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Development and evaluation of a training program to foster the use of written drug information in community pharmacies. Part 2: evaluation

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Abstract

Objective: To evaluate two educational interventions to foster the use of standardised written patient information (consumer medicine information, CMI).

Methods: A quasi-experimental, repeated measures design was selected to evaluate the impact of the interventions (written protocol only; workshop with follow-up training). Pharmacies were recruited into three groups: control ($n = 9$), protocol ($n = 9$) and workshop ($n = 6$). Pharmacists collected data on CMI provision and use in verbal counselling over a 3-day period at three time points: baseline (prior to commencement of study), post-box (after a box of CMI was provided to protocol and workshop groups) and post-intervention (after delivery of interventions to protocol and workshop groups). Repeated measures ANOVA was used to compare the mean rates of CMI provision and use.

Results: Data were collected for 608 prescription items. There were no significant changes in rates of CMI provision in the three groups. Protocol and workshop groups demonstrated an increase in the mean rates of CMI use in counselling. The workshop group demonstrated significant increases in the mean rates of CMI use with time, compared to protocol ($F(2,26) = 5.80$, $p < 0.01$) and control groups ($F(2,26) = 3.99$, $p = 0.03$).

Conclusions: The more intensive educational program led to increased use of CMIs in verbal counselling.

Keywords: *Educational program, pharmacists, written medicine information, evaluation, patient information*

Introduction

Written medicine information is an important tool which may be used by healthcare professionals in educating patients about their medicines (Koo, Krass, & Aslani, 2003). Patients are interested in receiving written information (Koo, Krass, & Aslani, 2002, 2006; Sleath & Wurst, 2002), and some are active in seeking this information (Raynor, Savage, Knapp, & Henley, 2004; Koo et al., 2006). Moreover, patients read the written information they receive and retain it for future use (Koo, Krass, & Aslani, 2005). There are many factors that influence readership, in particular the nature of the interaction with the healthcare professional when the information is provided to the patient (Koo et al., 2002, 2003). Patients view written information as less helpful than face-to-face counselling (Raynor et al., 2004) and prefer to receive written information and verbal counselling from pharmacists (Culbertson, Arthur, Rhodes & Rhodes 1988; Livingstone, Pugh, Winn, & Williamson, 1996; Sleath & Wurst, 2002).

Simply providing the information as a package insert has been suggested to be ineffective, as it does not guarantee that patients notice or read the information (Raynor & Knapp, 2000; Raynor, Knapp, Moody, & Young, 2005). Furthermore, the readability levels of information leaflets may exceed the reading capacity of many patients (Baker, 1997; Buchbinder, Hall, Grant, Mylvaganam, & Patrick, 2001; Foster & Rhoney, 2002). Patients may also have difficulty in understanding key concepts in information leaflets (Dickinson, Raynor, & Duman, 2001), thus reducing the usefulness of the information if provided without any explanation.

Written information combined with verbal counselling has been shown to increase drug knowledge recall (Morris & Halperin, 1979; Peura, Klaukka, Hannula, &

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Eerikainen, 1993; Livingstone et al., 1996) as well as increase compliance to therapy (Gotsch & Liguori, 1982; Myers & Calvert, 1984; Blaikie, 1999; Machuca, Espejo, Gutierrez, Machuca, & Herrera, 2003; Al-Saffar, Deshmukh, Carter, & Adib, 2005). Using written drug information while counselling patients, also enhances the professional role of pharmacists, provides an opportunity for practising clinical pharmacy and allows pharmacists to fulfil their professional role in providing information to, and becoming more involved with the consumer (Dolinsky & Sogol, 1989).

Despite the demonstrated positive impacts of written information, patient desire for this information, and need to incorporate written information in the counselling process, there is limited interaction between consumers and healthcare professionals in Australia when written medicine information is provided (Koo et al., 2002).

Thus, there is a need to encourage pharmacists to provide written medicine information and actively integrate the information into their verbal counselling process. One strategy to promote this behaviour is to provide educational programs for pharmacists (Aslani, Benrimoj, & Krass, 2006).

