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Comparative user testing of Australian and UK over-the-counter labels and leaflets for diclofenac

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2. Tong V, Raynor DK, Aslani P. User testing of over-the-counter medicine labels and leaflets in Australia and UK: a comparative study. *Australasian Pharmaceutical Science Association Annual Conference*. 2013. Dunedin, New Zealand. (oral presentation)

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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Comparative user testing of Australian and UK over-the-counter labels and leaflets for diclofenac

Abstract

Background

Limited research has evaluated the consumer usability of written information available with similar over-the-counter (OTC) products in different countries. This study evaluated the usability of labels and leaflets for Australian and UK OTC diclofenac products, and; explored consumer perspectives on their design, content, usability, and potential improvements.

Methods

Australian and UK OTC diclofenac products were selected for 'user testing'. Demographically matched groups of Australian and UK consumers were recruited to user test each label and leaflet set to determine whether 9 salient clinical messages could be found and understood. Consumer perspectives on the tested label and leaflet were explored using semi-structured interviews as part of user testing.

Results

Forty consumers user tested the Voltaren® Rapid 25 (Australia) and Voltarol® Pain-Eze Extra Strength 25mg tablets (UK) information (10 participants per brand per country). Dosage, maximum daily dose, and contraindications information was found and understood by most (≥ 9/10 per group), except Voltaren® dosage which was misunderstood by 4/20. However, 12/20 could not locate the maximum duration of continuous use in the Voltaren® leaflet. Participants had difficulty determining that another NSAID could not be used with

diclofenac (7/20 and 9/20 understood this in the Voltaren® and Voltarol® groups, respectively). Suggested label and leaflet improvements included increased font size, bolding/highlighting, and color.

Conclusion

When evaluated in both countries, not all key clinical information was effectively communicated by information accompanying Australian and UK diclofenac products. Improvements in how information is communicated are needed.

Key words

User testing; non-prescription drugs; drug labeling; medication safety; consumers.

Background

Prescription-only to over-the-counter (OTC) medicine rescheduling results in greater consumer accessibility to such medicines.[1,2] Consumers generally perceive OTC medicines as safe[3] even though they are not risk-free. Legislation provides minimum requirements to ensure the necessary provision of information with OTC medicines to ensure safe and appropriate use of the products. Labels and leaflets are medicine-specific sources of manufacturer-developed information that are available with products, depending on the regulatory context. In the European Union (EU) and Australia, OTC labels are mandatory.[4,5] However, in contrast to the EU (where all medicines must have leaflets available as package inserts[4]), only Pharmacist Only (Schedule 3)[2] OTC medicines (a subcategory of OTC medicines that must be supplied by a pharmacist to consumers[6]) and prescription medicines must legally have leaflets in Australia.[7]

Methods used to evaluate written OTC medicine information can vary significantly.[8] User testing is an effective method by which the performance of written medicine information (WMI) can be examined in relation to consumers' ability to find and understand key medicine information.[9-11] Although consumer involvement in leaflet evaluation is legally required in the EU,[12] it is not a legislative requirement for OTC labels in Australia or the United Kingdom (UK). Rather, it is recommended in labelling guidelines.[13,14] Furthermore, user testing is not routinely carried out for leaflets in Australia.[15] Therefore, the extent to which user testing is undertaken for OTC labels and leaflets in Australia is unknown, which could have negative implications on the quality of the information and OTC medication safety.

Non-steroidal anti-inflammatory drugs (NSAIDs) are widely used by consumers. One NSAID which has been available OTC, and which has attracted regulatory attention internationally, is diclofenac. Oral diclofenac was recently rescheduled (effective from 15 January 2015) to prescription only status in the UK due to increased cardiovascular risks associated with prolonged use or use at high doses.[16] Although available safety data were reviewed by the Australian Therapeutic Goods Administration,[17] no scheduling changes were made in Australia for diclofenac, where it is still available OTC in pharmacies. With the potential for medicine scheduling to change due to emerging evidence of medicine risks, it is important to ensure that information accompanying OTC medicines demonstrate optimal quality and usability, where user testing data generated in two different countries may be useful to inform the development of effective OTC medicine information for consumers.

