The development and evaluation of written medicines information for Type 2 diabetes

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Abstract

Written Medicines Information (WMI) is regarded as a key component in diabetes consumer education. In Australia, there is a paucity of WMI that specifically tailors to the extensive array of medicines used for the lifelong management of Type 2 diabetes. This research project aimed to employ a novel framework, the ‘Consumer Involvement Cycle’, to investigate consumer perspectives and needs of medicines information for Type 2 diabetes and develop appropriate WMI for the Type 2 diabetes population. The Consumer Involvement Cycle involved people with Type 2 diabetes and health professionals (HPs) working in partnership to design a series of WMI, incorporating a range of consumer-conceived ideas and concepts with professional evaluation from an expert panel of reviewing HPs. A total of 12 leaflets were developed. The Flesch-Kincaid Grade Level Score for the leaflets was approximately 8.0, which is considered to be ‘fairly easy’, in other words easily understood by a large proportion of the general public. The Consumer Involvement Cycle was validated as a useful framework in developing and evaluating appropriate consumer information. Consumer perspectives should be sought and well incorporated throughout the process of designing and assessing educational materials intended for consumer use.

Introduction

Written Medicines Information (WMI) is ideally unbiased, evidence-based, critically evaluated and aims to inform consumers about their medications. WMI has been widely regarded as essential to consumer education, facilitating consumer empowerment and self-care [1–7]. Provision of adequate, appropriate and effective WMI empowers consumers to make informed decisions in medicine-taking and work in partnership with health professionals (HPs) in regimen management. This consumer-centred approach is the key concept in concordance. Successful consumer education is of particular significance in chronic conditions like Type 2 diabetes where self-management has a key role in clinical outcomes. Consumers with Type 2 diabetes are often required to undertake various tasks in their daily self-management of the condition. These self-care behaviours include dietary modification, regular physical activity, self-monitoring of blood glucose levels, maintaining watchfulness for hypoglycaemia, appropriate foot care and taking an extensive array of prescribed medicines. Therefore, consumers with Type 2 diabetes need sound knowledge and effective skills in order to become competent self-carers of their condition. Diabetes education aims to educate consumers of the disease state, the treatment modalities and the technical self-management skills necessary to attain adequate disease control while maintaining quality of life. It
also aims to empower consumers with positive attitudes and motivation in an effort for them to become active participants in their diabetes care.

Since 1993 in Australia, legislation requires all new medicines to be accompanied by a package leaflet, the Consumer Medicine Information (CMI). CMI is produced by pharmaceutical manufacturers according to set regulations in an effort to inform consumers about their prescription-only and pharmacist-only medications. While huge resources have been dedicated to the development of CMI, including a consumer testing process, there are, however, limitations associated with its use. One limitation is brand specificity, i.e. CMI is not unique for any one generic drug. This is a potential source of confusion for consumers prescribed different brands of essentially the same drug. Moreover, CMI does not include any explanations regarding the complex multiple-drug regimens characteristic of the pharmacological management of Type 2 diabetes. Consumers with this condition are frequently prescribed anti-hypertensives, lipid-lowering medications and aspirin in addition to the standard anti-diabetic agents. The therapeutic significance of each medicine in the long-term management of diabetes and other cardiovascular risk factors is not emphasized in CMI. To date, CMI is the most prevalent form of WMI available to consumers with Type 2 diabetes in Australia.

There is, however, a need for more tailored, high-quality WMI for consumers. Moreover, to ensure that the information produced clearly communicates key messages and addresses their issues, consumers must be involved in their production [8, 9]. A useful framework for the development of such material is the Consumer Involvement Cycle, which illustrates how consumers and HPs can work in partnership to develop WMI that will better meet the information needs of consumers (Fig. 1) [9].

Thus, the overall aim of this project was to employ the Consumer Involvement Cycle in an effort to develop appropriate and consumer friendly WMI for Type 2 diabetes. The specific objectives of this study were 4-fold: (i) to explore consumers’ experiences with medicines information, (ii) to investigate consumer perspectives on the utility of WMI in diabetes consumer education, (iii) to identify consumers’ specific and unmet WMI needs regarding medications used in the management of Type 2 diabetes and associated conditions and complications and (iv) to develop appropriate WMI for Type 2 diabetes based on the acquired information.

