User testing as a method for identifying how consumers say they would act on information related to over-the-counter medicines

Abstract

Background

User testing evaluates written medicine information (WMI) usability by examining participants' ability to find and understand information. It can also be an effective method to determine how consumers say they will act on information on an over-the-counter (OTC) label.

Objective

To examine consumers' reported behaviors regarding dosage and storage as a measure of a medicine label's usability and consumers' functional health literacy.

Material and methods

User testing of 5 diclofenac OTC labels (by 50 subjects; 10 per label) measured consumers' ability to find and understand key points of information using a 13-item questionnaire. Consumers were required to elaborate on their behavior in regard to 2 additional questions: 1) when they would take diclofenac if they had constant back pain from 8am (dosage-related) and; 2) where they would store it in their home (storage-related). Responses were transcribed verbatim, and coded by 2 pharmacists.

Results

Appropriate dosing for constant back pain was reported by 29 consumers. However, dosing intervals shorter than the specified 8 hours were often reported (n=19), due to adjusting intervals to accommodate up to the maximum of 8 tablets in 24 hours, desire for pain relief, and/or

pragmatic dosing (e.g. around bedtime). Only 29 consumers stated completely appropriate storage location examples (e.g. medicine cabinet).

Conclusions

Consumers may act inappropriately on OTC label information about dosage and/or storage, which could potentially adversely impact medicine use. User testing can contribute to the development of high quality WMI and help identify where label wordings are inappropriate for the health literacy levels of consumers.

Key words

Health literacy; user testing; drug labeling; non-prescription drugs; self-management.

Article synopsis

This study sought to examine consumers' proposed behaviours in relation to dosage and storage as a measure of the usability of a medicine label and consumers' functional health literacy. Participants were asked two additional scenario questions as an extension of normal user testing protocol: 1) when they would take diclofenac if constant back pain was experienced (dosage-related) and; 2) where they would store the medicine in their home (storage-related). Twenty nine participants nominated dosage regimens as per the label; 20 participants chose to modify the specified dosing interval. Inappropriate storage locations were specified by about half of the participants.

Introduction

The importance of health literacy is clear within the context of healthcare. Health literacy can be defined as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions".[1(p32)] Health literacy can be further conceptualized within a three-tiered model of health literacy, consisting of functional (level 1), interactive (level 2), and critical health literacy (level 3), where functional health literacy is the foundation level upon which the other levels can be developed.[2] Functional health literacy is related to a person's capacity to utilize literacy skills in the context of health and medicine-related information.[3]

Suboptimal health literacy has been associated with a number of negative outcomes for individuals.[4-6] Thus, adequate health literacy levels are important, and have been associated with written medicine information (WMI) understanding.[7] A number of health literacy screening tools exist, but not all measure functional health literacy.[8] Those which require individuals to apply a range of skills inherent in functional health literacy include tools such as the Test Of Functional Health Literacy in Adults (TOFHLA), and the Newest Vital Sign (NVS).[8] In relation to written information, a wide range of tools exist for use in health and medicines information evaluation; however, most only assess readability and/or design.[8]

Suboptimal health literacy is widespread,[9] and there are a number of strategies that can be implemented to help improve the ease with which health and/or medicines information can be understood, with one such strategy being user testing.[10] Therefore, in light of the universal precautions approach to health literacy, where strategies to support patients in managing their health are underpinned by the premise that everyone may have problems understanding health-related information,[11] user testing can help to achieve this in relation to WMI.[12] User testing, developed by Sless and colleagues,[13] can be regarded as the gold standard method in evaluating

the performance or usability of WMI.[14] User testing is recommended[15] in the European Union, where the usability of leaflets must be assured via consultation with consumers.[16] Similarly, in Australia, user testing has been incorporated into guidelines on the development and testing of over-the-counter (OTC) labels,[17] and leaflets.[13]

