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Hamrosi, KK, Raynor, DK and Aslani, P (2014) Pharmacist, general practitioner and consumer use of written medicine information in Australia: Are they on the same page? Research in Social and Administrative Pharmacy, 10 (4). pp. 656-668. ISSN 1551-7411

https://doi.org/10.1016/j.sapharm.2013.10.002

*Title Page - showing Author Details

Pharmacist, general practitioner and consumer use of written medicine information in Australia: are they on the same page?

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Keywords: Written medicine information, patient education, information-sharing, health literacy, community pharmacists, general practitioners.

Funding Acknowledgement:

This study was part of a larger project called 'The Consumer Medicine Information Effectiveness Project'. We gratefully acknowledge the funding by the Australian Government Department of Health and Ageing as part of the Fourth Community Pharmacy Agreement Research and Development program managed by the Pharmacy Guild of Australia.

Declaration of Interest:

D.K. Raynor is co-founder and academic advisor of Luto Research Ltd, which develops, refines and tests health information.

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ABSTRACT

Background: Providing written medicine information to consumers enables them to make informed decisions about their medicines, playing an important role in educating and improving health literacy. In Australia, standardized written medicine information called Consumer Medicine Information (CMI) is available for medicines as package inserts, computer prints, or leaflets. Consumers want and read CMI, but may not always ask for it. General practitioners (GPs) and pharmacists are an important source of written medicine information, yet may not always provide CMI in their practice.

Objective: To examine and compare the awareness, use and provision of CMI by consumers, pharmacists and general practitioners (GPs).

Methods: Based on previous studies, structured questionnaires were developed and administered to a national sample of consumers (phone survey); community pharmacists and GPs (postal surveys) about utilisation of CMI. Descriptive, comparative and logistic regression analyses were conducted.

Results: The respondents comprised of 349 pharmacists, 181 GPs and 1000 consumers. Two-thirds of consumers, nearly all (99%) pharmacists and 90% of GPs were aware of CMI. About 88% of consumers reported receiving CMI as a package insert, however most pharmacists (99%) and GPs (56%) reported providing computer-generated CMI. GPs' and pharmacists' main reason for providing CMI was on patient request. Reasons for not providing were predominantly because consumers were already taking the medicine, concerns regarding difficulty understanding the information, or potential non-adherence. Of the 691 consumers

reportedly reading CMI, 35% indicated concerns after reading. Factors associated with reading included gender, type of CMI received and frequency of provision.

Conclusion: Consumers want and read information about their medicines, especially when received from their GP or pharmacist. Healthcare professionals report usually discussing CMI when providing it to patients, although continued improvements in dissemination rates are desirable. Regular use of CMI remains a challenge, and ongoing strategies to promote CMI use are necessary to improve uptake of CMI in Australia.

INTRODUCTION

Written medicine information is an important source of information for consumers and an integral component of their education about medicines [1]. The literature contains evidence of its role and value [2], and positive impact on medicine knowledge, satisfaction and health literacy [3]. Studies have focused on improving usability [4] and design [5] of written medicine information, advocating consumer input into the evaluation process to enhance its usefulness to end-users. Several factors have been shown to influence consumer evaluation and intended use of written medicine information, notably health literacy, comprehension and perceived usefulness, which can impact its benefits in practice [6].

Consumers want written medicine information in conjunction with spoken information, however many do not actively seek it [7,8]. Self-report studies have indicated that healthcare professionals regularly provide both oral and written information[9], but this is generally not reflected in consumer studies that report lower provision rates [9,10]. General practitioners (GPs) and pharmacists are considered the most important, trusted and reliable sources of written medicine information [11]. However, despite growing evidence surrounding consumer desire and interest in receiving written medicine information, healthcare professionals in Australia often fail to provide it, and if provided, do so with limited interaction [12].

In Australia, Consumer Medicine Information (CMI) is a standardized form of brand-specific written medicine information produced by manufacturers according to strict legislation[13], essentially with limited consumer input (unlike the European Union). This has lead to questions of sufficient independence of information, concerns regarding reliability and credibility, and perceptions of a dominant medico-legal theme within CMI.[14] CMI for prescription medicines is available electronically through dispensing or prescribing programs;

from the Internet via government, manufacturer or third party websites; inside the medicine box (package insert); or as loose leaflets through pharmacies (less commonly). The format can vary from a single-page package insert through to several computer-generated pages. In contrast to the European Union, Australian CMI is not legally required to be inside the medicine's box. Moreover, provision of CMI by healthcare professionals in Australia is not mandatory. Professional practice standards and guidelines to assist healthcare professionals in their legal and professional obligations have been developed but provision rates remain low [15-17].

The literature contains numerous studies evaluating the use and impact of written medicine information. However, few studies have been conducted with CMI, which differs in presentation, content, design and readability to other written medicine information. In comparison to many other countries, Australian CMI are standardized and regulated documents produced using the Usability Guidelines[18], and from templates or 'core CMI' (derived from guidelines first published in 1993) commonly used by manufacturers when writing CMI to meet their legislative obligations and to incorporate essential design and layout principles. This has resulted in Australia having the highest compliance on readability and visual presentation when compared with other English-speaking countries.[19] Furthermore, most studies have focused on consumers, and as such, healthcare professional interaction with written medicine information and more specifically CMI, is essentially an unexplored area that needs further investigation to furnish a more holistic picture. To date, no studies have compared the awareness, use and readership of CMI by consumers to community pharmacists and general GPs, whose responsibility it is to provide this information.

Therefore, informed by the findings of two previous exploratory qualitative studies with consumers[14] and healthcare professionals[20], this quantitative study was conducted which aimed to: (1) determine current awareness and use of written medicine information, specifically CMI,

for prescription medicines (2) examine the reasons surrounding readership and provision and (3) compare both consumer and healthcare professional (community pharmacist and GP) use of CMI.