**Methods**

The study used qualitative methods for the in-depth exploration of its objectives. Semi-structured interviews were conducted. Ethical approval to conduct the study was granted by the Human Research Ethics Committee, University of Sydney, Australia.

**Recruitment**

A convenience sample of people with Type 2 diabetes was recruited from five community pharmacies located in the North, East and South-East of Sydney, Australia. Inclusion criteria were as follows: age ≥18 years, a diagnosis of Type 2 diabetes, taking at least one oral medication for diabetes or associated conditions and complications and adequate language and comprehension skills in English. Eligible participants were invited by community pharmacists to participate in the study.
Interviews
Twenty-four in-depth, semi-structured face-to-face interviews of people with Type 2 diabetes were conducted in Sydney, 2003. Three carers (partners of the participants) volunteered to co-participate. All interviews were audio-taped, with permission from the participants, and subsequently transcribed verbatim. To ensure consistency, the same interviewer (DYL) conducted all interviews and the interview topics were guided by the interview protocol, which was used to ensure that the range of domains in the study objectives was explored by all participants in the course of the interviews.

Data analysis
Data were entered into the NVivo software and subjected to thematic content analysis to identify emergent themes. The themes and categories thus revealed were discussed and agreed upon by members of the project team. The data collection was terminated upon data saturation.

Application of the Consumer Involvement Cycle
The Consumer Involvement Cycle was consistently applied throughout this study to engage consumers and HPs working in partnership to produce a series of appropriate, consumer-friendly and diabetes-specific WMI leaflets [9]. The three key principles for high-quality consumer information are (i) accuracy—the provision of up-to-date information with sources of evidence explicitly stated, (ii) clarity—the unambiguous communication of information and (iii) relevancy—the use of practical information from which consumers will benefit [9]. The initial WMI drafts were developed based upon the principles of the framework and key findings from the interviews. The content and presentation of the draft WMI incorporated a range of consumer ideas and perspectives that emerged from the qualitative data and were subject to professional evaluation from an expert panel of reviewing HPs with experience in diabetes education and consumer information development. The WMI documents were checked for readability using the Flesch-Kincaid Grade Level Score which measures text difficulty by reference to word and sentence length and rates based upon school grade levels [10]. The revised WMI were exposed to comprehensive pilot testing by the participants and the expert panel to appraise the readability and review the content and visual presentation. Amendments were made to the WMI leaflets in response to the participant and HP feedback, followed by readability testing using the Flesch-Kincaid Grade Level Score [10]. This cycle of consumer involvement was repeated throughout the process of developing and evaluating WMI, as shown by Steps 1–9 in Fig. 1, to ensure that consumer perspectives were well incorporated. The WMI leaflets were designed to be stored on a disk and printed on A4 size paper that could then be photocopied, as this is a relatively economical and convenient method in producing, updating and disseminating WMI.

Results
Sample
Of the 24 participants in this study, 18 were male and most were Caucasian (n = 22), with a mean age of 63 years (range 44–79). Most participants (n = 21) had attained at least the level of secondary education. Respondents were taking an average of four diabetes-related medications (range 1–11) per participant to control diabetes and related comorbidities. Taking into account over-the-counter medications and prescriptions for other medical conditions, participants were taking an overall mean of six (range 1–13) different medications per day.

Three main themes emerged from the interviews, pertaining to knowledge of diabetes and prescribed medicines, experiences with medicines information and consumer-specific WMI needs.

Knowledge of diabetes and prescribed medicines
Knowledge of diabetes
The majority of respondents described a superficial level of knowledge of Type 2 diabetes as a
condition. While many could relate possible causes of Type 2 diabetes to hereditary and lifestyle factors such as lack of exercise and an unhealthy diet, their understanding of diabetic complications was generally poor and frequently misconceived. With reference to the theme of ‘knowledge regarding diabetic complications’, the excerpts below illustrate such knowledge gaps:

...only the infection, I don’t know what else [complications] it [diabetes] can cause. (R1)

It [complication] normally comes once you’re on the needle [insulin injections], I don’t think there is any cause of complications if you remain to be on the pills.” (R3)

The majority had limited awareness of the inter-relationship between the management of Type 2 diabetes, hypertension, dyslipidaemia and cardiovascular diseases:

...while there’s a relationship (between high blood pressure, high lipid levels and diabetes) it’s not a clear relationship that I see between them. I don’t see a clear link… (R22)

**Knowledge of prescribed medicines**

The level of understanding of prescribed medicines was generally poor. For the majority, all that they knew about their medicines were the respective brand names, dose, frequency and timing of administration and administration in relation to meals. Several respondents were even unable to name their medicines, identifying them only via visual inspection of the packaging, and/or the colour and size of the tablets:

I don’t go by the name, I go by the tablet. I know which is which… (R13)

Many respondents admitted an inability to remember the names of all their medicines because ‘there are so many of them’ (R20). Few were able to distinguish the purpose of their medicines, and among those who did, many were confused about the indications. With one exception, none of the respondents could describe how their medicines work to achieve diabetes control.