The process of user testing involves measuring the usability of WMI by indirectly utilizing consumers' functional health literacy,[3] as demonstrated by their interaction and understanding of the WMI being evaluated.[15] A range of demographics such as education, age, factors regarding occupation, amongst others, are considered when recruiting participants,[15, 18] to potentially include a range of health literacy levels within the study population. Individuals are required to demonstrate their ability to find and understand key points of information, which are the primary outcome measures in performance evaluation, which is followed by a qualitative, semi-structured interview where feedback is obtained on the information that was user tested.[15] Therefore, the questionnaire developed specifically to user test the WMI has a key influence over what is measured in terms of understanding. The strength of user testing lies in its iterative nature, whereby necessary changes are made to the information to address any identified shortcomings from the initial round of user testing, with the revised information then subject to further testing to ensure it is fit-for-purpose.[12]

User testing as a process exists at the interface of both: (a) ensuring WMI caters for the health literacy needs of the target patient population, and (b) as an indirect way to examine how an individual's functional health literacy influences both perceived and actual WMI usability. However, user testing has not been previously used as a method to help provide further insight into participants' functional health literacy via the examination of reported behaviors, as an extension of the user testing process in response to information read on a medicine label.

Therefore, the aim of this study was to examine participants' reported behaviors regarding dosage and storage as a measure of a medicine label's usability and consumers' functional health literacy.

Material and methods

This study forms part of a larger international research project, which aimed to develop and user test alternative OTC label formats that could be considered for implementation as part of an OTC label standardization strategy.

Four alternative OTC label formats were developed for the study medicine diclofenac. Two label formats were developed based on existing and proposed standardized label formats in the U.S.[19] and Australia,[20] respectively. A further two label formats were developed by applying good information design and findings from a consumer needs analysis.[21, 22] An existing OTC label for a diclofenac product available for purchase in Australia (Voltaren® Rapid 25[23]) was also selected as a comparator label. In order to determine whether these label formats were fit-for-purpose, they were then subject to user testing. However, only the findings related to the participants' proposed behaviors regarding dosage and storage will be reported.

Ethics approval for the conduct of this study was granted by the institution's Human Research Ethics Committee.

Participant recruitment

Recruitment took place between April and October 2015 through the use of online advertisements, flyers, and by a market research company.

Consumers were eligible to participate in the study if they were:

- 18 years or older,

- Conversant in English (did not require a translator to participate),

- Had purchased and used an OTC medicine, for themselves or had given it to a person under their care, within the 6 months prior to study participation (but had not used or given diclofenac), and

- Had not used or given someone under their care a medicine from the same therapeutic class as diclofenac (non-steroidal anti-inflammatory drugs for pain relief) within the previous month immediately prior to study participation.

Consumers were ineligible to participate if they:

- Were a health care professional, whether retired or practising,

- Currently employed in an occupation which primarily involves the use of medicines information,

- Had participated in a user testing study in the 6 months prior to study participation, or

- Had significant visual or cognitive impairment that would affect their participation.

User testing process and study protocol

User testing[12] was conducted with cohorts of 10 participants allocated to test one of the label formats (a total of 50 study participants). The cohorts were demographically matched according to age, gender, education, and occupation/use of written information in their occupation, using criteria adapted from a previous user testing study.[18]

Participants were required to demonstrate their ability to locate and understand key points of information about the diclofenac-containing product by using one of the label formats, via the administration of a 13-item core user testing questionnaire. Of the 13 items, 2 items related to dosage and storage. Directly after completion of the relevant dosage and storage questionnaire

items, participants were presented with an additional scenario question pertaining to dosage or storage, respectively:

1. Say you had back pain at 8am, what times in the day would you take it if you had constant back pain?

2. What is an example of where you would store the tablets in your house?

Of the key points encompassed in the user testing questionnaire, dosage and storage were selected as the basis for the additional scenario questions as the relevant label information would need to be further interpreted and applied in a real life setting beyond, for example, the act of seeking medical advice or not using the product. These additional questions inherently required participants to draw on their own medicine taking experiences and understanding to make decisions in light of the theoretical context of self-management using OTC diclofenac. All responses were audio recorded with permission from the participants and were analysed independently to the answers provided to the core user testing questionnaire items.

At the end of the interview, participants were asked to fill in an additional demographics questionnaire that supplemented the demographics information collected during recruitment, and were reimbursed for their time. The questionnaire included 3 questions related to self-reported WMI understanding and confidence in its use, or filling out medical forms. These were similar to those asked in a previous study,[18] with only minor wording changes made to focus the questions in relation to the context of this study.