Limited published user testing studies have evaluated the performance or usability of existing OTC labels and leaflets.[8] Previous international leaflet comparisons have highlighted significant variability in leaflet quality,[18,19] where Australian leaflets for prescription medicines demonstrated greater mean compliance to the United States Keystone Consensus Criterion 8 (recommendations pertinent to optimizing WMI design and readability) than UK leaflets.[19] However, these evaluations mainly involved prescription WMI and were not conducted with consumers. Although a recent study has investigated the perspectives of consumers and health care professionals on a leaflet for OTC diclofenac,[20] it did not aim to evaluate its fitness-for-purpose using performance-based user testing methods recommended in EU guidelines.[12]

To the best of our knowledge, there have been no studies to date that have evaluated and compared the usability of OTC labels and leaflets with consumers for similar products available in different countries to generate data that could be used to improve OTC label and leaflet quality internationally. Therefore, this study aimed to:

1) Evaluate the usability of Australian and UK OTC labels and leaflets in both Australia and the UK with consumers, using diclofenac as the exemplar study medicine, and;
2) Explore consumer opinions on the design, content, usability, and improvements that may be required for the user tested labels and leaflets.

Methods

This study received ethics approval from the Human Research Ethics Committee of Institution 1 and the Research Ethics Committee at Institution 2. Participants were reimbursed for their time.

Rationale for selecting diclofenac

Diclofenac was chosen as the exemplar study medicine because, firstly, at the time of the study, it was available on prescription and OTC in both countries. Secondly, as a Pharmacist Only medicine in Australia, it is required by law to have a leaflet,[7] which could then be compared with the leaflet for a UK diclofenac product. Thirdly, diclofenac brands were available in both countries from the same manufacturer. This allowed for a case study between the two countries of whether differences existed in the usability of WMI developed by the same manufacturer for comparable OTC products (same active ingredient, medicine strength, pack size, and only available for purchase from pharmacies).

The two OTC study medicine brands chosen for consumer evaluation were Voltaren® Rapid 25 tablets (Novartis Consumer Health Australasia Pty Ltd, Australia), and Voltarol® Pain-Eze Extra Strength 25mg tablets (Novartis Consumer Health, UK). The Voltaren® leaflet was last revised in January 2008[21] and the Voltarol® leaflet was last approved in May 2011.[22]

Modified user testing

User testing[10] was conducted to gain insight into consumer understanding and perspectives on the study OTC labels and leaflets in Australia and the UK. Primary outcome measures included the ability to find and understand information.[10] The user testing process was modified to test both the label and leaflet together as they are complementary information sources for OTC medicines, rather than stand-alone.

User testing questionnaire (UTQ) development

Key clinical points of information for diclofenac were identified by the research team using the OTC labels and leaflets[21-24] and reference texts,[25,26] and these were included in the core user testing questionnaire (UTQ) utilized for both study medicine brands. The UTQ consisted of 9 items. This was shorter than the 12 to 15-item UTQs commonly used[10] due to the total length of the face-to-face interview sessions, which included user testing and a qualitative interview component.[27]

The order of UTQ items was standardized. Three of the 9 UTQ items were selected to be asked first. The first two could be answered using either the label or leaflet, whereas the third item could only be answered using the leaflet. The intention of this was two-fold to examine:

- Whether both labels adequately communicated that a leaflet was enclosed, and
- Whether participants would consult this leaflet to find the relevant information.

The remainder of the UTQ items were then ordered to avoid key clinical points directly corresponding to the OTC label and/or leaflet information order. A short semi-structured

interview protocol was also developed to ascertain consumer perspectives on the design, content, usability, and improvements that may be required for the user tested WMI. The core UTQ and the semi-structured interview protocol were piloted for face and content validity. No further changes were made.

Recruitment and sampling frame

Interviews were conducted between April 2013 and April 2014. In accordance with user testing protocol and its use as a diagnostic process,[10] user testing was conducted with 10 consumers per group. Demographically matched groups of 10 consumers were recruited in both Australia and the UK (Table 1).