**Experiences with medicines information**

**Experiences with medicines information from HPs**

Medicines information was primarily imparted by HPs. The majority of respondents assumed a passive role, because, as one respondent simply said: ‘He [GP] is the one who is supposed to know (about medicines)’ (R12). It was noted that many respondents had unquestioning trust in doctors and considered the provision of the necessary information to be the responsibilities of HPs. There appeared to be an imbalance in information exchange between information providers and recipients:

...other than telling you what they’re [medications] for, I don’t know what she’d [doctor] tell you… I suppose she would (tell me more about the medicines) if she felt it was necessary. (R1)

Respondents regarded general practitioners and community pharmacists as the primary and secondary providers of medicines information, respectively. In general, respondents reported having received only minimal verbal information about medicines from their doctors and pharmacists. Few respondents reported the receipt of any WMI from HPs. Among those who had ever received medicines information from HPs, inadequate information was a common complaint. The majority were dissatisfied with the relative superficiality of the information provided by HPs. These respondents felt that they were left alone to gather necessary information on their own:

...I came home and looked it up on the internet … and sorted it out for myself, which means I’m probably doing everything wrong… (R19)

Information provision by HPs was viewed as having both positive and negative elements. Respondents
perceived doctors and pharmacists too time constrained to supply adequate medicines information:

If you go to the pharmacist, they don’t offer you any information, really ... And the GPs to a certain extent too ... They’ve got 15 minutes to see you ... that’s it. (R15)

However, several respondents recalled isolated positive experiences when obtaining medicines information from their HPs. Respondent perceptions of HPs as knowledgeable and supportive in response to their requests for information were important contributing factors towards their inclination to seek such information:

My chemist ... he was just wonderful. He sort of tucked me under his wing and said ‘Come with me and we will help you’. He photocopied sheets and sheets of information and paper, articles for me... (R19)

Experiences with medicines information from alternative sources

Although many respondents were dissatisfied with the quality and quantity of information they had received from HPs, few reported actively seeking additional information about their medicines. For the minority who had sought medicines information, a variety of professional and lay sources were used. The few respondents who had sought information stated that CMI in the form of package leaflets were the primary alternative source of information about their prescribed medicines other than HPs, with Diabetes Australia (DA) being the secondary alternative source of information. While a minority of those respondents had also used the Internet and reference books to search for medicines information, few of them regarded such resources as vital alternative sources of information.

The majority of respondents were aware of the availability of CMI as package leaflets, although most claimed to have never ‘bothered’ (R23) to study the information. Several respondents were not even aware of CMI package leaflets, despite taking the prescribed medicines for an extended period of time. Many participants voiced strong criticism of CMI package leaflets. The major issues limiting their usefulness related to the readability, legibility, length, design and appropriateness of the content. Respondents criticized the language used in CMI package leaflets as difficult to understand and too technical:

Too complicated ... the words they use, the actual way the documents are written ... people would tend to look at it and say ‘I don’t understand this!’ ... And it’s no point giving them the information if they’re not going to read it. (R16)

The key flaws of CMI package leaflets identified included small font size, extensiveness and bland design:

...Too much to read ... and a lot of it really doesn’t mean anything to me ... There’s apparently pages and pages of micro-writing ... you need magnifying glasses. Nobody’s going to sit down and read all that. (R11)

There were remarks indicating that the information regarding adverse effects of medications in CMI package leaflets could be frightening to the general population, hence leading to poor compliance:

They’d be scared to take it. They don’t understand that it might only happen once every hundred thousand people because they’d always think: ‘I might be that one person’. (R15)

DA’s information was considered as a secondary alternative source of medicines information by many respondents. However, its general usefulness in providing information about diabetes medicines was perceived as minimal:

I feel a lot of that stuff is not really relevant to someone like me who is really a mild diabetic ... they mainly talk about people on insulin and people who got really bad side effects... (R15)
Consumer-specific WMI needs

Ideal design characteristics of WMI

In general, respondents favoured the use of WMI in Type 2 diabetes. The preferred mode for receiving medicines information was verbal advice given by doctors supplemented with WMI. Respondents perceived doctors’ clinics, community pharmacies and DA as the most appropriate places for obtaining WMI. The majority voiced the need for better-designed WMI that was ‘easy to read’ (R5), in a shorter and more easily understood format, incorporating simple language, enlarged font size and short texts.