METHODS

The study was conducted between February and April 2009 after approval from the Institution's Human Research Ethics Committee. The study consisted of postal surveys to GPs and community pharmacists, and telephone surveys with consumers. Postal surveys for GPs and pharmacists allowed completion at a suitable time without intrusion on consultation or business activities. Conversely, telephone surveys were utilized to sample consumers to facilitate a higher response rate, and offered the advantage of capturing participants who were unlikely to complete a written survey.

Sampling

A sample size of 226 consumers was calculated [21], based on CMI receipt rates of 18% [15] and a 5% degree of precision. However, for the purposes of comparison to previous data [15] 1000 consumers were surveyed. Consumer telephone interviews were stratified by state and territory using Australian Bureau of Statistics (ABS) [22] population data to recruit a representative sample based on gender, age and including both metropolitan and rural populations.

Using the same method as above, the sample size for pharmacists was calculated as 108, based on CMI provision rates (7.6%) reported in an earlier study in New South Wales (NSW)[23]. Assuming a 30% response rate, a sample size of 360 pharmacists was required within NSW.

The survey was conducted Australia-wide, and sample sizes were calculated for the other states and territories using the number of pharmacies per state/territory as the denominator, giving a total sample distribution of 1046, rounded to 1100 subjects.

There were no published studies on the proportion of GPs or other prescribers providing CMI. Using estimates regarding response rate informed by other studies with medical practitioners (range: 47-68%[24,25]), a conservative 30% response was assumed as per pharmacist data and calculated the sample size for GPs to be the same as pharmacists, 1100 subjects.

Data Collection

Consumers were randomly telephoned from the Australian telephone directory by trained researchers and recruited using a pre-written script that included study information and eligibility (at least 18 years of age, able to participate without the need for a translator and taking at least one prescription medicine for the month prior to the telephone interview). The questionnaire was administered using a computer-assisted telephone interviewing system with responses entered directly into a database during the interview.

A random sample (stratified and distributed according to ABS[22] population data) of 1100 GPs and 1100 community pharmacists was collated from a database held by a healthcare data information company. Potential participants were sent a postcard inviting them to take part. A survey pack containing study information and questionnaire followed one week later. To increase response rates and encourage non-respondents, a further reminder and/or thank you postcard was sent two weeks later, and a final survey pack was sent after approximately four weeks.[26]

Questionnaires

The study questionnaires[27] were developed from earlier research [14], and previous findings[15,28]. A central structured questionnaire was developed and subsequently adapted for each of the three groups: consumer, GP and pharmacist. The questionnaires consisted of 7 sections: knowledge of CMI (Section A); current use of CMI in practice (B); experience after provision of CMI (C); opinions on the future provision of CMI (D); opinions on content and format of CMI (E); improving provision and use of CMI (F); and demographic characteristics. The survey contained primarily closed-ended questions with single or multiple response options, with an 'other' category included where suitable. This paper reports results relating to sections A, B and C. Two panels consisting of pharmacists (n=8), consumer representatives (n=2) and other experts in the field (n=9) reviewed all questionnaires for content and face validity. Questionnaires were then piloted with four pharmacists (postal) and twenty-five consumers (telephone). Any changes derived from feedback were reflected across all three questionnaires.

Data Analysis

All data were coded and entered into the Statistical Package for Social Sciences (Version 19.0 IBM). Not all questions were answered and/or some allowed multiple responses hence the number of respondents varied for each question. Descriptive and frequency distributions were compiled for all categorical values for each group. To determine the relationship between variables, univariate analyses were conducted using non-parametric Chi-squared or Mann Whitney U tests for each group and to compare differences between pharmacists and GPs. Variables that were significant at $p<0.25$[29] were included as predictors for logistic regression to predict readership and provision. As exploratory analysis was conducted with no prior

assumptions, logistic regression was performed using the forced entry method (all predictors entered into the equation simultaneously).[29] Models were checked for multicollinearity (variables with tolerance values <0.1 were removed) and outliers. Significance values were set at $p<0.05$ for interpretation of the final multivariate logistic regression models.

RESULTS

Demographics

To obtain 1000 eligible and consenting respondents, researchers conducting the phone surveys called 11,653 telephone numbers nationally in both metropolitan and rural areas stratified according to ABS[22] demographic data. A total of 5386 persons answered the phone, of which 2107 people refused to participate and a further 1644 did not meet the eligibility criteria, resulting in an overall response rate of 32%. The postal survey response rate was 34% (n=349) for pharmacists and 17% (n=181) for GPs. Sample sizes were sufficient to run valid bivariate and logistic regression analyses.

The median age of consumer participants was 60 (range 18-98) years, whilst pharmacists' and GPs' median ages were 47 (range 22-87) years and 52 (range 31-83) years, respectively. Concerning gender, 516 (52%) consumers, 189 (54%) pharmacists and 93 (52%) GPs were female. Most consumers (n=750, 75%) and pharmacists (n=246, 71%) were born in Australia with only 53% (n=96) of GPs born in Australia.

Consumer occupations consisted mainly of white-collar workers and retirees, and education level varied with over half of participants obtaining a high school (up to Year 12) education (n=526, 53%), 10% (n=96) certificate level qualifications and 37% (n=370) a tertiary education

(Bachelors degree or above). Pharmacists (median=23 years, range 7-33) and GPs (median=25 years, range 16-31) had similar years of professional experience. Most pharmacists primarily practiced in community pharmacy (n=336, 96%) working in independent (n=184, 53%) or chain (n=160, 46%) pharmacies (missing data n=5). Approximately 49% (n=170) were owners/partners of the pharmacy, with the remainder permanent (n=140, 40%) or casual (n=29, 8%) employees. Most GPs were in group practices (n=152, 85%) with 15% (n=27) in sole practice settings.

Awareness and sources

Of the consumers, almost half (n=474, 47%) were aware of CMI (for prescription medicines), with a further 207 (20%) reporting knowledge about medicine leaflets but not as CMI. In contrast, 99% (n=344) of pharmacists and 90% (n=162) of GPs were aware of CMI. Those consumers reporting they were aware of CMI, cited pharmacists, doctors or package inserts as common sources (Table 1). GP and pharmacist respondents indicated similar results, however, pharmacists did not report the doctor as a source of CMI as frequently as GPs and consumers. More GP and pharmacist respondents reported the Internet as a source of CMI than consumers, highlighting a lack of awareness of this source amongst consumers.