Australian participants were recruited through the distribution of flyers, online advertisements, and a market research company. UK participants were recruited using the consumer database of a spin-out company from Institution 2. This company is a health communications and testing company whose database consisted of people who have agreed to be contacted regarding potential participation in user testing studies. The same inclusion/exclusion criteria still applied, with an additional criterion specifying that the consumer should not have participated in a user testing study in the 6 months prior to study participation.

Once recruited, participants were allocated to user test either the Voltaren® or Voltarol® WMI based on their demographics to match the study criteria per group (similar to that used in a previous study[28]). These criteria ensured demographic diversity within each group (Table 1).

[Insert Table 1. Criteria relevant to study participant recruitment]

Table 1. Criteria relevant to study participant recruitment

Relevant criteria	Details
Inclusion criteria	Consumers could participate if they were: • 18 years or older; • Not currently using the study medicine diclofenac, or giving it to a child or person(s) under their care, and had not done so in the 6 months prior to their study participation; • Had purchased and used an OTC medicine (either for themselves or for a person under their care) in the 6 months immediately prior to study participation, and; • Proficient in English i.e. able to read and understand the consent form, participant information sheet, and study materials without the need for assistance from a translator.
Exclusion criteria	Consumers were ineligible to participate if: • Currently using a medicine from the same therapeutic class (NSAIDs for relief of pain), or giving one such medicine to a child or person(s) under their care, and/or has done so in the 3 months prior to their participation in the study; • A health care professional (whether practicing or retired) or who is currently employed in an occupation which primarily involves medicine information, or; • Significantly impaired visually (self-reported) or cognitively.

Relevant criteria	Details
Criteria used to demographically match study groups	Each group of 10 participants had: 1. At least 1 participant in each of the following age brackets: 18-29, 30-39, 40-49, 50-59, 60-69, and 70+ years; 2. At least 3 participants representing each gender; 3. No more than 3 participants who have completed a university degree or attained a higher qualification, and; 4. At least 2 participants who were currently unemployed, retired from the workforce, or did not routinely use written information as part of their daily professional practice.

Study process and data collection

All face-to-face user testing interviews were conducted by the same researcher (Author 1) at Institution 1 or the spin-out company (Institution 2). Upon arrival, the participant information statement and consent form were provided for the participant to read and complete. The user testing interview was then conducted using a standardized process (Figure 1).

