionally and so could not be kept.

Respondents' opinion about the amount of information received

At baseline, 69.2% of respondents in the intervention group reported that they had received an adequate amount of information about their medicine, compared with 64.2% in the comparison group. The proportion differed for the three drug classes: 61.5%, 76.5% and 66.7% for calcium channel blockers, HMG-CoA reductase inhibitors and biguanides, respectively (for the intervention group at baseline). At the first and second postintervention data collection times, all respondents (100%) in the intervention group reported that an

adequate amount of information was provided, compared with 69.3% and 60.7%, respectively, in the comparison group.

The numbers of consumers within each drug class in the intervention group were too small for statistical analysis. However, as a group, there was a significant increase in the proportion of consumers in the intervention group who reported adequate information was provided in the leaflets at the two postintervention data collection times compared with baseline ($\chi^2 = 29.90$, d.f. = 4, $P < 0.0001$). No significant differences were found in the comparison group over time ($\chi^2 = 5.41$, d.f. = 4, $P = 0.49$).

Language and preference for written or verbal medicine information

Eighty-two respondents (86.3%) preferred to receive written medicine information in Vietnamese, which was their mother tongue. Six respondents (6.3%) stated they would like to receive it either in English or in Vietnamese.

Just over half of all respondents (55.7%) preferred to receive the written information leaflets every time their medication was dispensed at the pharmacy. Less than one-third (30.2%) preferred to receive the leaflet only when requested. Interestingly, a very small proportion of respondents, 1.7% and 2.1%, preferred to receive the leaflet only when they first received the prescription medication from their doctor or pharmacist, respectively.

Seventy-nine percent of the respondents reported that they would like to receive verbal information in Vietnamese every time they collected their medication from the pharmacy. About 11% preferred to receive verbal information only when requested.

Knowledge of medicine information

The mean knowledge score increased over the study time in all three drug classes in both the intervention and comparison groups (Table 3). However, a larger increase was observed in the intervention group, which was higher than the comparison group over the three data collection times ($F = 18.5$, d.f. = 2, $P < 0.0001$). A significant difference was also observed between the two groups over the duration of the study when the knowledge scores were compared for each of the drug classes: calcium channel blockers ($F = 3.6$, d.f. = 2, $P = 0.032$), HMG-CoA reductase inhibitors ($F = 9.7$, d.f. = 2, $P = 0.004$) and biguanides ($F = 6.5$, d.f. = 2, $P = 0.003$).

Table 2

Specific items of information read by consumers

Specific items read	Calcium channel blockers (n = 14)		HMG-CoA reductase inhibitors (n = 19)		Biguanides (metformin) (n = 11)	
	Frequency	Relative frequency* (%)	Frequency	Relative frequency* (%)	Frequency	Relative frequency* (%)
Most of leaflet	5	35.7	9	47.4	4	36.4
What medicine is used for	12	85.7	11	57.9	11	100.0
How to take it	5	35.7	7	36.8	9	81.8
Side-effects	6	42.9	11	57.9	5	45.5
Benefits	2	14.3	3	15.8	–	–
When not to take	–	–	1	5.3	–	–
Storage	–	–	–	–	1	9.1
Disposal	–	–	2	10.5	–	–
Others	1	7.1	–	–	–	–
Missing data	–	–	4	21.1	–	–

The data for each drug class are not mutually exclusive. *Relative frequency calculated using total number of subjects per drug class as the denominator.

Table 3

Mean knowledge score of medication information for all respondents

Drug class	Study group (n)	Baseline (SD)	Post 1 (SD)	Post 2 (SD)
Calcium channel blockers	Comparison (17)	0.43 (0.08)	0.49 (0.13)	0.53 (0.09)
	Intervention (14)	0.44 (0.12)	0.61 (0.12)	0.63 (0.22)
HMG-CoA reductase inhibitors	Comparison (19)	0.44 (0.12)	0.47 (0.11)	0.51 (0.09)
	Intervention (19)	0.43 (0.11)	0.62 (0.15)	0.63 (0.14)
Biguanides	Comparison (15)	0.40 (0.08)	0.47 (0.13)	0.51 (0.08)
	Intervention (11)	0.37 (0.11)	0.58 (0.07)	0.61 (0.15)

Post 1, First postintervention; Post 2, second postintervention.

The data illustrate a significant increase in the mean knowledge scores at the first postintervention time compared with baseline for all three drug classes in the intervention group: calcium channel blockers ($F = 6.4$, d.f. = 2, $P = 0.017$), HMG-CoA reductase inhibitors ($F = 14.0$, d.f. = 2, $P = 0.001$) and biguanides ($F = 14.2$, d.f. = 2, $P = 0.003$). A further increase in mean knowledge score was observed at the second postintervention data collection time for the respondents in all three drug classes of the intervention group. However, this increase was not significant when compared with the first postintervention data collection time, but was higher when compared with baseline for respondents who were provided with the HMG-CoA reductase inhibitors ($F = 9.7$, d.f. = 2, $P = 0.004$) and biguanides ($F = 7.7$, d.f. = 2,

$P = 0.010$) leaflets only. No significant differences were observed in the mean knowledge scores over time for the comparison group, for all three drug classes combined or for each individual drug class.

Thus, the null hypotheses of no statistically significant difference in consumers' knowledge about their medication before and after receiving the intervention, and between the comparison and intervention groups at the three data collection times, can not be accepted.