Data analysis

All responses were transcribed verbatim, tabulated, and then reviewed by the interviewer (__). A coding framework was derived inductively from the data, and refined using the relevant

information included on the label regarding dosage (inclusive of dose, dosing interval, maximum daily dose) and storage, along with further storage information in the Voltaren® Rapid 25 package insert[24] and medicine information expertise of the research team members. Nominated dosage regimens were strictly coded according to the directions for use specified on the label. Storage locations were coded as appropriate if the example(s) given was a cool and dry location in the home (that is, not in the bathroom or refrigerator, for example). Participants' responses were coded by two pharmacists (__ and __) using this framework for the purposes of reliability, with any discrepancies discussed and final coding agreed upon.

Results

Participant demographics and self-reported indicators of WMI understanding

A total of 24 males and 26 females participated in the study, representative of a wide range of ages (Table 1). The majority of participants completed either Year 12 or a college qualification, and English was the predominant main language spoken at home.

The overwhelming majority of participants felt extremely (31/50) or quite (17/50) confident regarding their ability to fill our medical forms without assistance (Table 2). Similarly, most participants (37/50) did not require assistance in reading written medicine information, or required assistance a little of the time (8/50). However, only approximately half of the participants (27/50) reported never having difficulty learning about their medicines or medical conditions due to difficulties reading and understanding written information.

All 50 participants were able to successfully locate the relevant information pertaining to dosage and storage during the administration of the core user testing questionnaire.

Participant responses to the dosage scenario

A range of participant responses were given in relation to the dosage scenario. A total of 29 participants nominated an appropriate dose and dosing interval that strictly adhered to the dosage and dosing interval as per the label (Table 3). However, there were also a number of deviations; for example, "take 1 tablet 8 hourly"[23] included on the Voltaren® Rapid 25 label was misunderstood as take 1 tablet every hour for 8 hours, and carried forward in the dosage scenario (quote 1, Table 4), or less than the recommended initial dose was chosen to be taken due to fear of overdosing (quote 2, Table 4).

Despite the dosing interval of 8 hours stated on all labels, some participants decided to modify this. Dosing intervals shorter than the specified 8 hours were often reported (n=19), due to presumed calculation difficulty/error, adjusted intervals to accommodate up to the maximum of 8 tablets in 24 hours if needed, adoption of a pragmatic dosing approach in relation to their daily routine e.g. bedtime, or perceived needs and benefits expected or desired of the medicine e.g. achievement of adequate pain relief (quotes 3-6, Table 4). However, the maximum of 8 tablets in a 24 hour period was generally adhered to, as seen through the direct acknowledgement of the maximum dose in their response and/or reflected in the total number of tablets participants said they would take, even though inappropriate dosing was nominated. Of the 19 participants, 4 participants indicated a combination of shorter and longer dosing intervals.

Participant responses to the storage scenario

A variety of storage conditions and locations in the participants' own home were cited. Twenty one participants provided inappropriate storage examples (Table 3). Common inappropriate responses that did not correspond to the intended meaning of the storage information included the refrigerator or bathroom cabinet (unadvisable due to potential humidity/moisture levels in the bathroom). Other participants demonstrated a sound understanding and application of the information by providing appropriate examples (n=29) such as a kitchen cabinet (away from the stove), medicine cabinet, designated drawer in the bedroom, amongst others. It should be noted however that this study was not designed to test participants' knowledge that medicines should also be stored out of the reach of children.