There were suggestions for the inclusion of elements of humour (e.g. jokes) and an attractive visual presentation (e.g. colours, pictures, diagrams) to enhance the appeal of WMI. Several respondents advocated highlighting important information in text boxes with different shading of colours, to prevent overlooking. The use of bullet points as a means of simplifying information was also suggested to facilitate rapid search for specific information. Individualized tailoring of the information was also identified as a desired characteristic of ideal WMI. WMI that focused on only one class of medications was deemed more relevant to the individual consumers:

…it’s more appropriate to have a card for each class of drugs and just give the person the one that’s relevant to them rather than give them 4 pieces of paper where only maybe half a page that’s actually relevant to that particular person… (R15)

Desired content of WMI

The following were expressed by respondents as important specific information for their medicines: chemical and brand names, purpose, how the medicine works, dose, how and when to take the medicine, when to take it in relation to food/meals, instructions on what to do if a dose was missed, drug interactions, circumstances where the medicine cannot be used, tests needed prior to treatment and potential adverse effects.

Respondents required WMI with clear explanations on chemical/generic and brand names of medicines. It was noted that the differences between the chemical and brand names of medicines were a cause for great confusion in many respondents:

A lot of people don’t understand this thing that there is a chemical name and there is a brand name as well … (R15)

An appeal for more information about the adverse effects of treatment was a strong theme that emerged from the data:

I sincerely believe that anyone who’s taking medication … should be issued with such information so they can appreciate the importance of the medicine they take. At the same time nothing is hidden in regards to that medicine, if you know what I mean—side effects… (R18)

A greater emphasis on the benefits of adherence to treatment, as opposed to the detriments of non-compliance, was another significant issue. Respondents preferred incorporating greater advocacy of such benefits in order to obtain an evenly balanced view of their prescribed medicines. This positive reinforcement was perceived as a motivating factor for improving diabetes self-care and treatment compliance:

Instead of highlighting what can go wrong because you take the medicine, it should highlight just as much what is right about taking the medicine. The reason why you’re taking the medicine. (R15)

Development and evaluation of WMI

A total of 12 WMI leaflets were developed in this study based on the findings from the qualitative study and the key principles of the Consumer Involvement Cycle (Table I). Samples of the existing written patient materials in relation to Type 2 diabetes and its pharmacotherapy were examined, including those produced by the following credible Australian national organizations: (i) the DA (http://
The CMI documents on medications commonly prescribed for Type 2 diabetes and its associated conditions were also reviewed. An appraisal was performed on the abovementioned written patient educational documents in terms of their readability, content and visual presentation. Draft versions of the WMI documents were written on the basis of the existing evidence and the key findings from this qualitative study. The draft WMI incorporated a range of consumer-conceived perspectives and ideas in terms of the design and content of the information. The pilot WMI materials were checked for readability using the Flesch–Kincaid Grade Level Score and then evaluated by the expert panel of reviewing HPs for content and presentation.

The information in this series of WMI was presented in such a way as to promote easy understanding and referencing. Thus, simple language, avoidance of jargon, enlarged print and comprehensible layout were the major considerations put forward by respondents. Since the majority of respondents expressed an inclination for ‘easy-to-read’ materials, a conversational style of language was used in the WMI. In addition, the expert panel advised that information be constructed as gentle advice rather than orders and readers were addressed simply as ‘you’. Absolute statements such as ‘you will experience …’ were also avoided and statements such as ‘you may experience …’ were used instead as recommended. Jargon, technical terminology and abbreviations that were deemed incomprehensible were avoided. Medical terminologies that new diabetes consumers and/or carers might be unfamiliar with were clearly explained.