Most consumers (n=691, 69%) reported receiving CMI for their prescription medicine in the 6 months prior to their survey; supplied either by a pharmacist (n=267, 39%), doctor (n=124, 18%), pharmacy assistant (n=33, 5%), family member/carer (n=10, 1%) or found as a package insert (n=366, 53%). Almost half (n=327, 47%) reported receiving CMI every time they received a new medicine, whilst 272 (40%) received it when collecting a repeat prescription for a regular medicine. Ten percent (n=69) received it only when they asked for it.

There was disparity amongst the types of written medicine received or provided. Over three-quarters of pharmacists (n=272, 78%) and less than half of GPs (n=87, 48%) reported providing package inserts, yet most consumers (n=606, 88%) reported receiving them when provided with written medicine information. Computer generated CMI was commonly provided by pharmacists (n=347, 99%) and GPs (n=101, 56%), however this was not reflected in consumer responses that reported only 37% (n=257) receiving computer-generated CMI. Forty percent (n=141) of pharmacists and 25% of GPs (n=45) also reported providing loose leaflets/brochures yet only 7% (n=47) of consumers reported receipt.

Readership by consumers

Approximately two-thirds (n=457, 66%) of consumers reported usually reading the CMI, with 'side effects' and 'what the medicine is for' being most read (Table 2). Reasons provided for not reading the CMI were, they had taken the medicine previously (n=356/462, 77%) or received enough information verbally from their pharmacist or GP (n=53, 12%). Only a small percentage did not read the CMI because they found it too long (n=16, 4%) or contained too much information (n=8, 2%).

Logistic regression assessed the impact of various factors on the likelihood of consumers reading CMI. The variables demonstrated sampling adequacy. The model contained 11 independent variables relating to type of CMI, provider of CMI, frequency of distribution, gender and occupation. The final model produced was statistically significant (χ^2 (11, n=648) = 125.61, $p<0.001$), indicating that the model was able to distinguish between respondents who reported reading CMI and those who did not. Overall, the model successfully predicted 73.3% of cases. From the Wald statistics (Table 3a), type of CMI received, provider of CMI, frequency of provision and gender reliably predicted consumers who were likely to read CMI. Consumers

who received computer-generated written medicine information other than CMI from their GP or pharmacist were almost four times more likely to read this information. Females were twice as likely to read CMI than males. Consumers who received package inserts were approximately two times *less* likely to read CMI than those who received information from their healthcare professional.

Provision of CMI by pharmacists and GPs

All pharmacists (n=1 missing data) and 69% (n=125) of GPs reported providing CMI. Pharmacists reported providing CMI when dispensing a new medicine most (n=150, 43%) or all (n=168, 48%) of the time, and provided CMI with repeat medicines some (n=244, 70%) or none (n=101, 29%) of the time. Similarly, GPs provided CMI most (n=56, 31%) or all (n=18, 10%) of the time with new medicines, and some (n=53, 29%) or none (n=123, 68%) of the time with repeat prescribing. On the availability of new information about a medicine, GPs provided CMI most (n=53, 17%) or all (n=94, 52%) of the time in comparison to pharmacists (n=112, 32% and n=73, 21%, respectively).

Logistic regression was performed to determine healthcare professional variables that impact provision of CMI (Table 3b). Pharmacist data could not be included in analysis as these respondents all reported providing CMI, therefore regression was conducted using GP respondent variables. The model contained nine independent variables relating to gender, type of CMI provided, source of CMI and access to CMI. The final model was statistically significant χ^2 (9, n=179) = 127.83, p<0.001, and performed well in distinguishing GPs who reported providing CMI or not. Overall, the model successfully predicted 89.4% of the cases. Wald statistics (Table 3b) showed type, source and access to CMI reliably predicted GPs who provided CMI. GPs who used computer-generated CMI and relied on package inserts in

sample boxes were more likely to provide CMI. Similarly, those GPs with access to prescribing software and pharmaceutical company websites were also far more likely to provide CMI. Finally, GPs that reported themselves as the patient access point for CMI were almost eight times more likely to provide CMI.

The reported reasons for providing or NOT providing CMI (Table 4) by pharmacists and GPs varied. Pharmacists' were more likely to provide CMI, apart from on patient request, predominantly because of patients' right to information, informed choice, reinforcing medicine-taking behaviour and verifying their own knowledge, than GPs. This differed significantly from GPs whose reasons were mostly associated with requests by patients for CMI.

Pharmacists' were more likely NOT to provide CMI (Table 4) due to the reasons of knowing that patients had taken the medicine previously; or concerns with patients' difficulty in understanding/reading CMI, patient non-adherence and use of the medicine off-label, when compared to GPs. However, GPs reported NOT providing CMI (Table 4) predominantly because patients received sufficient spoken information from them and they experienced a lack of time with patients. Interestingly, GPs also did not provide CMI because they believed the patient would receive this information from their pharmacist.

CMI in practice

Mann-Whitney U testing revealed few differences in the use of CMI in patient interactions/consultations between GPs and pharmacists (Table 5). The majority of pharmacists and GPs reported verbally discussing sections of the CMI with patients or drew their attention to sections of the CMI, although pharmacists were more likely to do so most to all of the time in comparison to GPs who reported doing so some to most of the time. Most pharmacists or GPs were unlikely to provide CMI without verbal counseling, but few discussed

the entire CMI with their patients. Various sections of the CMI were discussed with patients (Table 2). Side effects were the most discussed section, followed by what the medicine is for.

Three-hundred and eighteen consumers reported directly receiving CMI from their pharmacist or GP; 108 (34%) reported CMI being given to them with no further discussion, and a similar proportion (n=93; 29%) had a CMI discussed in detail with them. Others (n=57, 18%) had sections pointed out to them and 45 (14%) were provided CMI, asked to read and return if they had questions.