1   Table 1 – Summary of participant demographics

Demographic		Total (n=50)
Gender	Male	24
	Female	26
Age (years)	18-29	15
	30-49	14
	50-69	14
	70+	7
Highest level of education	Year 10 or below	6
	Year 12 or College	33
	Bachelor's degree or higher	11
Main language spoken at home	English	46
	Other*	8
Regular use of written information as part of occupation	Yes	27
	No	23
Country of birth	Australia	26
	Overseas	24

2   * Four participants nominated that their main language spoken at home included both English and
3   another language, hence the total exceeds 50

4

5   Table 2- Study participants' self-reported health information understanding (n=50)

Question	Participant responses				
	1	2	3	4	5
1. How confident are you filling out medical forms by yourself?*	0	0	2	17	31
2. How often do you have someone help you read written medicine information?#	37	8	5	0	0
3. How often do you have problems learning about your medical condition or medicines because of difficulty reading and understanding written information?#	27	14	7	2	0

6   * Where the scale of 1 to 5 represents: not at all=1, a little=2, somewhat=3, quite=4, extremely=5.

7   # Where the scale of 1 to 5 represents: none of the time=1, a little of the time=2, some of the

8   time=3, most of the time=4, all of the time=5.

Table 3 – Participant responses to application questions pertaining to the dosage and storage of diclofenac tablets

	Dosage scenario question: Say you had back pain at 8am, what times in the day would you take it if you had constant back pain? (Directions on label state: • "Take 2 tablets initially with liquid. Then if necessary, take 1 tablet 8 hourly (maximum 8 tablets per day)." [Voltaren® Rapid 25 label[23]], or; • "Take 2 tablets at first, [and] then take 1 or 2 tablets every 8 hours if needed. Do not take more than 8 tablets in 24 hours." [All other labels])			Storage scenario question: What is an example of where you would store the tablets in your house? (Directions on label state: • "Store below 30°C" [Voltaren® Rapid 25 label[23]] or; • "Store in a cool, dry place at room temperature (below 30°C)" [All other labels])	
	Appropriate dose, appropriate dosing interval	Appropriate dose, inappropriate dosing interval	Inappropriate dose, inappropriate dosing interval	Appropriate example(s)	Inappropriate example(s)
Voltaren® Rapid 25 cohort (n=10) [Missing dosage question data for 1 participant]	4	3	2	3	7
All other label cohorts (n=40)	25	14	1	26	14
Total	**29**	**17**	**3**	**29**	**21**

10

Table 4- Illustrative quotes provided by participants in response to the dosage scenario

Theme/subtheme	Illustrative quote(s)
Misunderstood dosing interval	1. *"2 at when you first open, 2 then at 8am and then if it went on, 9 am just 1, up to 1 tablet each hour but up to 8 hours only." (P46- Voltaren® Rapid 25 cohort)*
Fear of overdosing	2. *"I'd take 1 tablet at 8am because I wouldn't want to take 2 and have an overdose" (P04- Medicine Facts cohort)*
Dosing interval altered due to factors such as achieving adequate pain relief, or pragmatism in relation to daily routine	3. *"I'd probably take it every 4 hours, I'd halve the 8 hours - I don't want to spend 4 hours in pain do I?" (P49- Voltaren® Rapid 25 cohort)* 4. *"I just probably take 'em 8[am], 10[am], 2[pm], and 6[pm]. If I had really bad back pain that is." (P30- Medicine Information cohort)* 5. *"If I was in pain, I'd probably take it when the pain occurred. In fact, I'd be one of those people who would do that. I'd say 'oh hang on, when did I have the last one?' And I'd have a read of it and I'd think 1 to 2 tablets every 8 hours if needed and I had some only an hour ago- I might… leave it for an hour but I wouldn't put up with it for much longer. I just use 4 hours as because I see here I can't have any more than 8 in 24 hours." (P32- Consumer Desires cohort)* 6. *"[Take] 1 before bed… 10-11pm, even though it says 8 hours on there... [I would] just be going to sleep and I wouldn't be bothered to wait for another 1 hour." (P12- Voltaren® Rapid 25 cohort)*

Discussion

The extension of user testing to assess in more detail what participants say they would do in response to information read on an OTC medicine label is an enhancement of normal user testing practice that can be used for capturing information regarding consumers' functional health literacy and any underlying health literacy concerns. Through these additional questions incorporated as part of the user testing process, this study identified people's non-compliant proposed behaviors in relation to storage locations, and most importantly, dosage instructions. Storage location examples given were not always compliant with the intended advice. Although many adhered to the directions for use on the label, the most common inappropriate consumer response regarding dosage involved taking diclofenac at dosing interval(s) shorter than the specified 8 hours.