In Australia, written medicines information, known as consumer medicine information (CMI) is available through community pharmacy. CMI is standardised up-to-date written information about prescription medications prepared by pharmaceutical manufacturers in one or more of three formats: package inserts (found inside or attached to the medicines box); loose leaflets (LL); and electronic (E) (printed from the dispensary computer). The content of CMI conforms to Schedule 12 of the Therapeutic Goods Regulations, which requires CMI to be "in English, clearly legible, written in a language easily understood by consumers and consistent with the product information (within the meaning of section 32 of the Act) of the medicinal product" (Therapeutic Goods Regulations, 1993a,b).

The aim of this study was to evaluate the impact of two educational interventions previously described (Aslani et al., 2006) on the rates of provision of LL and E CMIs to consumers with prescription medications; and rates of use of LL and E CMIs in the verbal medication counselling provided by community pharmacists.

Materials and methods

A quasi-experimental repeated measures design (Figure 1) was selected to evaluate the impact of the two educational interventions (written protocol only; and workshop (which included the written protocol) and follow-up training), on the provision of CMI and its use in counselling.

Pharmacy sample

A total of 111 community pharmacies were selected at random from a stratified list of pharmacies in metropolitan Sydney ($n = 1136$), and randomly allocated to one of the three study groups. A total of 30 community pharmacies (10 per study group) agreed to participate in the project. Recruitment rates of 52.6, 47.6 and 28.6% for the control, protocol and workshop groups, respectively, were obtained. One community pharmacy from the control and protocol groups, and four pharmacies from the workshop group dropped out of the study (at various stages) indicating that they had limited time to participate in the study.

Study design

The researcher visited each community pharmacy in week 2–3 of the study to train all pharmacists on the study process including data collection (Figure 1). During week 6, the CMI boxes were delivered to each of the community pharmacies in the protocol and workshop groups. The researcher explained the purpose of the CMI box, suggested a location in the pharmacy for its storage and accessibility, and demonstrated its use in conjunction with dispensing and verbal counselling. Pharmacists were informed to contact the researcher if they needed additional copies of the CMIs, or to keep a record of how many extra copies of the CMIs they photocopied.

Two educational interventions were delivered. The protocol group received the written protocol only, while the workshop group attended an off-site 1-day educational workshop (including didactic and interactive sessions), received the written protocol at the workshop, and received follow-up on-site training (Aslani et al., 2006). The written protocol was delivered to all community pharmacies in the protocol group (Figure 1) after the "post-CMI box" data collection period was completed (week 10). The protocol was a 17 page document providing guidance on when CMI should be provided and how it should be used as a counselling tool. The community pharmacists in the workshop group attended the educational workshop (Aslani et al., 2006) in week 10 (Figure 1).

Data collection

Pharmacist data sheets. Pharmacists were requested to collect data on every occasion a CMI was provided to a consumer with their prescription medication(s). A separate data sheet was completed for each prescription medication item. The data sheets, adapted from earlier research (Caleo, 1995; Benrimoj, Berry, Collins, Lauchlan, & Stewart, 1997), collected information on the consumer