Concerns and queries

Of the 457 consumers who reported reading CMI, 164 (35%) reported a concern or query after reading; the predominant being experiencing a side effect (n=101, 62%), drug-drug interactions (n=43, 26%) and needing more information and/or instructions about the medicine (n=24, 15%). Most pharmacists (n=320, 92%) and GPs (n=161, 89%) reported that their patients had concerns or queries after reading CMI. Consumers' initial action was to contact the doctor (n=98, 60%), followed by the pharmacist (n=51, 31%) with 5% (n=8) refusing to take the medicine. Pharmacists and GPs reported the reverse, indicating pharmacists being the first contact (reported by 315 or 90% of pharmacists; and 145 or 81% of GPs), followed by the GP (n=135, 39% pharmacists; n=97, 54% GPs). Over two-thirds of GPs (n=112, 62%) and about a quarter of pharmacists (n=95, 27%) reported patients refusing/ceasing to take their medicine. Following on from the initial action and after consulting with the doctor or pharmacist, over half of consumers (n=73, 55%), pharmacists (n=156, 58%) and GPs (n=81, 57%) reported no change in the patients' medicine. The other half reported changing the medicine (n=21, 16% consumers; n=39, 14% pharmacists; n=14, 10% GPs), ceasing the medicine (n=19, 14% consumers; n=19, 7% pharmacists; n=19, 13% GPs), changing dosages (n=17, 13% consumers;

n=5, 2% pharmacists; n=1, 1% GPs) or providing reassurance, further clarification/explanation (n=18, 14% consumers; n=26, 10% pharmacists; n=23, 16% GPs).

DISCUSSION

This study compared consumers', pharmacists' and GPs' awareness, use and provision of CMI, and identified some factors associated with its readership and provision. A representative consumer sample was achieved for demographic distribution through recruiting according to geographic stratification quotas, with proportional representation per State and Territory, and metropolitan and rural populations. In terms of gender the study contained 52% females, similar to the desired sampling frame of 52.5% females. The median age for consumer participants was 60 years in comparison to 37 years for the Australian population.[30] As the study specifically targeted medicine users the higher median age of participants is not unexpected as medication use and proportion of medicines used increases with age. Of note, consumer respondents' education levels varied significantly, particularly the percentage of participants who held tertiary qualifications was much higher than ABS[31] reported data (37% vs 23%) which may have influenced consumers use of CMI.

The results showed that over two-thirds of consumers were aware of written medicine information, predominantly as CMI, an encouraging improvement from previous studies[10,15]. In the main, community pharmacists and GPs were aware of CMI, which is encouraging as consumers regard them as the two important sources of CMI. Approximately 69% of consumers reported receiving CMI in the six months prior to the survey. Earlier Australian studies reported CMI receipt rates as 36% in 1996, 57% in 1999[32], and 82% in 2005[10] for prescription medicines. In contrast, a 2009 study[16] reported receipt rates of 22%, but did not differentiate CMI for prescription and over-the-counter medicines. The common trend in these

studies has been an increase in CMI provision over the last two decades, although the results indicate a small decline from 2005, indicating the need for vigilance and periodic awareness campaigns and education strategies among consumers and healthcare professionals.

Written medicine information in conjunction with spoken information is considered more effective than either alone.[33,34] The prevalence of package inserts in Australia has been steadily declining with electronic distribution of CMI through dispensing and prescribing software considered preferable in order to provide up-to-date information. Interestingly, most consumer respondents reported receiving a package insert in contrast to half reportedly receiving CMI from their pharmacist or doctor. The awareness of CMI as a package insert was notable, and a steady decline in availability of package insert CMI may have implications for consumer awareness and use. Comparatively, pharmacists and GPs reported greater distribution of computer-generated CMI compared to package inserts, however whether they actively distribute the package insert or assume its presence is unclear.

Patients often prefer to receive medicine information from their doctor, however time restrictions may limit a doctor's ability to provide this [35], which was mirrored in over a third of GP respondents reporting insufficient time to spend with the patient on providing CMI compared to less than one-tenth of pharmacists. This may explain the study results showing pharmacists as the predominant source of CMI for consumers (88% vs 70% for GPs); perhaps seen as 'medicine experts', readily accessible, able to fill information gaps post- consultation (with potential to alleviate time burdens on GPs); and they are often the final healthcare professional patients consult before taking their medicine[36,37]. GPs too, predominantly rely on pharmacists to provide CMI and counseling[20], see pharmacists as the primary source of CMI and as such their belief may explain the lack of CMI provision in consultation, as highlighted in the results (96% of GPs indicated pharmacists as a source of CMI).

Similar to previous studies, 66% of consumers in this study reported reading CMI, with females twice as likely to read CMI as males[10,38]. Readership may be influenced by the nature and quality (design, flimsy nature and small font) of written medicine information (i.e. package inserts) which in turn affects readability and usability by consumers.[39] Despite observations to the contrary[14], this study found negligible impact of quantity and length on consumer readership of CMI. Consumer respondents were more likely to read medicine information provided by their healthcare professional, compared to package inserts, substantiating the influence of personally provided information on readership, and perception of its usefulness.[40] Previous findings indicate a positive association with physician counseling and reading written medicine information.[37] Interestingly, computer-generated written medicine information other than CMI strongly predicted consumer readership in this study, with consumers almost four times more likely to read this information. It can only be speculated, since it was not elucidated, that GPs' and pharmacists' personal preference and perceptions of other written medicine information as more patient-focused, relevant, and readable to consumers than CMI may influence the interaction and time afforded to consumers in disseminating this information, providing a sense of tailoring or personalization that impacts consumer readership. Findings from previous studies indicate patient preference is for written medicine information tailored to the individual [41] and which highlights the medicine's benefits[42].

