Consumer opinions on the availability of a leaflet for an over-the-counter medicine

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SUMMARY

Introduction
Adequate information is needed to ensure consumers can use over-the-counter (OTC) medicines safely and appropriately. Globally, the availability and quality of written medicines information (WMI), including labels and leaflets, provided with OTC medicines is variable. Limited consumer-centred research has explored their opinions on such information. This study explored consumers' perspectives on the quality and availability of WMI provided with an exemplar Australian OTC product.

Materials and methods
A leaflet was developed for an Australian pholcodine-containing proprietary product (Benadryl® Dry, Tickly Cough) that did not have one, using good information design. The existing product label and study-developed leaflet were user tested with consumers (altogether n=20) in Australia and the United Kingdom (UK). Their perceptions about the quality and availability of the WMI were explored. Discussions were audio-recorded, transcribed verbatim, and thematically analysed.

Results
Overall, consumers liked the label and leaflet design. However, consumers voiced mixed opinions on the WMI content. Some thought the label had good overall information coverage, however others felt it lacked critical information and suggested inclusion of further key points, for instance additional warnings and safety information. Consumers were surprised that a leaflet was not available with this product and were receptive for one to be provided.

Conclusions
The perceived lack of critical information included on the existing label contributed to consumer acceptability and preference for leaflet availability. WMI supplied with an OTC medicine can be improved to ensure the inclusion of critical information to better meet consumers' needs.

Keywords
Written medicines information, leaflets, drug labelling, over-the-counter medicines, self-medication, consumers.

INTRODUCTION

Over-the-counter (OTC) medicines are widely used by consumers of all ages and varying health statuses. To ensure that consumers use OTC medicines safely and appropriately, written medicines information (WMI) must convey the necessary information using simple, understandable language, in a format that can be easily navigated. Furthermore, WMI has an important function in complementing spoken information provided by healthcare professionals (HCPs) such as pharmacists.

OTC WMI refers to the information included on the product label, which can be found on the product box and/or packaging, as well as the leaflet, which is often included inside the box; that is, provided as a package insert. Internationally, WMI availability for OTC medicines varies due to regulatory differences. In the United States for instance, legislative emphasis is placed on the OTC medicine label, where a standardised "Drug Facts" label format has been implemented for OTC medicines (Department of Health and Human Services Food and Drug Administration 1999). In the European Union (EU), leaflets provided as package inserts are required for all medicines (European Commission 2001). However, in Australia, leaflets known as Consumer Medicine Information (CMI) are only compulsory for prescription and Pharmacist Only OTC medicines (Aslani 2007). Pharmacist Only medicines are OTC medicines required to be supplied by a pharmacist (New South Wales Government c2016). Accordingly, WMI supplied with OTC medicines varies from the label alone (that is, the information found directly on the medicine box/packaging) to both a label and leaflet.

Prior research has shown that consumers have considered OTC label content as adequate (Trajanovska, Manias et al. 2010). However, room for improvement in OTC label usability has been reported in other consumer studies (Bolaños 2005, Bennin and Rother 2015). Overall, there is limited research on consumer perspectives about existing WMI for OTC medicines, and specifically, leaflets as an additional source of WMI for OTC medicines. Therefore, this study aimed to explore Australian and UK consumer perspectives on the quality of WMI provided with an exemplar Australian proprietary OTC product, and the availability of a leaflet for this medicine.

MATERIALS AND METHODS

This study was part of a larger international project which aimed to explore strategies to optimise WMI provided with OTC medicines (Tong 2016). This paper reports on the qualitative study component of individual, face-to-face user testing interview sessions, which consisted of quantitative WMI user testing followed by semi-structured, open-ended questions (Tong 2016). It focuses on consumers' perceptions of the quality of WMI provided with an exemplar OTC medicine, and leaflet availability. Ethics approval for the study was granted by the University of Sydney Human Research Ethics Committee (Australia) and the School of Healthcare Research Ethics Committee at the University of Leeds (UK).