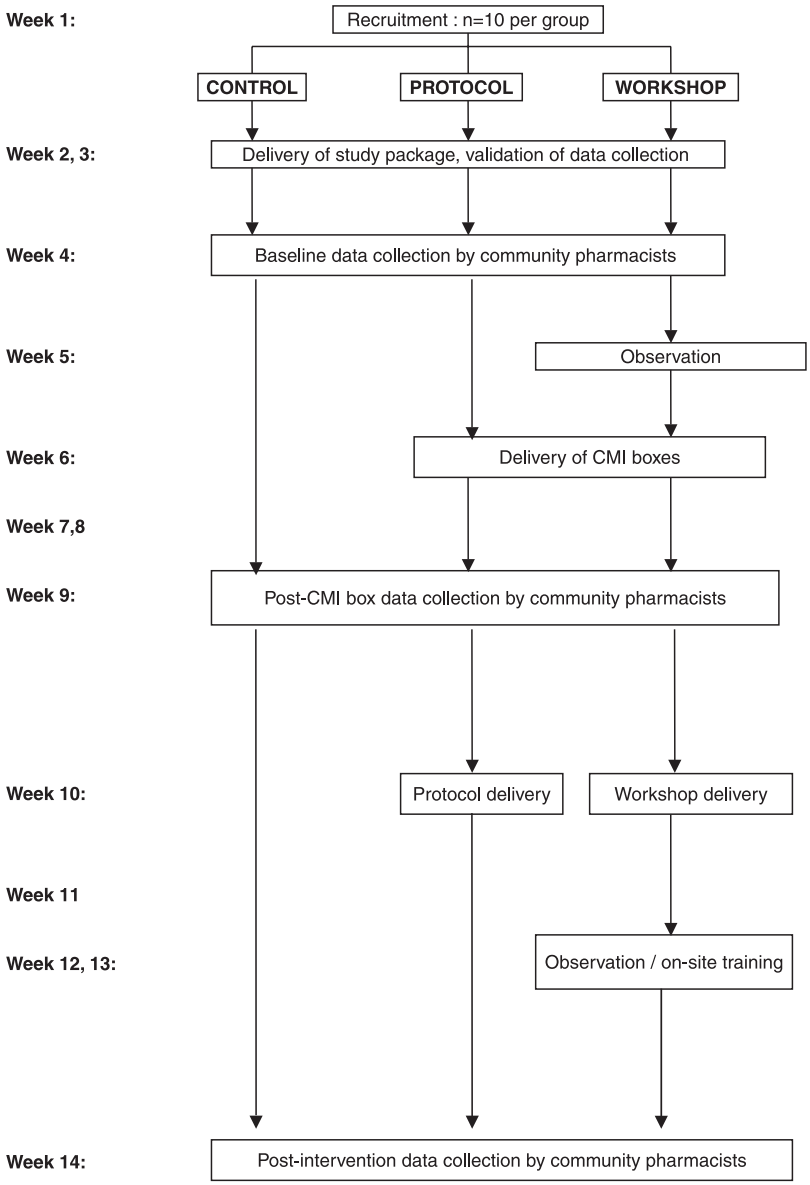

Figure 1. Intervention study design.

collecting the prescription medication, types and numbers of CMIs provided and used in verbal counselling, and the mode of CMI use in counselling (four mutually exclusive options and an "other" option provided). These data were used in calculating the rates of CMI provision and the rates of CMI use in verbal counselling, per community pharmacy.

Observer data sheets and follow-up training. As part of the feedback process for the workshop group participants, an observer collected data on the pharmacists' communication and verbal counselling skills, and provision and use of CMI in verbal counselling, during the on-site visits in weeks 5, 12 and 13 (Figure 1). The consumer-pharmacist interaction which was observed was defined as "any face-to-face verbal communication between a pharmacist and patient about medications during the dispensing of a prescription to that patient" (Schommer, 1995). To minimise the Hawthorne effect, observations were conducted as unobtrusively as possible by the observer (Berardo, Kimberlin, & Barnett, 1989; Schommer, 1995). The data collected were used only as part of the follow-up on-site training of the workshop participants.

Data collection times. Pharmacists collected data over a 3-day period at three time points (Figure 1): baseline (prior to commencement of the study); post-CMI box (2 weeks after the delivery of the CMI box to the protocol and workshop groups); post-intervention

(4 weeks after the delivery of the educational interventions). The observer collected data in the workshop group at baseline and approximately 2 weeks prior to the post-intervention data collection period. The observer spent 1-day in each pharmacy at both periods.

Daily drug usage reports. A detailed daily report of all prescription medications dispensed was collected from each participating community pharmacy for each data collection day. The data were used in calculating the rates of CMI provision and use in verbal counselling. Where daily drug usage reports could not be generated by the pharmacies, monthly drug usage reports were collected and used to estimate the daily total and types of prescription medications dispensed.

Data analysis

All data forms ($n = 608$) were screened for correct completion, the data coded and entered into the Statistical Package for the Social Sciences database (Windows, 1997). Any data sheets which were completed for prescription medications without CMIs, were excluded ($n = 8$). Frequency distributions were compiled for all variables and examined for outliers and other inaccuracies in data entry.