Evidence shows consumers value face-to-face contact [43]. Two thirds of consumers reported a range of interactions with the pharmacist or GP when being provided with CMI. In this study, GPs and pharmacists were unlikely to provide CMI without verbal counseling, the downside of which may mean consumers are missing out on receiving CMI if time is limited, which is often the case in consultations.[14] However, if CMI is provided, the interaction or discussion transpiring between healthcare professional and consumer is likely. The active engagement of

healthcare professionals in providing written and spoken information is a vital component in maximizing the impact and importance of CMI, as well as assisting consumers to understand the risks and benefits of their medicines[37,44].

Time limitations and imparting sufficient spoken information were significantly more likely to be reasons for not providing CMI for GPs than pharmacist respondents. Short consultation times, high workloads and limited resources contribute to the down-prioritisation of CMI in consultations[20]. This, along with perceptions around role responsibility (as inferred in the results as the preference for the pharmacist as a source of CMI) may further explain why often only spoken information is provided by GPs. This study also found factors such as ready access to CMI from prescribing software, pharmaceutical websites and sample packs significantly influenced the provision of CMI, as did self-identification by GPs as a source of CMI for patients predicting that GPs who self-identify as a source of CMI are almost eight times more likely to provide it. Pharmacists were more likely to support providing CMI due to beliefs surrounding consumers' rights to information, duty of care, and promoting informed choice than GPs, although this was still notable among them. In Australia, the provision of medicines information as a key role is reinforced by professional practice guidelines[45], education programs[23] and at practice level through remuneration linked to CMI provision.

Despite the welcome increases to provision rates and ongoing improvements to CMI over the last decade, negative perceptions from healthcare professionals still persist.[20] The idea of written medicine information must be compatible with GP and pharmacist needs, values and experiences as well as that of consumers. Past negative experiences such as consumers declining CMI when offered, concerns or failure to take medicines after reading CMI (which may be valid and appropriate actions) may pose barriers and interfere with the successful adoption by GPs and pharmacists of CMI in everyday practice. Many GPs (89%) and pharmacists (92%)

reported situations where consumers had concerns or queries after reading CMI, resulting in consumers refusing to take or ceasing their medicine, reflecting an earlier study with physicians[46]. Notwithstanding these results and accounts in the literature of a relationship between side effect fear and ceasing medication[47], very few consumer respondents in this study reported refusing to take or ceasing their prescribed medicine, possibly inferring a confidence in their practitioners treatment decisions. Thus, this relatively low incidence does not support GP and pharmacist perceptions, nor justify their reluctance to provide CMI to patients on this basis. Concerns about understandability, usability and readability expressed by a significant proportion of GPs and pharmacists may also contribute to the undervaluing of CMI as a tool for information-sharing and further contribute to non-provision of CMI to consumers. Despite these concerns and some negative perceptions of the value of CMI held by healthcare professionals, consumers find CMI useful, informative and educational and as such should at each opportunity be at the very least offered the option of receiving a CMI.[38,48]

Limitations to this research must be considered when interpreting the results. The response rates may indicate a bias towards participants with a specific interest in CMI. The results have been derived from self-report data, and subject to personal, social desirability and/or recall bias. However, a representative consumer sample was achieved with regard to gender and location in accordance with ABS data. Data was not collected on the medicines consumers were currently taking and the influence this may have had on their responses. Consumers may receive written medicine information for various medicines and illnesses, and it is possible that their perception and readership of the leaflets may have been influenced by the seriousness or chronic nature of their treatment. Consideration should also be given to the limitations of telephone surveys despite the advantages of rapid data collection and accessibility to respondents. Inattentiveness, time constraints or open-ended questions may negatively affect participant responses. Consumers with mobile telephones only or silent numbers may not have been represented, as

calls were limited to unrestricted landlines. Due to increases in telemarketing, many households employ call screening and thus may have opted not to answer the telephone. GP response rates were lower than expected, despite follow-up, which may reflect the low priority that CMI has for invitees. The GPs' and pharmacists' respondent sample whilst not generalisable, may provide constructive insight into the use and provision practices of GPs and pharmacists in relation to CMI, providing a basis from which to direct further research.

CONCLUSION

The awareness of CMI among consumers, community pharmacists and GPs has increased in Australia over the past decade, along with the proportion of consumers receiving CMI. However, provision rates remain lower than desirable, implying that the value of CMI has not been fully realized or accepted by healthcare professionals, despite improvements in access, development and quality of CMI, associated education programs and professional guidelines. Although CMI may not be the best source of medicine information for all consumers, it is currently the most comprehensive written information available for all prescription medicines in Australia. At a minimum all consumers should at least be offered CMI in consultation, providing healthcare professionals with the opportunity to engage consumers and determine their beliefs, expectations and needs surrounding the amount and type of information desired.

The introduction of strategies and education programs for consumers and healthcare professionals to support understanding of the purpose and function of CMI, alongside its role as a tool to improve health literacy and education about medicines may be beneficial in promoting it's explicit effects, such as improved adherence, knowledge or satisfaction with medicines. Indeed, considering the role of CMI in dissemination of medicine information and patient empowerment, the involvement of healthcare professionals along with consumer, professional

and government bodies to develop minimum practice standards, education and change management strategies to routinely incorporate CMI in consultation is warranted. Further research is needed to fully understand consumers', pharmacists' and GPs' underlying attitudes, motivations and rationale surrounding utilisation of CMI and determine ways in which to support facilitation and utilization of CMI in practice.

The results from this study may have relevance to countries where written medicine information supply and provision is regulated and legally mandated such as in the EU, New Zealand, and for the US, where consultations continue on the development and distribution of standardized Patient Medication Information[49].