STUDY MEDICINE CHOICE AND LEAFLET DEVELOPMENT

The antitussive pholcodine (proprietary product Benadryl® Dry, Tickly Cough, Johnson & Johnson Pacific (200mL), Australia) was chosen as the exemplar study OTC medicine as in Australia, pholcodine is a Pharmacy medicine (that is, an OTC medicine sold only in pharmacies), and thus, a CMI leaflet is not mandated with its supply. Furthermore, when the label on the product box of Benadryl® Dry, Tickly Cough was reviewed by the authors, it was found that there was limited information on precautions, contraindications, monitoring, side effects, and timely referral (**Table 1**). This is medicines information that consumers want (Nair, Dolovich et al. 2002) but, based on the existing label content, would not be able to find on the product label for this medicine.

To develop the leaflet for the pholcodine product, an existing evidence-based, user tested leaflet format (Aslani, Hamrosi et al. 2010) was utilised as the scaffold with respect to design, some content, and content ordering. Leaflet content was written using plain English, based on a combination of resources to ensure adherence to CMI leaflet legislative requirements (Commonwealth of Australia 1990) and inclusion of sound clinical content (Johnson & Johnson Pacific, McNeil Products Ltd 2009a, McNeil Products Ltd 2009b, Aslani, Hamrosi et al. 2010, Pharmaceutical Society of Australia 2010a, Pharmaceutical Society of Australia 2010b, Rutter and Newby 2011, Australian Government Department of Health Therapeutic Goods Administration 2012, Australian Medicines Handbook 2012, NPS Medicinewise 2012). The final leaflet was three A4 pages in length.

Table 1. Comparison of content included in the existing Benadryl® label and study-developed leaflet

Key clinical point(s)	Existing Benadryl® label* (back panel) (Johnson & Johnson Pacific)	Study-developed leaflet
Indication	✔	✔
Contraindication for use in children < 6 years	✔	✔
Other warnings/contraindications and action to be taken e.g. allergy to pholcodine, asthma, productive cough	✘	✔
Precautions and action to be taken before using the product – use of other cough/cold medicines, use in children > 6 years	✔	✔
Other precautions to consider before using the product e.g. chronic cough; action to be taken if using any other medicines	✘	✔
Directions for use – dosage, maximum daily dose	✔	✔
Treatment duration	✘	✔
Missed dose/overdose and action to be taken	✘	✔
Action to be taken – persistent cough	✔	✔
Other monitoring information and action(s) to be taken	✘	✔
Warning – drowsiness	✔	✔
Warning – avoid alcohol use	✔	✔
Further side effects information and action to be taken	✘	✔
Information on how to manage cough and cold symptoms	✘	✔

✔ = included ✘ = not included

** The label refers to the information found on the product box/packaging; specifically, the back panel of the box.*

STUDY PROTOCOL

The existing Benadryl® label and study-developed leaflet were user tested with consumers in Australia (n=10) and the UK (n=10) (Tong 2016). The two research sites allowed for comparisons to be drawn between the perspectives of consumers residing in regulatory contexts that differ in OTC WMI provision.

All face-to-face interview sessions were conducted at either The University of Sydney (Australian interviews) or on premises at Luto Research (UK interviews) by the one researcher (VT) between April 2013 and March 2014. Participants provided written informed consent. Consumers were recruited via a multi-modal recruitment strategy in Australia (flyer distribution, online advertisements, and through a market research company), and the Luto Research consumer database in the UK, using explicit criteria (**Table 2**).

The face-to-face interview session, lasting approximately 1 hour in total, consisted of consumer user testing of the label and leaflet, followed by a semi-structured interview. The user testing questionnaire component was completed first, using a standardised protocol (Tong 2016). Immediately after, a semi-structured interview, the qualitative component of user testing, was conducted to explore participants' perspectives on the label and leaflet they had user tested and future improvements that could be made to the information (**Appendix 1**). Once feedback on the existing label and study-developed leaflet was obtained, participants were advised that the product was currently supplied without a leaflet and were asked for their opinions on this, as well as their views on any improvement(s) required for the leaflet. Upon interview completion, participants completed a demographics questionnaire and were reimbursed for their time.