The content of the WMI included a range of consumer ideas and perspectives to ensure that the information was highly relevant to the target audience. Figure 2 demonstrates a prototype of the WMI leaflets. Repetition was used judiciously in order to reinforce the most important parts of the information. Other references and website links that offer further information about the medications were provided for consumers who desired to learn more about their treatment (Fig. 3). Importantly, the dates of information update or revision were also displayed at the end of the documents.

Improved legibility was another feature identified by respondents as lacking in existing WMI and is of particular significance in this consumer population. Many people with Type 2 diabetes have visual impairments and require intelligible written information. Clearly defined headings, a minimum of 12-point font, Times New Roman text font and dark type on a pale background were hence adopted throughout the WMI leaflets. Paragraphs were made short, conveying one idea or theme at a time.

### Table I. Summary of the 12 developed WMI leaflets

<table>
<thead>
<tr>
<th>Leaflet no.</th>
<th>Title of WMI leaflet</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leaflet 1</td>
<td>‘Medicines for Type 2 Diabetes’</td>
</tr>
<tr>
<td>Leaflet 2</td>
<td>‘Insulin for Type 2 Diabetes’</td>
</tr>
<tr>
<td>Leaflet 3</td>
<td>‘Blood Sugar-Lowering Tablets for Type 2 Diabetes—Sulphonylureas &amp; Meglitinides’</td>
</tr>
<tr>
<td>Leaflet 4</td>
<td>‘Blood Pressure Tablets for Type 2 Diabetes—ACE Inhibitors’</td>
</tr>
<tr>
<td>Leaflet 5</td>
<td>‘Blood Fat-Lowering Tablets for Type 2 Diabetes—Statins &amp; Fibrates’</td>
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<tr>
<td>Leaflet 6</td>
<td>‘Aspirin Tablets for Type 2 Diabetes’</td>
</tr>
<tr>
<td>Leaflet 7</td>
<td>‘Blood Pressure Tablets for Type 2 Diabetes—Calcium Channel Blockers’</td>
</tr>
<tr>
<td>Leaflet 8</td>
<td>‘Blood Pressure Tablets for Type 2 Diabetes—Beta Blockers’</td>
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<tr>
<td>Leaflet 9</td>
<td>‘Blood Pressure Tablets for Type 2 Diabetes—Angiotensin II Receptor Antagonists’</td>
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<tr>
<td>Leaflet 10</td>
<td>‘Blood Sugar-Lowering Tablets for Type 2 Diabetes—Biguanides &amp; Glitazones’</td>
</tr>
<tr>
<td>Leaflet 11</td>
<td>‘Blood Sugar-Lowering Tablets for Type 2 Diabetes—Acarbose’</td>
</tr>
<tr>
<td>Leaflet 12</td>
<td>‘Further Information About Your Medicines’</td>
</tr>
</tbody>
</table>

Blood Pressure Tablets for Type 2 Diabetes

ACE Inhibitors

People with type 2 diabetes are at a greater risk of having high blood pressure (BP) than the general population. Good control of diabetes and BP will help lower your risk of diabetic complications such as:

- Stroke
- Heart attack
- Heart disease
- Kidney disease
- Eye disease
- Nerve damage (e.g. ulcers, loss of sensation)
- Impotence in men

In extreme cases, these complications can lead to blindness, kidney failure and amputation of legs, feet and toes. If you have high BP, your doctor may prescribe tablets to help reduce your BP in order to lower your risk of diabetic complications.

Tablets, healthy eating and regular physical activity are all important for the control of your diabetes. Taking tablets does not mean that you no longer need to eat the right foods or keep active.

High BP usually causes no symptoms and you cannot usually tell if your BP is too high by the way you feel. Therefore it is important to have regular BP checks by your doctor.

BP readings consist of two numbers. The upper, or systolic, number measures the pressure in the blood vessels when the heart contracts. The lower, or diastolic, number measures the pressure when the heart relaxes and fills with blood.

In general, the target BP for people with diabetes is below 130/80mmHg. However, your target BP depends on many personal factors such as your age and general health. Your doctor will discuss with you what target BP is most appropriate for you.

There are different types of BP tablets. Your doctor may use a tablet, or a combination of tablets to help you control your BP. This is because these tablets work differently and therefore work with each other in controlling your BP more effectively. No matter which tablets your doctor prescribes for you, make sure you take them as advised.