REFERENCES

1. Koo MM, Krass I, Aslani P. Factors influencing consumer use of written drug information. *Ann Pharmacother*. Feb 2003;37(2):259-267.
2. Grime J, Blenkinsopp A, Raynor DK, Pollock K, Knapp P. The role and value of written information for patients about individual medicines: a systematic review. *Health Expect*. Sep 2007;10(3):286-298.
3. Nutbeam D. The evolving concept of health literacy. *Soc Sci Med*. Dec 2008;67(12):2072-2078.
4. Raynor DK, Knapp P, Silcock J, Parkinson B, Feeney K. "User-testing" as a method for testing the fitness-for-purpose of written medicine information. *Patient Educ Couns*. Apr 27 2011.
5. Raynor DK, Dickinson D. Key principles to guide development of consumer medicine information--content analysis of information design texts. *Ann Pharmacother*. Apr 2009;43(4):700-706.
6. Koo MM, Krass I, Aslani P. Patient characteristics influencing evaluation of written medicine information: lessons for patient education. *Ann Pharmacother*. Sep 2005;39(9):1434-1440.
7. Koo M, Krass I, Aslani P. Enhancing patient education about medicines: factors influencing reading and seeking of written medicine information. *Health Expect*. Jun 2006;9(2):174-187.
8. Sleath B, Wurst K. Patient receipt of, and preferences for receiving, antidepressant information. *Int J Pharm Pract*. 2002;10:235-241.
9. Puspitasari HP, Aslani P, Krass I. A review of counseling practices on prescription medicines in community pharmacies. *Res Social Adm Pharm*. Sep 2009;5(3):197-210.
10. Koo M, Krass I, Aslani P. Consumer use of Consumer Medicine Information. *Journal of Pharmacy Practice Research*. 2005;35(2):94-98.

11. Narhi U. Sources of medicine information and their reliability evaluated by medicine users. *Pharm World Sci*. Dec 2007;29(6):688-694.

12. Koo M, Krass I, Aslani P. Consumer opinions on medicines information and factors affecting its use-an Australian experience. *Int J Pharm Pract*. 2002;10(2):107-114.

13. Australian Government. Therapeutic Goods Regulations. . In: Department of Health and Ageing, ed. Vol Part 2A- Patient Information Statutory Rules 1990 No. 394 as amended. Canberra: Federal Register of Legislative Instruments; 1990.

14. Hamrosi KK, Aslani P, Raynor DK. Beyond needs and expectations: identifying the barriers and facilitators to written medicine information provision and use in Australia. *Health Expect*. Mar 6 2012.

15. Benton M, Snow K, Parr V. *Evaluation of the Medicines Information for Consumer (MIC) Program*: Pharmacy Guild of Australia;2004.

16. Vitry A, Gilbert A, Mott K, Rao D, March G. Provision of medicines information in Australian community pharmacies. *Pharm World Sci*. Apr 2009;31(2):154-157.

17. Puspitasari HP, Aslani P, Krass I. Pharmacists' and consumers' viewpoints on counselling on prescription medicines in Australian community pharmacies. *Int J Pharm Pract*. Aug 2010;18(4):202-208.

18. Sless D, Shrensky R. *Writing about Medicines for people in: Usability guidelines for consumer medicine information*. 3rd ed: Australian Self-Medication Industry; 2006.

19. Luk A, Tasker N, Raynor DK, Aslani P. Written medicine information from english-speaking countries--how does it compare? *Ann Pharmacother*. Feb 2010;44(2):285-294.

20. Hamrosi KK, Raynor DK, Aslani P. Pharmacist and general practitioner ambivalence about providing written medicine information to patients-A qualitative study. *Res Social Adm Pharm*. Sep-Oct 2013;9(5):517-530.

21. Kalton G. *Introduction to survey sampling*. Beverly Hills: Sage Publications; 1983.

22. Australian Bureau of Statistics. *Australian Demographic Statistics June 2008. Accessed from: http://www.abs.gov.au/AUSSTATS/abs@.nsf/DetailsPage/3101.0Jun%202008?OpenDocument#Publications* 2008.

23. Aslani P, Benrimoj SI, Krass I. Development and evaluation of a training program to foster the use of written drug information in community pharmacies. Part 2: Evaluation *Pharm Educ* 2007;7(2):141-149.

24. Newnham GM, Burns WI, Snyder RD, et al. Attitudes of oncology health professionals to information from the Internet and other media. *Med J Aust.* Aug 15 2005;183(4):197-200.

25. Parker MH, Cartwright CM, Williams GM. Impact of specialty on attitudes of Australian medical practitioners to end-of-life decisions. *Med J Aust.* Apr 21 2008;188(8):450-456.

26. Dillman DA, Smyth JD, Christian LM. *Internet, mail and mixed-mode surveys: the tailored design method.* 3rd ed. Hoboken, N.J.: Wiley & Sons; 2009.

27. Aslani P, Hamrosi K, Feletto E, et al. Investigating Consumer Medicine Information (CMI) Report. CMI Effectiveness Tender. 2010. http://www.guild.org.au/sites/The_Guild/tab-Pharmacy_Services_and_Programs/Research_and_Development/Fourth%20Agreement/Investigating%20Consumer%20Medicine%20Information%20(I-CMI)%20Project.page.

28. Koo MM, Krass I, Aslani P. Evaluation of written medicine information: validation of the Consumer Information Rating Form. *Ann Pharmacother.* Jun 2007;41(6):951-956.

29. Hosmer DK, Lemeshow S. *Applied Logisitic Regression.* 2nd ed. New York: Wiley-Interscience; 2000.

30. Australian Bureau of Statistics. Population by Age and Sex, Australian States and Territories, June 2008. Accessed from:

http://www.abs.gov.au/AUSSTATS/abs@.nsf/allprimarymainfeatures/2DB211BA9B6E1A25CA2576860017C2F8?opendocument. 2008.

31. Australian Bureau of Statistics. Education and Work, Australia May 2008. Accessed from: http://www.ausstats.abs.gov.au/ausstats/subscriber.nsf/0/656CB57FE56C0491CA25750C000EF65B/$File/62270_may%202008.pdf. 2008.

32. Pharmaceutical Health and Rational use of Medicines Committee (PHARM) and Australian Pharmaceutical Advisory Council (APAC). Quality Use of Medicines: a decade of research, development and service activity 1991-2001. In: Department of Health and Aged Care, ed. Canberra2001.

33. Myers ED, Calvert EJ. Information, compliance and side-effects: a study of patients on antidepressant medication. *Br J Clin Pharmacol*. Jan 1984;17(1):21-25.