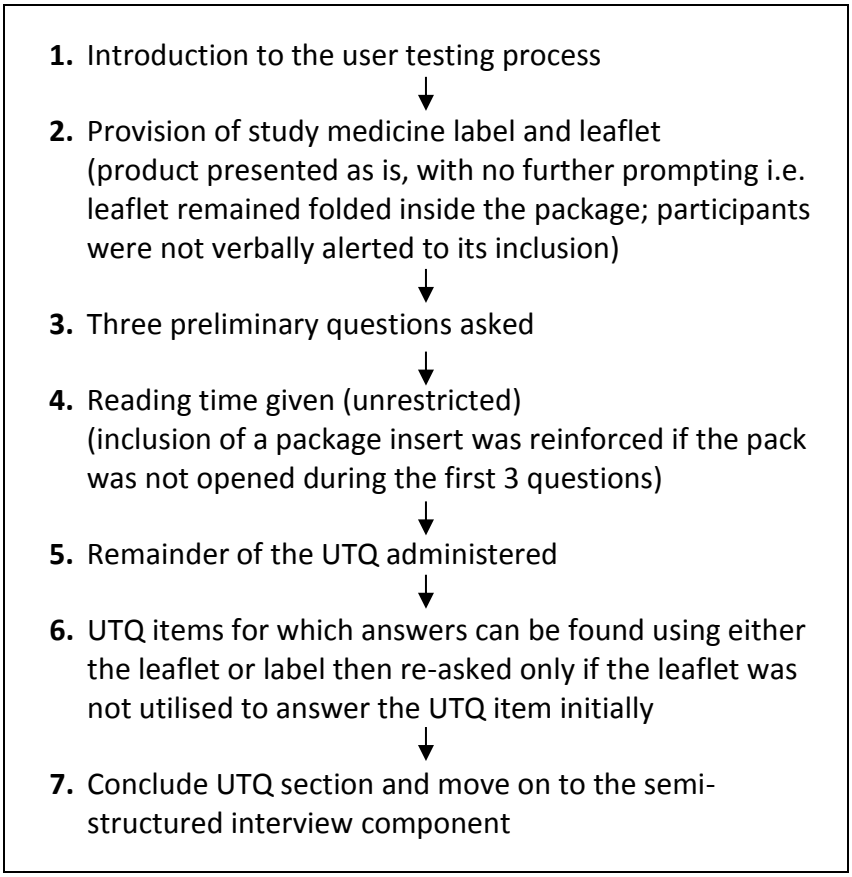

Figure 1. Step-by-step flowchart outlining the modified user testing process

When the label and leaflet were provided to the participant (Step 2, Figure 1), the participant was requested to imagine that they had bought this medicine from the pharmacy and that the UTQ to follow could involve various hypothetical scenarios. Once the UTQ was completed, participants were asked to provide their feedback on the user tested label and leaflet via a short semi-structured interview. Additional demographic information was collected at the end of the interview to supplement the information gathered during the recruitment process, which included adapted questions[28,29] on self-reported understanding of WMI and perceived confidence regarding medical form completion.

Data analysis

All interviews were audio-recorded with permission from the participants. All responses were transcribed verbatim and coded by one researcher (Author 1) according to the UTQ indicative answers which had been determined via consensus among the research team members. Coding of the participant responses reflected the primary outcome measures of whether key information was found and understood. A second researcher (Author 3) also reviewed any participant responses that did not fully correspond to the UTQ indicative answers to ensure consensus in the final data coding.

Transcripts of the semi-structured interview component were thematically analyzed,[30] where matrix displays[31] were constructed to help identify and refine the emergent themes and subthemes within each group. Data were first analyzed within each individual group of Australian and UK consumers. As a number of trends in consumer perspectives between the Australian and UK groups were identified, core themes have been pooled for reporting in this paper.

Results

A total of 20 Australian and 20 UK consumers participated in the study (Table 2). The majority (n=35) reported feeling quite or extremely confident filling in medical forms. Most did not need help to read WMI (n=29) and did not have difficulty learning about their medicines or medical condition (n=24) (Supplementary Table S1).

[Insert Table 2. Summary of participant demographics]

Table 2. Summary of participant demographics

Demographic		Voltaren® Australia (n=10)	Voltaren® UK (n=10)	Voltarol® Australia (n=10)	Voltarol® UK (n=10)	Total (n=40)
Gender	Male	5	5	4	4	18
	Female	5	5	6	6	22
Age (years)	18-29	3	3	2	2	10
	30-49	2	4	4	5	15
	50-69	4	2	3	2	11
	70+	1	1	1	1	4
Highest level of education attained	School certificate/ GCSE[a] (Year 10) or below	0	2	1	3	6

Demographic		Voltaren® Australia (n=10)	Voltaren® UK (n=10)	Voltarol® Australia (n=10)	Voltarol® UK (n=10)	Total (n=40)
	Higher School Certificate/ A Level[b] (Year 12) or college qualification	7	6	6	5	24
	Bachelor's degree or higher	3	2	3	2	10
Regular use of written information as part of occupation	Yes	6	5	5	5	21
	No	4	5	5	5	19
Main language spoken at home	English	9	10	8	10	37
	Other	1	0	2	0	3
Country of birth	Australia	8	0	8	1	17
	UK	0	10	0	9	19
	Other	2	0	2	0	4

[a]GCSE = UK General Certificate of Secondary Education

[b]A level = UK General Certificate of Education Advanced Level

User testing findings

Generally, across both Australian and UK groups, the information accompanying both the Voltaren® and Voltarol® products adequately communicated some of the key clinical points of information, namely contraindication in pregnancy and stomach ulcer, maximum daily dose, action to be taken if vomiting blood, and warnings regarding driving while using the medicine (Table 3).

Regarding dosage, all participants who user tested the Voltarol® information were able to find and understand it. However, 4/20 participants misunderstood the Voltaren® dosage on the label. The dosing interval of 8 hours (expressed as "8 hourly"[23]) was interpreted as a dose should be taken every hour (for 8 hours or up to 8 tablets).