Satisfaction with medicine information received

The mean satisfaction scores of the intervention group increased at the first postintervention data collection period compared with baseline for all three drug classes:

Table 4

Mean satisfaction score of drug information received for all respondents

Drug class	Study group (n)	Baseline (SD)	Post 1 (SD)	Post 2 (SD)
Calcium channel blockers	Comparison (17)	0.65 (0.13)	0.69 (0.10)	0.67 (0.11)
	Intervention (14)	0.64 (0.12)	0.86 (0.06)	0.87 (0.06)
HMG-CoA reductase inhibitors	Comparison (19)	0.60 (0.08)	0.63 (0.11)	0.65 (0.08)
	Intervention (19)	0.65 (0.11)	0.88 (0.07)	0.89 (0.09)
Biguanides	Comparison (15)	0.65 (0.15)	0.66 (0.14)	0.68 (0.05)
	Intervention (11)	0.67 (0.11)	0.86 (0.10)	0.85 (0.07)

Post 1, First postintervention; Post 2, second postintervention.

calcium channel blockers ($F = 19.0$, d.f. = 2, $P < 0.0001$), HMG-CoA reductase inhibitors ($F = 23.1$, d.f. = 2, $P < 0.0001$) and biguanides ($F = 19.0$, d.f. = 2, $P < 0.0001$) (Table 4). A further increase in mean satisfaction score was observed at the second postintervention data collection time for the respondents in all three drug classes of the intervention group. However, this increase was not statistically significant compared with the first postintervention data collection time, but was significant compared with baseline: calcium channel blockers ($F = 34.5$, d.f. = 2, $P < 0.0001$), HMG-CoA reductase inhibitors ($F = 37.5$, d.f. = 2, $P < 0.0001$) and biguanides ($F = 34.5$, d.f. = 2, $P < 0.0001$). The comparison group showed no statistically significant change in their satisfaction scores over the period of the study in any of the three drug classes.

Overall, there was a statistically significant difference between the two groups over the three data collection times ($F = 19.8$, d.f. = 2, $P < 0.0001$). A significant difference was also observed between the two groups over the duration of the study for each of the drug classes: calcium channel blockers ($F = 19.8$, d.f. = 2, $P < 0.0001$), HMG-CoA reductase inhibitors ($F = 18.9$, d.f. = 2, $P < 0.0001$) and biguanides ($F = 4.1$, d.f. = 2, $P = 0.025$).

Thus, the null hypothesis of no statistically significant differences in the consumers' satisfaction with the information received between the comparison and intervention groups at the three data collection times can not be accepted.

Discussion

Vietnamese consumer medicine information leaflets were developed for three drug classes and their impact, in combination with verbal counselling, on consumer knowledge and satisfaction with medicine information received was evaluated. An overall positive effect was demonstrated, with consumer knowledge and satisfac-

tion increasing after receiving verbal and written medicine information in Vietnamese.

The readership of the Vietnamese written medicine information leaflets was found to be higher than that reported in the literature [20, 21] and specifically of Australian CMI leaflets [2, 22]. One possible explanation for this high readership could be that in the current study leaflets were prepared in the patients' native language and were therefore more likely to be read. More importantly, however, the study pharmacist actively used the leaflet in the counselling process, drawing the consumers' attention to it and its information content. This active use, as opposed to the passive provision of leaflets, may have influenced consumer readership. This has important implications for healthcare professionals and highlights the significance of interacting with the written information leaflets in consumer consultations, and not simply handing out leaflets or relying on the consumer to find and read package inserts. Those few consumers in the study who did not read the leaflets, possibly due to poor eye sight or low literacy levels, found someone to read for them, illustrating the importance that they attributed to the leaflets after the consultation with the pharmacist.

It is also possible that being part of a research study and knowing that their medicine knowledge would be evaluated influenced the consumers' readership.

The high level of satisfaction with the amount of information received emphasizes the importance of combining verbal and written information in counselling patients about their medication. The mean satisfaction score of the respondents in the intervention group increased significantly after receiving the written leaflets and verbal information, and this increase was maintained after 2 months. This result correlates with the increased satisfaction reported in the literature [4, 10, 23]. Gibbs *et al.* [23] have shown that consumers are satisfied with the information received even after 1 year of receiving the information. Although our current study

evaluated satisfaction over a period of only 2 months, it is possible that satisfaction may be maintained long-term.

The knowledge scores increased significantly in the intervention group after delivery of the combined Vietnamese written and verbal information. Furthermore, the increase was maintained at 2 months after delivery of the information. This increase in knowledge is consistent with studies reported in the literature [8, 9, 22–25]. Increased knowledge is important, not only because consumers will have increased awareness of their medicine, but increased knowledge can lead to increased satisfaction with therapy as well as increased adherence [26].

The use of one community pharmacy and the sample size limit the generalizability of the results of the study to the Vietnamese-speaking population. However, the positive results obtained justify conducting larger and more representative studies, not only in the Vietnamese-speaking population, but also in other major non-English-speaking population subgroups.

In conclusion, this study has demonstrated an increase in consumers' knowledge about their prescription medications as well as an increase in their satisfaction with the information received, after receiving written and verbal medicine information in Vietnamese (the consumers' native language). Moreover, the increases in satisfaction and knowledge were maintained 2 months after receiving the information. The positive impacts observed, together with desire by the consumers to receive information in their language (rather than English), highlights the importance of availability of written medicine information, particularly standardized leaflets such as the Australian CMI or European patient package inserts, in languages other than English, especially in English-speaking countries which have a large non-English-speaking population.

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