Rates of CMI provision and use in counselling. The rates of CMI provision and use were calculated, per pharmacy per data collection period. The rate of provision was calculated as the total number of E and LL CMIs handed out as a proportion of the total number of prescription medications with E and LL CMIs dispensed. Package insert CMI provision was not calculated, as package insert CMIs are found inside the medication box, and unless actively removed by the pharmacist, are automatically provided to consumers with their prescription medications.

The rate of E and LL CMIs use in verbal medication counselling was calculated as the total number of E and LL CMIs used in counselling as a proportion of the total number of E and LL CMIs handed out to consumers. These rates of use gave an indication of the extent of CMI use in counselling. In other words, they illustrated whether the majority of CMIs were simply handed out to consumers, or whether they were also incorporated in verbal counselling.

Repeated measures analysis of variance (ANOVA) was used to test the following null hypotheses: that there was no statistically significant difference in (a) rates of E and LL CMI provision, and (b) rates of E and LL CMI use in verbal medication counselling process, between and within the three community pharmacy groups (control, protocol and workshop) prior to and after the delivery of the CMI box and the implementation of the two interventions.

In performing the repeated measures ANOVA, a fixed effects design was used (Norusis, 1997) and the data were tested for both main and interaction effects. Simple contrasts were nominated for examining differences in the factor levels in the repeated measures analysis. A 3×3 repeated measures ANOVA was conducted first to compare all three groups at all three data collection times. If any statistically significant differences were observed, 2×3 repeated measures ANOVA were next conducted to compare two pharmacy groups only, at the three data collection times.

χ^2 test for trends (Mantel–Haenszel χ^2 test) was used to compare proportions (where applicable) and determine any trends in data over time in each of the three pharmacy groups. The Wilcoxon signed-rank test and the paired *t*-test were used (for non-parametric and parametric data, respectively) to test for differences between the rates of E and LL CMI use in the verbal counselling of each pharmacy group (within group tests) at each of the three data collection periods.

Unless otherwise stated, the significant level for all analyses was set at 0.05.

Results

A total of 25 community pharmacies completed the study, 9 in the control and protocol groups and 6 in the workshop group (Table I).

Rates of electronic and loose leaflet CMI provision

The rates of E and LL CMI provision were highest in the workshop group compared to the other two groups (Table II). The protocol and workshop groups demonstrated an increase in the mean and median rates of CMI provision after receiving the CMI box, however, the rates decreased at post-intervention. There were no statistically significant changes in the mean rates of E and LL CMI provision in the three groups over the three data collection periods ($F(4,42) = 0.35$, $p = 0.84$). Thus, there was insufficient evidence to reject the null hypothesis.

Use of electronic and loose leaflet CMIs in verbal medication counselling

Both protocol and workshop groups showed higher rates of CMI use compared to the control group at all data collection times (Table III). However, there were no statistically significant differences between the rates of E and LL CMI use in the verbal counselling of the three pharmacy groups at baseline ($F(2,21) = 0.20$, $p = 0.82$).

Table I. Community pharmacist demographics.

Pharmacist characteristic	Pharmacy group		
	Control (relative frequency, %)	Protocol (relative frequency, %)	Workshop (relative frequency, %)
Gender			
Male	6 (66.7)	7 (77.8)	6 (85.7)
Female	3 (33.3)	2 (22.2)	1 (14.3)
Position in pharmacy			
Pharmacy proprietors	5 (55.6)	6 (66.7)	5 (71.4)
Partners	2 (22.2)	–	–
Salaried pharmacists	2 (22.2)	3 (33.7)	2 (28.6)

Table II. Rates of E and LL CMI provision.

Pharmacy group	Data collection period (*n*)	Mean rate (%)	Standard error of mean	Median rate (%)	Interquartile range
Control	Baseline (9)	7.14	2.21	6.77	0.65–13.64
	Post-CMI box (9)	6.72	2.48	6.31	0.31–10.59
	Post-intervention (9)	6.26	2.57	5.34	0.47–7.48
Protocol	Baseline (9)	5.94	2.19	4.42	1.18–8.57
	Post-CMI box (9)	7.02	1.89	6.52	1.26–12.40
	Post-intervention (9)	4.88	0.85	4.88	3.19–5.68
Workshop	Baseline (6)	9.67	3.17	9.09	1.89–16.77
	Post-CMI box (6)	11.20	3.66	9.84	3.30–20.67
	Post-intervention (6)	7.91	2.15	7.61	3.54–10.88

n = number of community pharmacies.