In the Australian and UK groups, 5 and 7 participants, respectively, were unable to find the maximum treatment duration of 7 days in the Voltaren® leaflet (Table 3). However, when attempting to locate this information, participants located that its use should not exceed more than a few days at a time in another part of the leaflet.

Determining from the leaflet that the concomitant use of two NSAIDs is not advised (Table 3, UTQ item 7) proved to be problematic for some participants across all groups. Only 7/20 and 9/20 participants correctly found and understood this information when the Voltaren® and Voltarol® WMI was user tested, respectively. Specifically, when using the Voltaren® leaflet, some only read the instruction to not use any medicines for arthritis whilst taking Voltaren® and dismissed its relevance to the scenario, and thus did not read on to find the relevant information. Participants also stated they were trying to look for terms such as "cold and flu" or "Nurofen®". Other participants found information stating they should speak to their doctor or pharmacist if they were taking other medicines, or concluded that

the two should not be used together based on information stating to avoid the medicine if allergic to anti-inflammatories, which was not relevant to the scenario. Anti-inflammatory medicines were mentioned in multiple places under the one Voltarol® section heading, which contributed to a few participants being unable to demonstrate complete understanding that diclofenac could not be used together with Nurofen® Cold and Flu.

The majority of participants did not locate the information relevant to the action to be taken if heartburn was experienced (UTQ item 3), aside from the Voltarol® UK group (Table 3). Only 5/20 found and understood this clinical point in the Voltaren® groups combined, compared with 5/10 and 8/10 in the Australian and UK Voltarol® groups, respectively (Table 3). Participants did not attempt to access the enclosed leaflet. Some participants extrapolated the action to be taken from the label, for instance, in relation to an allergic reaction or if symptoms do not resolve (i.e. to consult their doctor and/or stop taking the medicine). Others said in general that they would just stop taking the medicine and/or see their doctor. Of those who said that there was no heartburn-specific information on the label, when asked where they would find the answer to this question, most participants said they would consult other information sources such as the pharmacist, doctor, or the Internet.

The UTQ items that could be answered using either the label or leaflet (UTQ items 1, 2, 4, 5, and 7, as indicated in Table 3) were re-asked if the participant initially answered the question using only the label. Almost all participants were able to locate the relevant key clinical point in the leaflet when the questions were re-asked (Supplementary Table S2).

[Insert Table 3. Summary of Australian and UK user testing results for Voltaren® and Voltarol® labels and leaflets]

Table 3. Summary of Australian and UK user testing results for Voltaren® and Voltarol® labels and leaflets

Key clinical point of information	User testing questionnaire (UTQ) item	Answer can be found in the:		Voltaren® Australia (n=10)		Voltaren® UK (n=10)		Voltarol® Australia (n= 10)		Voltarol® UK (n=10)	
		Leaflet	Label + leaflet	Found	Under-stood	Found	Under-stood	Found	Under-stood	Found	Under-stood
Dosage	1. You are taking [insert full product name] to relieve your back pain. How much should you take and how often?		✓	10	9	10	7	10	10	10	10
Contra-indication (pregnancy)	2. If you are a pregnant female and your baby is due next month, what does the information say about taking [insert brand name]?		✓	10	9	10	10	10	9	10	10

Key clinical point of information	User testing questionnaire (UTQ) item	Answer can be found in the:		Voltaren® Australia (n=10)		Voltaren® UK (n=10)		Voltarol® Australia (n= 10)		Voltarol® UK (n=10)	
		Leaflet	Label + leaflet	Found	Under-stood	Found	Under-stood	Found	Under-stood	Found	Under-stood
Side effect (heartburn) and action to be taken	3. You have taken [insert brand name] for the past few days. You start to get heartburn that you have never experienced before. It is concerning you. What should you do?	✓		1	1	4	4	5	5	8	8
Maximum daily dose	4. You have already taken [SIX (Voltaren®) / TWO (Voltarol®)] [insert brand name] tablets so far today for your pain. How many more tablets can you [still] take today?		✓	10	10	10	10	10	10	10	10