Table 2. Inclusion and exclusion criteria for study participation

Criteria	Details
Inclusion criteria	1. Aged 18 years or older; 2. Not currently using the study medicine pholcodine and had not used pholcodine in the 6 months prior to the study; 3. Not currently giving pholcodine to a child or person(s) under their care and had not done so in the 6 months prior to the study; 4. Had bought and used an OTC medicine (either for themselves or a person under their care) in the 6 months prior to the study; and 5. Had an adequate command of the English language, thus able to read and understand the consent form, participant information statement, and study materials without translator assistance.
Exclusion criteria	1. Using a medicine from the same therapeutic class (opioid cough suppressants) and/or had used one such medicine in the 3 months prior to the study; 2. Giving a child or person(s) under their care a medicine from the same therapeutic class as pholcodine at the time of the study and/or had given one such medicine in the 3 months prior to the study; 3. A practising or retired healthcare professional (HCP), or currently employed in an occupation which mainly involved medicines information use; 4. A trained HCP but who is no longer practising as a HCP; 5. Significantly visually impaired; or 6. Significantly cognitively impaired, which could affect their performance during the face-to-face user testing interview session.

DATA ANALYSIS

Discussions were audio-recorded and transcribed verbatim. The interviewer (VT) checked all verbatim transcripts against the original audio recording for accuracy. All transcripts were thematically analysed (Green and Thorogood 2014) primarily by the interviewer (VT), with a proportion analysed by a second researcher (PA) for reliability checking.

Data for each cohort were analysed individually initially, prior to synthesis of the findings for comparison. Preliminary matrix displays (Miles and Huberman 1994) were developed, where data from the transcripts were systematically transposed into the relevant matrix to help visually structure the data.

Table 3. Participant demographics

	Demographic	Australia (n=10)	UK (n=10)	Total
Gender	Male Female	5 5	6 4	11 9
Age (years)	18-29 30-49 50-69 70+	2 5 2 1	1 3 3 3	3 8 5 4
Highest level of education attained	School certificate/ GCSE* (Year 10) or below	1	4	5
	Higher School Certificate/ A Level† (Year 12) or college qualification	7	4	11
	Bachelor's degree or higher	2	2	4
Regular use of written information as part of occupation	Yes No	4 6	6 4	10 10
Main language spoken at home	English	10	10	20
Country of birth	Australia UK Other	9 0 1	0 10 0	9 10 1
Parent/carer of child(ren) below 18 years	Yes No	3 7	3 7	6 14

**GCSE = UK General Certificate of Secondary Education.*
†A Level = UK General Certificate of Education Advanced Level.

Additional matrix displays were generated to help refine the themes and subthemes that were inductively derived from the data. Australian and UK data have been presented together to help identify common trends and key differences in the feedback obtained.

RESULTS

A total of 20 participants (2 cohorts of 10 participants) provided their perspectives on the Benadryl® label and study-developed leaflet (**Table 3**); cohorts of 10 participants are sufficient for the purposes of diagnostic user testing of WMI (Raynor 2013). There was a wide range of participant ages in each cohort and similar proportions who did not use written information routinely as part of their work (**Table 3**).

PERSPECTIVES ON THE BENADRYL® WMI

The design of both the existing label and study-developed leaflet were generally favoured across both cohorts (**Table 4**). However, although there was mention of good information coverage on the label, some participants raised that there was limited or insufficient information. Suggested improvements for the Benadryl® label content received from both cohorts primarily included additional contraindications/warnings information, treatment duration, and side effects information (**Table 4**).

Overall, there were mixed perspectives on the leaflet content. Although the leaflet content was regarded as a suitable amount, on the other hand, others viewed it as lengthy, with a large amount of information and repetition. In contrast to the label, in order to improve the leaflet, consumers suggested content deletion and to make the information more succinct (**Table 4**). Participants also suggested that the leaflet be included as a package insert.

PERSPECTIVES ON WMI LEAFLET AVAILABILITY WITH BENADRYL® DRY, TICKLY COUGH

Participants in both the Australian and UK cohorts were surprised to learn that a leaflet was not currently available with the Benadryl® product.

"I'm totally shocked by that. Totally shocked..... Because I've been brought up with medicines that always have a leaflet..... and not everything you need to know is on that label. Although, it's the important things [that] are on there, I guess. But this [leaflet] just gives you a lot more information if you're worried." (*Participant UTP64-UK)*

It was acknowledged that the Benadryl® label at present did not contain sufficient information. Hence, participants were favourable towards receiving additional information via a leaflet.