Fig. 2. Prototype of a WMI leaflet entitled ‘Blood Pressure Tablets for Type 2 Diabetes—ACE Inhibitors’.
Angiotensin-Converting Enzyme Inhibitors (ACE Inhibitors)

ACE inhibitors are a group of medicines that include:

- Captopril (Brand names: Accnorm, Capace, Capoten, Captohexal, DBL Captopril, SBPA Captopril, Enzace, Topace)
- Enalapril (Brand names: Renitec, Renitec M, Renitec Plus, Alphapril, Amprace, Auspril, Enahexal)
- Fosinopril (Brand names: Monopril, Monoplus)
- Lisinopril (Brand names: Prinivil, Zestril, Bibsoll, Lirprace, Lisinopril Hexal, Lisodur)
- Perindopril (Brand names: Coversyl, Coversyl Plus)
- Quinapril (Brand names: Accupril, Asig, Accuretic)
- Ramipril (Brand names: Ramace, Triticace)
- Trandolapril (Brand names: Gopten, Odrik)

Points to Remember

- ACE inhibitors lower BP by relaxing and widening the walls of blood vessels.
- Your doctor may use these tablets although your BP is normal. This is because people with diabetes are at an increased risk of kidney diseases. Taking these tablets may help protect your kidneys from diabetic kidney damage without abnormally lowering your BP.
- You may be prescribed these tablets for other reasons such as to help prevent or treat symptoms of heart failure.
- These tablets are not a ‘cure’ for high BP. Once your target BP is achieved, you still need to take these tablets to maintain effective BP control. Most people need to take these tablets for life.

Possible side effects include:

- Dizziness
- Nausea
- Headache
- Dry cough

Rare side effects include:

- Skin rash
- Angioedema

Angioedema is a rare but serious side effect where swelling occurs in different parts of the body, e.g., face, eyes, lips, tongue, mouth, and throat. This can make swallowing and breathing very difficult. If you think you may have developed angioedema, you should immediately see a doctor.
- Move slowly when getting out of bed or standing up, because doing so quickly may make you feel faint, dizzy, or light-headed.

Talk to your doctor, pharmacist or credentialled diabetes educator if you think you are experiencing any side effect from your tablets.

Fig. 2. (Continued).
and lines were spaced adequately. Bullet points and short words and sentences were employed in an effort to aid understanding and retention of information. Participants additionally proposed the use of boldface type and highlighting important points in text boxes as a means to emphasize key messages and directing focus.

The draft versions of the WMI were mailed to participants for consumer appraisal. Participants were subsequently contacted by telephone to obtain their feedback, seeking their views on the design and overall comprehensibility of the WMI leaflets. For example, participants were asked to report on terminology or concepts considered difficult to grasp and whether the information satisfied individual requirements. Amendments were made to the WMI in response to the feedback received from consumers and the expert panel in an effort to ensure a high readability and well-balanced information on risks versus benefits of treatment. Terms perceived by consumers as too technical were reworded. For example, ‘blood glucose’ and ‘lipids’ were replaced by ‘blood sugar’ and ‘blood fats’, respectively. Words written in capital letters were removed as they were thought to be distracting by consumers when reading. The final versions of the WMI were checked again for readability using the Flesch-Kincaid Grade Level Score. The readability score of the final WMI was approximately 8.0, which means that an eighth grader with an average age of 13 years old can easily read and understand the documents. A readability score of approximately 7.0–8.0 is recommended for most documents for easy reading [10].

**Discussion**

This is the first study that has demonstrated the utility of the Consumer Involvement Cycle in assisting researchers and HPs in the development of appropriate and consumer friendly written materials to better meet the information needs of people with Type 2 diabetes.

To initiate this process, we conducted the first qualitative study that has intensively explored the experiences, opinions and perspectives of people with Type 2 diabetes in relation to WMI in a community-care environment. Overall, current WMI was considered to be inadequate both with respect to content and design. As has been previously reported in the literature, our respondents were especially concerned about receiving adequate information on the risks associated with their medicines [5, 11–16]. In addition, respondents in the present study urged for greater emphasis to be placed on the potential benefits of medication adherence, rather than repeated warnings against non-compliance. Participants advocated the importance of integrating benefit information within WMI in facilitating consumers and carers to obtain a better balanced benefit-risk perception of prescribed medicines, which was suggested by respondents as a potential motivating factor for treatment compliance and improving diabetes self-care.