Key clinical point of information	User testing questionnaire (UTQ) item	Answer can be found in the:		Voltaren® Australia (n=10)		Voltaren® UK (n=10)		Voltarol® Australia (n= 10)		Voltarol® UK (n=10)	
		Leaflet	Label + leaflet	Found	Under-stood	Found	Under-stood	Found	Under-stood	Found	Under-stood
Contra-indication (stomach ulcer)	5. Your father has just bought some [insert brand name] from the pharmacy. He tells you that he forgot to tell the pharmacist that he has a stomach ulcer at the moment. What would you tell your father about taking [insert brand name]?		✓	10	10	10	10	9	9	9	9

Key clinical point of information	User testing questionnaire (UTQ) item	Answer can be found in the:		Voltaren® Australia (n=10)		Voltaren® UK (n=10)		Voltarol® Australia (n= 10)		Voltarol® UK (n=10)	
		Leaflet	Label + leaflet	Found	Under-stood	Found	Under-stood	Found	Under-stood	Found	Under-stood
Maximum continuous use	6. What is the maximum number of days that [insert brand name] can be used for at a time?	✓		5	5	3	3	10	10	10	10
Concomi-tant use of NSAIDs unadvised	7. SHOW CARD**:** A picture of Nurofen® Cold and Flu tablets Active ingredient: Ibuprofen (NSAID anti-inflammatory) Pseudoephedrine (relieves blocked noses) You are currently taking [insert brand		✓	5	3	4	4	7	6	5	3

Key clinical point of information	User testing questionnaire (UTQ) item	Answer can be found in the:		Voltaren® Australia (n=10)		Voltaren® UK (n=10)		Voltarol® Australia (n= 10)		Voltarol® UK (n=10)	
		Leaflet	Label + leaflet	Found	Under-stood	Found	Under-stood	Found	Under-stood	Found	Under-stood
	name] tablets and have just come down with a cold. You have some Nurofen® Cold and Flu tablets at home. It contains an anti-inflammatory pain reliever called ibuprofen. What does the information say about taking this medicine together with [insert brand name]?										

Key clinical point of information	User testing questionnaire (UTQ) item	Answer can be found in the:		Voltaren® Australia (n=10)		Voltaren® UK (n=10)		Voltarol® Australia (n= 10)		Voltarol® UK (n=10)	
		Leaflet	Label + leaflet	Found	Under-stood	Found	Under-stood	Found	Under-stood	Found	Under-stood
Serious side effect (vomiting blood) and action to be taken	8. You have been taking [insert brand name] for the past few days. This morning, you felt ill and vomited. You noticed that your vomit was blood-colored, and contained small brown lumps. What should you do?	✓		8	7	10	10	10	10	10	10
Warnings regarding driving	9. Why should you take care when taking [insert brand name] if you drive?	✓		10	10	10	10	10	9	10	10

Participant perspectives on the user tested OTC WMI

Mixed opinions were raised regarding the study OTC WMI (Table 4). Many strategies proposed to improve the OTC labels and leaflets (Table 5) were clearly associated with the perceived consumer dislikes raised (Table 4), for instance:

- Increasing font size (to overcome the perceived small font),
- Superior bolding/highlighting (to better emphasize key information),
- Deletion of content (where content was seen as too much and/or repetitive), and
- Re-organization of content (to address suboptimal information grouping).

[Insert Table 4. Summary of consumer perspectives on the user tested WMI for diclofenac common to both Australian and UK groups]

[Insert Table 5. Summary of core suggested improvements for Voltaren® and Voltarol® OTC labels and leaflets provided by all groups]

Table 4. Summary of consumer perspectives on the user tested WMI for diclofenac common to both Australian and UK groups