"I think overall the leaflet gives you pretty in-depth information about Benadryl® and so it's definitely important that you make a leaflet..... with Benadryl®. Because it has a lot of side effects and there is a lot of guidelines to actually using it, which someone like me would never have known just from picking up the box." (*UTP44-UK)*

In particular, the majority of the UK cohort expressed that they would want a leaflet with Benadryl®, with preference for a package insert.

"I would be very happy with that leaflet in that box..... I mean it gives you so much information here and you know, we're not all doctors and pharmacists are we? You know, it tells you about if you're taking other things and if you've got other symptoms, other illnesses. I wouldn't buy a bottle of strong cough medicine, which is what I think this is, without a leaflet inside." (*UTP50-UK)*

On the other hand, a few Australian participants raised that a leaflet may not be required, provided the label included sufficient content, or that the leaflet content was common sense.

However, a few Australian participants mentioned that even though they may not read the leaflet, the product should still be provided with one.

DISCUSSION

Overall, varied opinions were put forward in relation to the content of the OTC WMI, ranging from inadequate information on the existing product label to too much information included in the study-developed leaflet. Despite this, consumers indicated receptivity to leaflet provision, particularly participants who felt that the label provided insufficient information.

Participants suggested that Benadryl® label content improvements were needed due to the perceived lack of clinically-relevant information when compared with the leaflet. Importantly, this perceived need for improvement was voiced prior to consumers being advised that a leaflet was not available with the product in a real-life setting. This indicates that consumers' unmet information needs correspond to key clinical information gaps identified by the research team and signals the need for improvement of existing WMI. Although leaflets have been rarely received with OTC medicine purchases in Australia (Kelly, Williams et al. 2009), from the present study,

Table 4. Participant opinions and suggested improvements raised in both Australian and UK cohorts in relation to the existing Benadryl® label and study-developed leaflet

	Existing label	Study-developed leaflet
Participant opinions	**Content and/or wording** ✔ Generally good coverage of information; sufficient ✔ Concise ✘ Minimal/insufficient information ✘ Limited information compared to the leaflet ✘ Inadequate content specificity (e.g. regarding dosage (Australia), if symptoms persist (UK))	**Content and/or wording** ✔ Clear; easy to read and understand ✔ Informative, comprehensive ✔ More detailed when compared to the label ✔ Suitable amount of information ✔ Useful lifestyle advice regarding cough and cold ✘ Large amount of information; too much; lengthy leaflet ✘ Repetition of content
	Design/format ✔ Good, clear layout/design ✔ Easy to read, use/navigate ✔ Easy to find indications, contraindications, dosage ✔ Good headings– easy to read ✔ Tabulated dosage easy to read ✔ Ticks and crosses good ✔ Font size adequate ✔ Good use of colour; white background was clear ✘ Old fashioned/unattractive colour scheme	**Design/format** ✔ Fit for purpose, effective, easy to use ✔ Good use of headings (to section information) ✔ Likes tabulated side effects– clear ✔ Good use of bullet points ✔ Good layout ✔ Good order of information • Standard leaflet; the design was similar to other leaflets
Suggested improvements	**Content addition** • More content (broad suggestion for additional content) • Include contraindication for use in children less than 6 years on principal display (front) panel • Contraindications/warnings e.g. use in asthma • Side effects • Treatment duration • Ingredients	**Content deletion** • Reduce leaflet length (1 or 2-page leaflet instead); make information more succinct • Product details (section of leaflet including information such as ingredients, product description, sponsor/manufacturer information) • Entire first column (introductory remarks about the leaflet, contact information, and list of key leaflet sections) before Section 1 of the leaflet
	Design/format • Increase font size • Contraindication for use in children less than 6 years should be more prominent	**Design/format** • Place important information on the first page of the leaflet • Move emergency/contact information to the end of the leaflet • Split information for adults and children into different sections • Include as a package insert

✔ = positive feedback ✘ = negative feedback

consumers are not averse to receiving more information on the label and/or additional information via a leaflet. As there may be a tendency for OTC medication use to lead to a postponement in seeking medical advice (Allotey, Reidpath et al. 2004), inclusion of treatment duration for pholcodine use for instance, in the context of self-management, is critical to help ensure appropriate OTC medication use by parents/carers and facilitate timely referral. Minor ailments such as cough may be inappropriately managed with an OTC medicine (Eiland, Salazar et al. 2008) and moreover, previous research has indicated that most caregivers felt that the provision of both the label and various leaflets for OTC paracetamol, together rather than individually, would ensure that they had enough information to give the medicine to their child (Bennin and Rother 2015).