34. Raynor DK, Blenkinsopp A, Knapp P, et al. A systematic review of quantitative and qualitative research on the role and effectiveness of written information available to patients about individual medicines. *Health Technol Assess*. Feb 2007;11(5):iii, 1-160.

35. Livingstone CR, Pugh ALG, Winn S, Williamson VK. Developing community pharmacy services wanted by local people:information and advice about prescription medicines. *Int J Pharm Pract*. 1996;4:94-102.

36. Machuca M, Espejo J, Gutierrez L, Machuca MP, Herrera J. The effect of written information provided by pharmacists on compliance with antibiotic therapy. *Ars Pharmaceutica*. 2003;44(2):141-157.

37. Schmitt MR, Miller MJ, Harrison DL, et al. Communicating non-steroidal anti-inflammatory drug risks: verbal counseling, written medicine information, and patients' risk awareness. *Patient Educ Couns*. Jun 2011;83(3):391-397.

38. Nathan JP, Zerilli T, Cicero LA, Rosenberg JM. Patients' use and perception of medication information leaflets. *Ann Pharmacother*. May 2007;41(5):777-782.

39. Moorthi C, Saravanakumar RT, Senthil Kumar C, Manavalan R, Kathiresan K. Systematic assessment of the quality of patient information leaflets supplied by the pharmaceutical manufacturers. *Pharmacie Globale.* 2012;3(2):1-3.

40. Raynor DK, Knapp P. Do patients see, read and retain the new mandatory medicines information leaflets? *Pharm J.* 2000;264:268-270.

41. Dickinson R, Hamrosi K, Knapp P, et al. Suits you? A qualitative study exploring preferences regarding the tailoring of consumer medicines information. *Int J Pharm Pract.* Nov 13 2012.

42. Hamrosi K, Dickinson R, Knapp P, et al. It's for your benefit: exploring patients' opinions about the inclusion of textual and numerical benefit information in medicine leaflets. *Int J Pharm Pract.* Nov 9 2012.

43. Raynor DK, Savage I, Knapp P, Henley J. We are the experts: people with asthma talk about their medicine information needs. *Patient Educ Couns.* May 2004;53(2):167-174.

44. Morris LA, Halperin JA. Effects of written drug information on patient knowledge and compliance: a literature review. *Am J Public Health.* Jan 1979;69(1):47-52.

45. Pharmaceutical Society of Australia. Guidelines for Pharmacists on Providing Medicines Information to Patients. *Pharmacy Practice Handbook*: PSA; 2000.

46. Vander Stichele RH, De Potter B, Vyncke P, Bogaert MG. Attitude of Physicians toward patient package insers for medication information in Belgium. *Patient Educ Couns.* 1996;28:5-13.

47. Bandesha G, D.K. R, Teale C. Preliminary investigation of patient infromation leaflets as package inserts. *Int J Pharm Pract.* 1996;4:246-248.

48. Rollins BL, Sullivan DL. Evaluating consumer understanding of two patient instructions for use inserts provided by manufacturers. *Drug Inf Jnl.* 2005;39(1):43-51.

49. U.S. Food and Drug Administration. Development and Distribution of Patient Medication Information for Prescription Drugs; Public Hearing,. 2010; http://www.fda.gov/drugs/newsevents/ucm219716.htm,. Accessed 09/07/2013.

Table(s)

Table 1. Reported sources where consumers may access CMI

Reported Source of CMI	Consumer n=1000 (%)	Pharmacist n=349 (%)	GP n=181 (%)
Pharmacist / Community Pharmacy	881 (88)	348 (100)	172 (96)
Inside the medicine box	857 (86)	280 (80)	164 (91)
Doctor	695 (70)	138 (40)	140 (78)
Internet	517 (52)	239 (69)	131 (73)
Pharmaceutical Company Website	492 (49)	203 (58)	116 (64)
Hospital Pharmacy	Not reported	196 (56)	118 (66)
Other	33 (3)	11 (3)	7 (4)

NB: Responses are not mutually exclusive

Table 2. Sections of the CMI read by consumers (Column 2); or discussed by pharmacists (Column 3) or GPs (Column 4) with consumers

Section of the CMI	Consumer n=457(%)	Pharmacist n=349 (%)	GP n=181 (%)
Side effects	442 (97)	325 (93)	137 (76)
What the medicine is for	442 (97)	290 (83)	108 (60)
Before starting the medicine	426 (93)	171 (49)	77(43)
How to take the medicine	426 (93)	291 (83)	107 (59)
How to store the medicine	399 (87)	131 (38)	35 (19)
Drug-drug interactions	391 (86)	178 (51)	81 (45)
List of contents of the leaflet	362 (79)	132(38)	25 (14)
What the ingredients are	281 (62)	43 (12)	19 (11)
How to dispose of leftover medicine	274 (60)	33 (10)	4 (2)
Manufacturer contact details	215 (47)	3 (1)	3 (2)

NB: Responses are not mutually exclusive

Table 3. Logistic regression predicting likelihood of (a) consumers reading CMI or (b) GPs providing CMI

Independent Variables		Regression Coefficient (B)	Wald (z-test)	p	Odds ratio	95% C.I.	
						Lower	Upper
(a) CONSUMERS READING CMI							
Type of CMI Received	Package Insert – not received, received (ind)	0.55	0.03	0.876	1.06	0.53	2.11
	Computer generated CMI – not received, received (ind)	0.23	0.38	0.537	1.26	0.61	2.62
	Computer generated medicine information (not CMI) – not received, received (ind)	1.37	4.56	0.033	3.94	1.12	13.84