Additional significant issues emerged from this study. Firstly, the level of existing knowledge of Type 2 diabetes as a condition and its associated complications was, at best, superficial in the majority of the respondents. Knowledge with regards to medicines was also poor and mostly limited to commercial names and the appearance of medications. The international literature has consistently revealed knowledge deficits about Type 2 diabetes and its specific management in this consumer population [17–19]. Nevertheless, none of those studies specifically investigated knowledge of medications commonly used in managing this condition and its associated comorbidities. This is the first research that has closely examined the knowledge level of medicines commonly used to treat hyperglycaemia, hypertension and dyslipidaemia in a community-based Type 2 diabetes sample. The participants in the present study demonstrated poor understanding of these different classes of medications. The relationship between controlling blood glucose levels, lipid profiles and blood pressure in the context of diabetes is unclear to the vast majority of respondents. It is essential to educate diabetes consumers about the roles and importance of taking their standard anti-diabetic tablets as well as anti-hypertensives, lipid-lowering medications and aspirin tablets.
Nevertheless, these specific educational objectives are currently not being achieved by CMI, the most prevalent form of WMI for people with Type 2 diabetes in Australia.

The findings of the initial qualitative study reinforced the urgent need and informed the development of a series of well-designed, consumer friendly and diabetes-specific WMI to bridge this significant knowledge gap and satisfy other consumer requirements with respect to design characteristics and use of lay language. These WMI leaflets may also serve as educational tools to assist

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**Further Information About Your Medicines**

- For more information about your tablets, you should talk to your doctor, pharmacist, or credentialed diabetes educator.

- It is also useful to read the leaflet (i.e. Consumer Medicine Information, or CMI) that comes with the medicine in its packaging for details about your medicine (e.g. full list of precautions and possible side effects). Not all medicines come with CMI. Ask your pharmacist or doctor for a copy of CMI if you do not already have one.

- You can go to the following websites for more information about diabetes and medicines:

- You can access these websites from the computers at your local library, if you do not have internet access at home. The library is also a good source of information on diabetes. Ask the librarians for books with information on diabetes.

- You may consider becoming a member of Diabetes Australia (DA). DA produces information leaflets on all topics related to diabetes that they mail to their members on a regular basis. They have many branches throughout the country. For information about the DA branch in your state/territory, go to the DA website or call the DA Help Line on 1300 136 588.

**Diabetes Australia - NSW**

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Glebe NSW 2037  
GPO Box 9824 Sydney NSW 2001

Phone: (02) 9552 9900  
Fax: (02) 9660 3633  
Email: [info@diabetesnsw.com.au](mailto:info@diabetesnsw.com.au)  

**Fig. 3.** WMI leaflet entitled 'Further Information About Your Medicines'.
HPs in communicating more effectively with consumers about their prescribed regimens.

This study had several limitations. The first concerns the accuracy of consumer recall regarding the receipt of medicines information. It is well recognized that consumers only recall or comprehend parts of the information that they have been given [3, 12, 13, 17, 20]. It should also be noted that respondents might have been given more information by HPs than they reported when questioned during the interviews. The second concerns the range of opinions which pertained to older consumers with Type 2 diabetes. With the increasing prevalence of Type 2 diabetes among younger consumers, it will be important to canvas their perspectives in future studies. Furthermore, the consumer sample in this qualitative study consisted predominantly of older male participants and may not represent the general Type 2 diabetes population in Australia. In particular, many of our participants had a high level of education. However, as is conventional with qualitative research, the main intention was to capture a range of opinions, ideas and perspectives within a target group to the point of data saturation to inform the development of the WMI. Any future qualitative studies would need to sample the population in a different way.

This study has demonstrated the feasibility of systematically involving a small sample of community-based Type 2 diabetes consumers in Australia in the design and evaluation of consumer friendly and diabetes-specific WMI in accordance to the Consumer Involvement Cycle. The application of this qualitative theoretical framework to other target groups, such as consumers from different cultural backgrounds with different medical conditions, remains to be explored in future research.

### Implications for HPs

The Consumer Involvement Cycle has been demonstrated to be a useful framework in the development and evaluation of written consumer information. The importance of consumer perspectives in the production of educational materials intended for consumer use was highlighted. The findings of this study also call for the delivery of more effective verbal and written communication of medicines information by HPs to facilitate the best use of medicines and thus better health outcomes.

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### Conflict of interest statement

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### References


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