An appropriate level of OTC label content, such as the inclusion of adequate contraindications or warnings information, is imperative to assist in appropriate product selection, particularly if a leaflet is not supplied with a product. As a proportion of Australian participants commented that a leaflet may not be required if the label was revised, this emphasises the importance of ensuring access to information regardless of the delivery format. Limitations to labels as sole WMI sources are certain, where consumers should have various WMI options available to utilise in order to meet their information needs. This can be further enabled via leaflet availability in the first instance, and may assist consumers in identifying further information they require to help self-manage the condition.

This study was novel in that perspectives on leaflet availability were sought from consumers within two different regulatory contexts pertinent to WMI. When taking into account leaflet availability mandated in Australia (Aslani 2007) compared to the EU (European Commission 2001), the preference of UK consumers for a leaflet to be available as a package insert is likely attributed to the status quo of WMI receipt with medicines within the EU (European Commission 2001). Although this does highlight that regulatory frameworks have a degree of influence on consumers' expectations and perceptions on information that should be available with medicines, consumers' desire for appropriate information goes beyond locally implemented WMI regulations. This was demonstrated by positive receptivity towards the availability of the study-developed leaflet in both cohorts. The provision of leaflets with all OTC medicines is not common practice in other countries like Australia. Therefore, the true fitness-for-purpose of existing OTC labels to facilitate safe consumer self-medication is brought into question, as are regulatory approaches that only mandate OTC WMI leaflet development and availability for a select group of OTC medicines. Thus, this indicates a need for policy review.

Strategic development of WMI for OTC medicines should adequately cater for consumers' information needs (International Pharmaceutical Federation 2017). In regulatory contexts like Australia where WMI leaflets are not routinely produced for the vast majority of OTC medicines, leaflets are an underutilised source with limited availability. There may also be a potential mismatch between the information manufacturers feel should be provided with the medicine in comparison to what consumers and HCPs believe should be provided. Interestingly, most OTC medicine manufacturers surveyed around the time package inserts were made compulsory for all medicines in the EU felt that enough information was being provided with OTC medicines prior to this requirement (Bradley, McCusker et al. 1995). Many expressed that the requirement would lead to a surplus of OTC medicine information being provided, where it was approximated that no more than about half of those who read leaflets would be able to understand the label and/or leaflet (Bradley, McCusker et al. 1995). This is a matter of clear concern, particularly if these perceptions still persist today among key stakeholders responsible for OTC WMI development. It is therefore pertinent to further evaluate WMI currently provided with OTC medicines and ensure manufacturers are alerted to any WMI inadequacies. Such efforts will effectively support a WMI culture that encourages the development of high quality WMI for OTC medicines together with timely WMI optimisation.

This study has some limitations. Having an existing label that could be compared with information that could potentially be made available with the medicine was intended to provide a stimulus for reflection on the label's existing level of content. Consequently, exposure to the leaflet content had a likely impact on consumers' opinions on the lack of leaflet availability. Moreover, only one exemplar OTC medicine and subsequent product-specific WMI was studied. Thus, further research is required to examine whether the identified consumer preferences are applicable to consumers outside of a user testing interview context, for instance where a leaflet was not presented for evaluation and comparison, and for other available OTC medicines.

CONCLUSIONS

Regardless of leaflet availability differences between regulatory contexts, the perceived lack of content included on the Benadryl® label contributed to participants from both Australia and the UK to be supportive of a leaflet to be made available with the product. The present study demonstrated the feasibility of developing a novel leaflet for an OTC medicine that is acceptable to consumers, using good information design principles and the consumer user testing approach. Future research should systematically evaluate the quality and level of content of WMI provided with OTC medicines to identify how existing OTC product labels and/or leaflets can be improved for the benefit of consumers.