An increase in the rates of E and LL CMI use in counselling was observed in both protocol and workshop groups, over the study period (Table III). However, the mean rate of CMI use was greater in the workshop group at post-intervention, than the protocol group. The high rates of use demonstrate that a large proportion of the E and LL CMIs which were provided to consumers, were used as part of the verbal medication counselling process.

The 3×3 repeated measures ANOVA ($F(2,42) = 5.70$, $p < 0.01$) illustrated a statistically significant time effect, with the difference being more notable at post-intervention when compared to baseline. Further 2×3 repeated measures ANOVA analyses were conducted for each combination of two pharmacy groups. The workshop group demonstrated significant increases in the mean rates of CMI use in counselling with time, compared to the protocol ($F(2,26) = 5.80$, $p < 0.01$) and control groups ($F(2,26) = 3.99$, $p = 0.03$). No other significant differences were detected.

There was therefore sufficient evidence to reject the null hypotheses of no statistically significant differences in the rates of E and LL CMI use in verbal counselling, between and within the pharmacy groups over the study period.

Modes of electronic and loose leaflet CMI use in verbal medication counselling

The four modes of E and LL CMI use reported by the participating pharmacists included drawing the consumer's attention to the presence of the CMI; encouraging the consumer to read the CMI and

Table III. Rates of E and LL CMI use in verbal medication counselling.

Pharmacy group	Data collection period (*n*)	Mean rate (%)	Standard error of mean	Median rate (%)	Interquartile range
Control	Baseline (9)	38.17	13.55	38.17	0–78.57
	Post-CMI box (9)	39.04	15.72	9.09	0–100.00
	Post-intervention (9)	45.40	14.76	45.40	5.57–100.00
Protocol	Baseline (9)	49.01	14.14	50.00	5.56–100.00
	Post-CMI box (9)	64.01	12.07	66.67	37.50–100.00
	Post-intervention (9)	68.25	9.96	68.25	61.91–92.86
Workshop	Baseline (6)	47.55	10.80	50.00	35.66–62.56
	Post-CMI box (6)	58.96	13.97	67.57	33.33–86.88
	Post-intervention (6)	83.32	7.24	88.05	64.29–100.00

n, number of community pharmacies.

return if necessary; pointing out relevant sections of the CMI during verbal counselling; and actively referring to the CMI, highlighting and discussing the relevant sections of the CMI during verbal counselling.

A specific trend in the modes of E and LL CMI use by the control group was not observed (Figures 2–4). However, over the study period, the protocol group demonstrated a decrease in active referral to E and LL CMI during the counselling process (Figures 2–4). The workshop group demonstrated an increase over time, in the proportion of prescription items where the E and LL CMI was used to reinforce verbal counselling, and a decrease in encouraging the consumer to read the CMI and return if necessary (Figures 2–4).

Statistical analysis was not used to compare the proportions observed in the above tables because subdividing the rates of CMI use in counselling into the four modes, resulted in insufficient numbers.

Discussion

The results of the study indicate that providing a multi-faceted educational intervention to community pharmacists can enhance the provision and use of written patient medicine information in their practice.

The rates of CMI provision were low in all groups during the study, but overall, the workshop group provided more CMIs than the other two groups throughout the study period, in particular at post-CMI box. However, this increased rate was not maintained at post-intervention. Additionally, the pharmacists in the protocol and workshop groups (and not the control group) also demonstrated an increase in the rates of E and LL CMI use in verbal counselling. The box may have addressed the limited availability of CMIs in the pharmacies, as well as encouraged pharmacists to provide CMIs, resulting in more CMIs being given out and used in verbal counselling.