Storage information on the label was not always interpreted as intended, with consumers nominating inappropriate storage locations in the home. Due to the conciseness of information and pragmatic constraints on the amount of OTC label content, the resulting information ambiguity or lack of detail may lead to misunderstanding of the information and/or its application. A survey conducted in 2015 highlighted that approximately 1 in 5 perceived OTC medicine storage information to be confusing.[25] Moreover, of those who had sought this information in the past, the most common source was an OTC label.[25] The leaflet accompanying Voltaren® Rapid 25 includes further storage information that was not provided on the label, such as not to store the medicine in the bathroom[24] (which was a common inappropriate storage location nominated). As the leaflet was not provided to participants who user tested the Voltaren® Rapid 25 label, this may have impacted the storage location examples given in this cohort if this information was normally sourced from the leaflet. Interestingly, the proportion of participants who nominated an inappropriate storage location example was higher in the Voltaren® Rapid 25 cohort in comparison to all other cohorts collectively. Accordingly, this signifies a need to re-examine and improve how

storage information is communicated to consumers on OTC labels, and may suggest that more specific wording of storage advice would be more appropriate. Also, it is important to ensure that all OTC products are accompanied by a more detailed leaflet. While this is legislation in the European Union,[26] there is no legal requirement for the inclusion of package inserts in all OTC products in Australia.[27]

When examining how diclofenac would be reportedly taken if constant back pain was experienced, it was noted that consumers may ignore dosage information that has been read on the label in favor of their own views on medicine taking and what would be considered as an appropriate application of the information in their personal circumstances. This was evident in the deviations from the recommended dosing interval and the parallel conscious decision to adhere to the maximum daily dose. Similarly, in a survey commissioned by the National Council on Patient Information and Education in the United States, a third of respondents had exceeded the recommended dose for an OTC medicine, with shortened dosing intervals commonly reported.[28] Reasons for exceeding the recommended dose included symptom severity, the perception that it would provide faster relief, or that relief was not achieved with the recommended dose.[28] In light of this and the findings from the present study, the condition and/or symptom of pain may have influenced participants' answers regarding dosage and dosing interval for diclofenac in comparison to, for example, a medicine used in the management of a primarily asymptomatic medical condition. Other contributing factors were unintentional non-adherence due to suspected calculation difficulties or sub-optimally communicated information, as seen from the misunderstanding and subsequent application of the dosing interval for Voltaren® Rapid 25 ("take 1 tablet 8 hourly"[23]). Conversely, as the additional dosage question was asked immediately after it was located on the label, some participants may have opted to adopt a conservative approach i.e.

dosing strictly as per the label, which would differ from their real life behavior(s); thus, underreporting of medication use differing from the label directions may also be feasible.

Although some of the dosing intervals nominated by participants may not lead to clinically significant, negative patient outcomes, the present study findings still raise the question of the true extent or prevalence of inappropriate applications of other seemingly straightforward key points in OTC WMI and their clinical significance in self-management. Although, in the case of the OTC non-steroidal anti-inflammatory drug ibuprofen, its increased widespread availability over the years has been associated with a decrease in the proportion who appropriately use ibuprofen as per the label.[29] Therefore, this reiterates the importance of seeking to improve consumers' functional health literacy by improving WMI quality as per the universal precautions approach.[11] This can then contribute to improved interactive health literacy, which is aimed at "improving personal capacity to act independently on knowledge, specifically to improving motivation and self-confidence to act on advice received",[2(p265)] and is thus, fundamental to promoting safe, appropriate, and effective consumer self-management using OTC medicines.