	Loose leaflets – not received, received (ind)	0.50	1.91	0.167	1.64	0.81	3.32
Provider	Not provided, Package insert provided (ind)	-0.95	5.69	0.017	0.39	0.18	0.85
Frequency	New medicine – not provided, provided (ind)	0.37	3.58	0.058	1.45	0.99	2.14
	Repeat medicine – not provided, provided (ind)	-0.57	8.38	0.004	0.57	0.39	0.83
Gender	Male/Female (ind)	0.76	14.72	0.000	2.14	1.45	3.15
Occupation	Retired/white-collar (ind)	-0.42	4.01	0.045	0.66	0.44	0.99
	Retired/blue-collar (ind)	-0.59	3.95	0.047	0.55	0.31	0.99
	Retired/homemaker (ind)	0.35	0.72	0.396	1.41	0.64	3.14
N		648					
Model χ^2 test		χ^2=125.61, df=11, p<.001					
Hosmer & Lemeshow test		χ^2=6.97, df=8, p=.540					
Nagelkerke R^2		0.25					
(b) GENERAL PRACTITIONERS PROVIDING CMI							
Type of CMI Provided	Package Insert in sample box– not provided, provided (ind)	1.45	5.79	0.016	4.24	1.31	13.79
	Computer generated CMI – not provided, provided (ind)	3.43	24.05	0.000	31.00	7.86	122.32
	Loose leaflets – not provided, provided (ind)	1.32	3.32	0.068	3.74	0.91	15.42
Source where Patients Access CMI	Other, Hospital pharmacist (ind)	-0.56	0.93	0.335	0.57	0.18	1.78
	Other, doctor (ind)	2.07	9.81	0.002	7.93	2.17	28.96
GP access to CMI	Prescribing software – not used, used (ind)	1.98	11.07	0.001	7.27	2.26	23.41
	MIMS – not used, used (ind)	0.80	1.70	0.192	2.23	0.67	7.40
	Pharmaceutical Website – not used, used (ind)	2.22	5.09	0.024	9.18	1.34	63.16
Gender	Male/Female (ind)	0.84	2.07	0.150	2.32	0.74	7.31
N		179					
Model χ^2 test		χ^2=127.83, df=9, p<.001					
Hosmer & Lemeshow test		χ^2=4.830, df=8, p=.776					
Nagelkerke R^2		0.72					

ind = indicator category

Table 4. Comparison of pharmacist and GP reasons for providing and NOT providing CMI

What are your reasons for providing a CMI?	Pharm n=349 (%)*	GP n=181 (%)*	Statistics	What are your reasons for NOT providing a CMI?	Pharm n=349 (%)*	GP n=181 (%)*	Statistics
Patient requests a CMI	320 (92)	111 (61)	χ^2=72.34 p<.001	Patient has taken the medicine previously	281 (81)	126 (70)	χ^2=7.95 p=0.005
Duty of care to inform the patient about their medicine	313 (90)	79 (44)	χ^2=131.18 p<.001	Patient has difficulty understanding or reading the content of CMI	169 (48)	65 (36)	χ^2=7.57 p=0.006
Patient has a right to information about the medicine	278 (80)	74 (41)	χ^2=80.33 p<.001	Concern the patient will not take the medicine	127 (36)	40 (22)	χ^2=11.28 p=0.001
Provide information for the carer/parent	262 (75)	75 (41)	χ^2=58.23 p<.001	Medicine used for a purpose other than indicated	109 (31)	7 (4)	χ^2=52.20 p<0.001
Assist patient to make an informed choice to aid adherence	260 (75)	84 (46)	χ^2=41.29 p<.001	Medicine for short term treatment (<2 weeks)	81 (23)	41 (23)	χ^2=.02 p=0.885
Reinforce the benefits and how to take the medicine	257 (74)	72 (40)	χ^2=58.04 p<.001	Patient receives sufficient spoken information from me	59 (17)	61 (34)	χ^2=19.20 p<0.001
Check that I did not forget to verbally provide any information	204 (59)	62 (34)	χ^2=27.92 p<.001	The CMI is not useful to the patient	33 (10)	19 (11)	χ^2=.15 p=0.702
Patient had a previous bad experience	93 (27)	41 (23)	χ^2=1.01 p=.316	Other^	32 (9)	19 (11)	χ^2=.24 p=0.623
Other#	12 (3)	8 (4)	χ^2=.32 p<.574	Insufficient time to spend with the patient	29 (8)	71 (39)	χ^2=74.42 p<0.001
				The patient receives CMI from the pharmacist[c] or the doctor will provide CMI[d]	15 (4)	100 (55)	χ^2=182.11 p<0.001

* Responses are not mutually exclusive

#Other: reinforce instructions [a,b], encourage patient responsibility[a,b], highlight side effects[a,b] medicine has narrow therapeutic indices[b] or serious side effect[b], check contraindications[b] (a=GP, b=Pharmacist responses)

^Other: patient anxiety[a], CMI in medicine box[a], CMI usability[a], patient CMI access via internet[a], patient refusal[b], non-provision requests by carer/doctor[b], inducing fear of side effects[b], CMI confusing[b] (a=GP, b=Pharmacist responses)

c. GP survey statement

d. Pharmacist survey statement

Table 5. Median scores of pharmacist and GP use of CMI with verbal counseling

How do you currently use a CMI with your patients?		None/Some of the time n(%)	Most/All of the time n(%)	Median Score #	IQR
Provide CMI only, with no verbal counseling	Pharmacist	303 (97)	8 (3)	1	1-2
	GP	111 (98)	2 (2)	1	1-1
Discuss the entire CMI	Pharmacist	303 (96)	11 (4)	1	1-2
	GP	111 (96)	4 (4)	1	1-1
Provide CMI, ask the patient to read and return if	Pharmacist	204 (64)	114 (36)	2	2-3
have any questions	GP	87 (65)	46 (35)	2	1.5-3
Verbally discuss sections of CMI I feel are	Pharmacist	63 (19)	269 (81)	3	3-4
important	GP	58 (42)	79 (58)	3	2-3
Draw attention to specific sections of CMI with	Pharmacist	56 (17)	281 (83)	3	3-4
some verbal counseling	GP	66 (49)	70 (52)	3	2-3

#Score: 1=None of the time, 2= Some of the time, 3= Most of the time, 4= All of the time

IQR = Interquartile Range