The workshop plus protocol plus on-site training intervention program appears to have been more effective in promoting the use of E and LL CMIs in counselling than the written protocol alone. This suggests that the training workshop enhanced the effectiveness of the written protocol. It provided an opportunity for pharmacists to learn about CMIs and their use in practice, away from the busy environment of their pharmacies (which was the case when written protocols were provided to the protocol group), in an environment more conducive to learning. Furthermore, participants had opportunities to perform role plays in the workshop and practice skills. Moreover, they were able to exchange ideas and learn from their peers as well as the workshop facilitator. Any problems or barriers that they had experienced or they had perceived about the use of CMIs could be addressed during the workshop.

The results observed support the need for a more intensive educational programme with follow-up training, where the structure of the programme is based on theoretical models of individual behaviour (Aslani et al., 2006).

Whilst rates of CMI use in counselling improved in the protocol and workshop groups, and high rates were observed, in particular in the workshop group, overall the rates of CMI provision remained low at the end of the study. There are several factors which may explain the observed limited impact of the interventions on the provision of CMI. Firstly, there may have been an under reporting of CMI provision, as the respondents were required to complete a data sheet every time a CMI was given out. CMIs' high readability and the fact that they can only be understood by 40% of the English speaking population (Baker, 1997), may have limited their use in practice. Participating community pharmacists may have believed that the CMIs were too difficult and complicated to be read by some of their consumers, and chose to give them out to selected consumers.

Awareness of the study outcomes through use of the self-reported data sheets may have influenced the data collected by the pharmacists. Thus, pharmacists may have provided more CMIs at baseline than they normally would have if they were not recording their provision and use. This may have masked any significant changes in the mean rates of CMI provision and use in the two intervention groups.

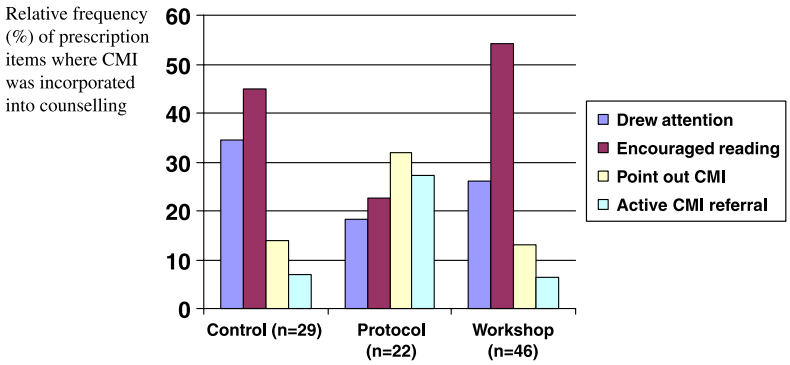

Figure 2. Modes of E and LL CMI use in verbal counselling at baseline.

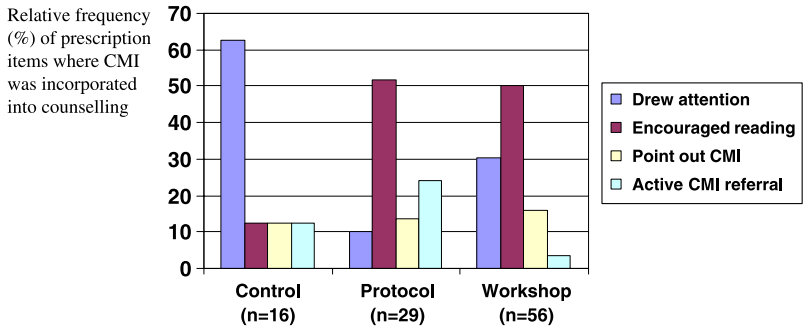

Figure 3. Modes of E and LL CMI use in verbal counselling at post-CMI box.

Additionally, one of the reasons cited by the study participants for not providing CMIs was lack of time. Lack of time (Knapp, 1979; Morrow & Hargie, 1992; Herrier, 1994; Schommer & Wiederholt, 1994) and lack of staff (Knapp, 1979; Herrier, 1994) have been reported as barriers to patient counselling and could have presented as barriers to the provision and use of CMIs during the study period. Savage (1997) demonstrated that at peak dispensing times when the pharmacist is very busy dispensing, the time spent counselling patients on prescription medications decreases.