The user testing questionnaire has a large influence over what is captured in the way of understanding as an outcome measure. Health literacy issues in relation to medication use or medical conditions may be better understood if user testing questionnaire items explore in more detail how participants say they will act on particular points of information. Thus, care must be taken in their design to ensure, as was done in the current study, that an additional outcome measure alongside the ability to find and understand information is used. This outcome measure can be extended beyond proposed behaviour, to, for example, demonstration of a complete and appropriate application of the information, such as requiring participants to calculate and measure out a dose,[30, 31] or demonstrate the use of a medical device according to their understanding of written instructions. With respect to OTC medicine information, user testing has only been utilized

in a small number of published studies in the development and/or testing of OTC medicine information specifically.[18, 32-34] Routine user testing can be a method by which to iteratively improve OTC labeling (with its effectiveness demonstrated previously[32, 33]), thus contributing to the development of WMI that supports the universal precautions approach to health literacy.[11] With enhancement of normal user testing practice, this can help identify underlying issues impacting OTC medication use and medication safety which should be addressed, whether through improved labelling or via other means, in order to ensure safe and effective consumer self-management.

There are some limitations in the present study. As user testing is conducted under controlled conditions, disparities may exist when comparing the understanding of the key point(s) of information in an interview compared to when consumers actually use OTC medicines in self-management. Only two scenarios exploring proposed behaviors were presented to participants which impacted the scope of the projected application of key points of information examined. However, these are two important scenarios that can adversely impact quality use of medicines. In addition, it should be noted that consumer understanding of the general advice to store medicines out of the reach of children was not explicitly evaluated, as the focus was on the understanding and application of the product-specific storage directions. In the wider context, this is a relevant issue that must also be taken into consideration.

Conclusions

Information on a label regarding dosage and storage may not always be interpreted and acted upon as intended by WMI developers. When presented with hypothetical real-life scenarios, people may choose to disregard aspects of the directions for use, as seen by the frequent modification of dosing intervals, underpinned by various factors. Storage information on a label

may not always be interpreted as appropriate examples of storage locations in the home. Together, these inappropriate behaviors in response to dosage and storage information can potentially impact the quality use of OTC medicines such as diclofenac. User testing can be used as a method to identify health literacy issues, depending on the items included as part of the user testing questionnaire and process itself. Thus, through the identification of these proposed behaviors, these can be used to inform improvements to WMI that can enhance their quality and may also lead to improved health literacy through the optimized communication of medicine information. This is of particular importance in the context of OTC medication use in self-management.

References

1.   Institute of Medicine. *Health literacy: a prescription to end confusion*. Washington, D.C.:

        National Academies Press; 2004.

2.   Nutbeam D. Health literacy as a public health goal: a challenge for contemporary health

        education and communication strategies into the 21st century. *Health Promot Int.*

        2000;15:259-267.

3.   Parker RM, Baker DW, Williams MV, Nurss JR. The test of functional health literacy in

        adults: a new instrument for measuring patients' literacy skills. *J Gen Intern Med.*

        1995;10:537-541.

4.   Baker DW, Wolf MS, Feinglass J, Thompson JA, Gazmararian JA, Huang J. Health literacy

        and mortality among elderly persons. *Arch Intern Med.* 2007;167:1503-1509.

5.   Berkman ND, Sheridan SL, Donahue KE, Halpern DJ, Crotty K. Low health literacy and health

        outcomes: an updated systematic review. *Ann Intern Med.* 2011;155:97-107.

6.   Wolf MS, Gazmararian JA, Baker DW. Health literacy and functional health status among

        older adults. *Arch Intern Med.* 2005;165:1946-1952.

7.   Koo MM, Krass I, Aslani P. Patient characteristics influencing evaluation of written

        medicine information: lessons for patient education. *Ann Pharmacother.* 2005;39:1434-

        1440.

8.   Luk A, Aslani P. Tools used to evaluate written medicine and health information: document

        and user perspectives. *Health Educ Behav.* 2011;38:389-403.

9.   Australian Bureau of Statistics. Health literacy. *4102.0- Australian social trends, June 2009.*

        http://www.abs.gov.au/AUSSTATS/abs@.nsf/Lookup/4102.0Main+Features20June+2009.

        Published June 30 2009. Updated December 23 2009. Accessed June 01 2016.

10.   Raynor DKT. Health literacy: is it time to shift our focus from patient to provider?. *BMJ.* 2012;344:e2188.

11.   Brega AG, Barnard J, Mabachi NM, et al. AHRQ health literacy universal precautions toolkit. 2nd ed. Rockville, M.D.: Agency for Healthcare Research and Quality; 2015.