Conflict of interest: David K. Raynor is co-founder and academic advisor to Luto Research (www.luto.co.uk) which develops, refines and tests health information materials.

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TIIVISTELMÄ

Kuluttajien mielipiteitä itsehoitolääkkeen potilasohjeen laadusta ja saatavuudesta

Johdanto

Kuluttajat tarvitsevat riittävästi tietoa itsehoitolääkkeistään käyttääkseen niitä oikein ja turvallisesti. Siitä huolimatta kirjallisen lääkeinformaation, kuten pakkausselosteiden ja muiden potilasohjeiden, saatavuus ja laatu vaihtelevat eri maissa. Asiakaslähtöistä tutkimusta kuluttajien näkemyksistä kirjallisesta lääkeinformaatiosta on rajoitetusti. Tässä tutkimuksessa tarkasteltiin kuluttajien näkemyksiä kirjallisen lääkeinformaation laadusta ja saatavuudesta yhtä australialaista itsehoitovalmistetta esimerkkinä käyttäen.

Aineisto ja menetelmät

Folkodiinia sisältävälle itsehoitolääkevalmisteelle (Benadryl®, kuiva, kutiseva yskä) laadittiin potilasohje. Olemassa olevaa lääkevalmisteen etikettiä ja tutkimusta varten laadittua potilasohjetta testattiin kuluttajille (n=20) Australiassa ja Isossa-Britanniassa. Kuluttajien näkemyksiä potilasohjeen saatavuudesta ja laadusta selvitettiin ryhmäkeskustelujen avulla. Keskustelut nauhoitettiin, kirjoitettiin auki ja analysoitiin temaattisen sisällönanalyysin avulla.

Tulokset

Tutkimukseen osallistuneet kuluttajat pääsääntöisesti pitivät potilasohjeesta ja sen visuaalisesta ilmeestä. Heidän mielipiteensä potilasohjeen sisällöstä olivat kuitenkin vaihtelevia. Osa piti potilasohjeen sisältöä kattavana, mutta osa toivoi potilasohjeeseen lisätietoa lääkehoitoon liittyvistä varoituksista ja turvallisuudesta. Tutkimukseen osallistuneet olivat yllättyneitä, että kyseiselle lääkevalmisteelle ei ollut erillistä potilasohjetta, ja pitivät sen saatavuutta tärkeänä.

Johtopäätökset

Kriittisten tietojen puuttuminen potilasohjeesta vaikutti kuluttajien näkemyksiin potilasohjeen hyödyllisyydestä ja toiveisiin sen saatavuudesta. Potilasohjetta tulee kehittää niin, että se vastaa entistä paremmin kuluttajien tarpeisiin ja sisältää heidän kannaltaan oleellista tietoa lääkkeen käytön turvallisuudesta.

Avainsanat

Kirjallinen lääkeinformaation, potilasohje, lääkkeiden etiketit, itsehoitolääkkeet, itsehoito, kuluttajat

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Appendix 1. Relevant core semi-structured interview questions

Protocol section	Core question(s)
Perspectives on the label	1. Firstly, what are your overall thoughts about the box/product packaging, in terms of how easy/hard it is to read and the information that is included on it? 2. Looking at the information that is written on the box/product packaging, what do you think about the amount of information that it contains? 3. What do you think about the layout of the information on the box? 4. Thinking back to how you used the box/product packaging to answer the questions before, what information was easy or difficult to find and/or understand?
Improvement(s) needed to the label	5. From your point of view, how can we improve the information on the box in the future to improve its readability and how well it is understood?
Perspectives on the leaflet	6. What are your overall thoughts about the leaflet? 7. Thinking back to how you used the leaflet when answering the questions earlier, what information was easy or difficult to find and/or understand in the leaflet?
Perspectives on leaflet availability	8. The leaflet that you helped us test today is not actually available inside the pack. We developed the leaflet for the purposes of the study. Benadryl® Dry, Tickly Cough does not come with a leaflet. What do you think about this medicine not having a leaflet?
Improvement(s) needed to the leaflet	9. From your point of view, how can we make this leaflet better in the future?