It is also possible that the two educational interventions did not adequately meet the learning needs of all of the pharmacists who participated in the study. Individuals have different learning styles (Honey & Mumford, 1992). A written protocol alone or in combination with an 1-day workshop with its follow-up on-site training may have been insufficient in changing some pharmacists' behaviour. A longer workshop and/or more frequent on-site training may have been more effective (Aslani et al., 2006). Additionally, the two interventions may not have addressed all the issues pertinent to changing the pharmacists' practice behaviour. Although the training workshop and the written protocol provided a technique for the provision and use of CMIs in practice, they did not address pharmacists' therapeutic knowledge. A lack of confidence in therapeutic knowledge may have acted as a barrier to the use of CMIs as has been previously been reported (Knapp, 1979; Herrier, 1994; Campagna & Newlin, 1997; Venkataraman, Madhavan, & Bone, 1997).

A pharmacist's perception of their patients' expectations (Lewis, Lasack, Lambert, & Connor, 1997) or importance of providing information (Schommer & Wiederholt, 1995), will also determine the provision of information. A majority of pharmacies in the protocol and workshop groups did not have a separate area dedicated to patient counselling. This may have presented as a barrier to the use of CMIs (Knapp, 1979; Herrier, 1994).

The educational interventions were designed to change individual behaviour. However, in seeking to change an individual's behaviour it is also important to consider the context; namely the influence of the organisational structure and community expectations on practice behaviour.

Study limitations

Two specific limitations not discussed above are the recruitment rates and the sample size. Recruitment (or response) rates of 52.6, 47.6 and 28.6% were obtained for the control, protocol and workshop groups. The varying recruitment rates may indicate a differing

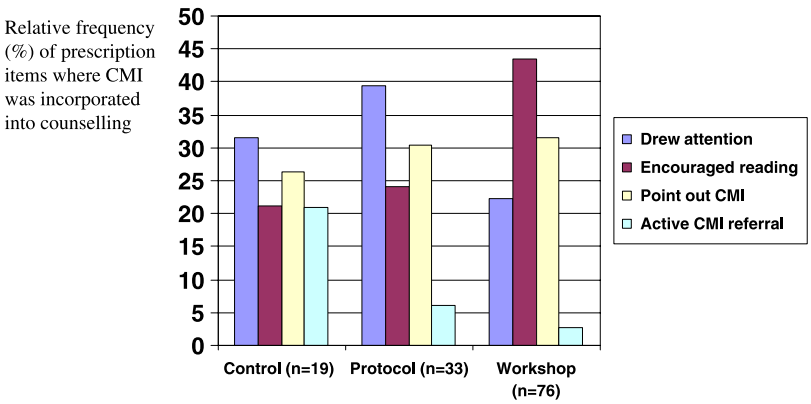

Figure 4. Modes of E and LL CMI use in verbal counselling at post-intervention.

degree of self-selection of participants in the three groups, which is not unexpected in a study which involves voluntary participation. Self-selection may have biased the results, as only those pharmacists keen to participate and/or already using CMIs, may have agreed to participate.

Additionally the small pharmacy sample size may have introduced a greater variance in the data, and precluded detection of an effect of the educational interventions. The small sample size together with the bias of self-selection also reduces the generalisability of the data. However, as recommended in the literature, more emphasis should be placed on the internal validity of an educational programme rather than the external validity, as it is important to ensure that the programme is effective with the target sample before it can be extrapolated to the target population (Windsor, Baranowski, Clark, & Cutter, 1984).

Conclusions

Providing an educational programme (based on theoretical models of behaviour), consisting of a written protocol in combination with an 1-day workshop and follow-up on-site training, as well as provision of a box of E and LL CMIs, facilitated the use of E and LL CMIs in the verbal counselling of community pharmacists.

To promote increased provision of CMIs and use in verbal counselling, educational interventions are appropriate, but used alone are insufficient until other barriers, such as CMI format and availability, dispensing layout, staff, equipment and remuneration, have been fully addressed, and the needs of both organisation and the individual are addressed to achieve new practice behaviour.

With increasing patient demand for medicine information, it is imperative that pharmacists are the primary health professionals who provide this information.

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