12.   Raynor DK. User testing in developing patient medication information in Europe. *Res Social Adm Pharm.* 2013;9:640-645.

13.   Sless D, Shrensky R. *Writing about medicines for people: usability guidelines for Consumer Medicine Information.* 3rd ed. Sydney, Australia: Australian Self-Medication Industry; 2006.

14.   Jay E, Aslani P, Raynor DK. User testing of consumer medicine information in Australia. *Health Educ J.* 2011;70:420-427.

15.   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.* 2011;83:404-410.

16.   Medicines and Healthcare products Regulatory Agency. Always read the leaflet: Getting the best information with every medicine. Report of the Committee on Safety of Medicines Working Group on Patient Information. London, UK: The Stationery Office; 2005.

17.   Communication Research Institute of Australia. Labelling code of practice: designing usable non-prescription medicine labels for consumers. Canberra, Australia: Communication Research Press; 2004.

18.   Aslani P, Hamrosi K, Feletto E, et al. Investigating Consumer Medicine Information (I-CMI) project. Sydney, Australia: The Pharmacy Guild of Australia, Australian Government Department of Health and Ageing; 2010.

19. Department of Health and Human Services, Food and Drug Administration. Over-the-counter human drugs; Labeling requirements. *Federal Register.* 1999;64:13254-13303.

20. Australian Government Department of Health and Ageing Therapeutic Goods Administration. Guideline for the labelling of medicines: draft- version 1.0, August 2014. Australian Capital Territory, Australia: Therapeutic Goods Administration; 2014.

21. Tong V, Raynor DK, Aslani P. 'It's all there in black and white' – or is it? Consumer perspectives on the proposed Australian Medicine Information Box over-the-counter label format [published online July 31 2015]. *Health Expect.* 2015. doi: 10.1111/hex.12389.

22. Tong V, Raynor DK, Hamrosi KK, Acharya B, Panchal N, Aslani P. Consumer opinions on existing and proposed Australian over-the-counter medicine labeling strategies in comparison with the standardized US Drug Facts label [published online February 09 2016]. *Ther Innov Regul Sci.* 2016. doi: 10.1177/2168479016628301.

23. Voltaren® Rapid 25 (10 tablets): Novartis Consumer Health Australasia Pty Ltd; n.d..

24. Voltaren® Rapid 25 [package insert]. Mulgrave, VIC: Novartis Consumer Health Australasia Pty Ltd; 2008.

25. Consumer Healthcare Products Association. Consumer attitudes on over-the-counter (OTC) medicine use, storage, and disposal. http://www.chpa.org/MedicineUseStorageDisposal.aspx. 2015 Accessed June 01 2016.

26. European Commission. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use. Brussels, Belgium: European Commission; 2001.

27. Aslani P. Consumer medicine information conundrums. *Aust Prescr.* 2007;30:122-124.

28. Harris interactive Inc. Attitudes and beliefs about the use of over-the-counter medicines: a dose of reality; a national survey of consumers and health professionals. http://www.bemedwise.org/survey/final_survey.pdf. Published 2002. Accessed June 01 2016.

29. Stosic R, Dunagan F, Palmer H, Fowler T, Adams I. Responsible self-medication: perceived risks and benefits of over-the-counter analgesic use. *Int J Pharm Pract.* 2011;19:236-245.

30. Simon HK, Weinkle DA. Over-the-counter medications: do parents give what they intend to give? *Arch Pediatr Adolesc Med.* 1997;151:654-656.

31. Emmerton L, Chaw XY, Kelly F, et al. Management of children's fever by parents and caregivers: practical measurement of functional health literacy. *J Child Health Care.* 2014;18:302-313.

32. Rogers D, Shulman A, Sless D, Beach R. Designing better medicine labels: report to PHARM. Australia: Communication Research Institute of Australia; 1995.

33. Sless D, Tyers A. Medicine labelling for consumers. Australia: Communication Research Institute of Australia; n.d..

34. Dickinson D, Raynor DK, Duman M. Patient information leaflets for medicines: using consumer testing to determine the most effective design. *Patient Educ Couns.* 2001;43:147-159.