OTC WMI	Positives	Negatives	Illustrative quote(s)
Voltaren® label	• Clear layout overall • Sufficient content covering key points • Dosage easy to locate • Use of bullet points • Highlighted headings	• Small font • Dosage discrepancy between label and leaflet • Dosage on label unclear, ambiguous, and could be misconstrued • Confusing pregnancy statement	1. *"Every eight hours, up to eight [tablets a day]. So I would be confused how that would add up to eight, based on the one [tablet], where it should say one to two [tablets] like it says on the leaflet." (Participant UTP16-AUS)* 2. *"[Do not use during] your first six months [of pregnancy, unless on doctor's advice], [do not use at all in the last] three months……. I've got no months' leeway." (UTP53-UK)*
Voltarol® label	• Clear layout overall • Sufficient content covering key points • Dosage easy to locate • Easy to read • Bolded information	• Small font • A lot of information • Lack of distinct sectioning and/or highlighting of key information	3. *"There's not as much to read per line which makes it easier to digest." (UTP75-UK)* 4. *"Just a sea of information in a small space." (UTP26-AUS)*

OTC WMI	Positives	Negatives	Illustrative quote(s)
Voltaren® leaflet	• Relatively clear ordering of information, on occasion	• Hard to navigate • Small font • Too much content • Content repetition • Suboptimal organization/ information grouping • Ineffective use of bolding • Suboptimal headings • Content discrepancies between label and leaflet, such as dosage information • Advice to avoid concomitant use of multiple NSAIDs not clear enough	5. *"Things are bold in text and things aren't bold and you're like 'What?!' Nothing stands out. It's designed to not give information." (UTP82-AUS)* 6. *"It should say don't take any… other NSAIDs, not if you have arthritis. Because people will read it and be like 'I don't have arthritis. I'll take it'…… It's not clear at all. It's not clear enough. It should say don't take it with any other of those [NSAIDs]." (UTP27-AUS)*

OTC WMI	Positives	Negatives	Illustrative quote(s)
		• Inconsistent presentation of information regarding maximum duration of use	
Voltarol® leaflet	• Helpful headings • Relatively good use of bolding • Complete/ comprehensive content • Information worded fairly	• Hard to navigate • Small font • Too much content • Content repetition • Suboptimal organization/ grouping of information • Medical jargon/certain terms possibly hard to understand or could confuse • Difficult to find information regarding NSAID use	7. *"I suppose when we're talking about the use of something else … like the ibuprofen- the problem is they, they put the various things about ibuprofen in different [sub]sections… of the leaflet." (UTP75-UK)*

Table 5. Summary of core suggested improvements for Voltaren® and Voltarol® OTC labels and leaflets provided by all groups

	Label		Leaflet	
	Voltaren®	Voltarol®	Voltaren®	Voltarol®
Design	• Increase font size • Bold/highlight key terms or points			
	• More prominent "Dosage" • Utilize different color(s) to present certain information • Re-order information (Aus)* • Increase dot point spacing (Aus) • Separate heading for	• Bold "Do not take" • Place "Read the enclosed leaflet" at the top • Utilize different color(s) to present certain information • Re-order information (Aus) • More spacing (Aus) • Include some headings (UK); make headings clearer (Aus)	• Clearer, more highlighted headings/sections • Different colored section(s)/information • Re-order information e.g. side effects • Black font (UK)** • Tabulate dosage (Aus) • Use similar format as label e.g. dot points, banded headings	• Bold/highlight not to use other NSAIDs • Highlight pregnancy information, subheadings • Color e.g. red for important information • Re-order information • Group related information • Black print • Headings at top of column (Aus)

	Label		Leaflet	
	Voltaren®	Voltarol®	Voltaren®	Voltarol®
	pregnancy information (Aus)		(UK) • Highlight updated information (UK)	• Split (Aus) or tabulate (UK) Section 2 (before you take Voltarol®) • Portrait layout/2-column A4 (Aus)
Content	• Ensure dosage on label corresponds to leaflet • Content addition e.g. specific treatment duration or side effects (Aus); all key ingredients (UK) • Content clarification e.g. "if necessary"	• Content addition e.g. driving warning (Aus); title (Aus); if taking other medicines (under "Speak to your doctor or pharmacist") (UK); consult pharmacist prior to purchase if you have any other conditions (UK) • Content deletion (Aus)	• Content addition: link to online leaflet (Aus); "turn overleaf" to distinguish first page (Aus); table of contents and numbered sections (UK); more about taking with other medicines (UK); treatment duration for migraines/ menstrual pain (Aus) • Reduce content	• Content addition: website (Aus); "do not take" with certain medicines (UK) • Content deletion: information about consulting a health care professional to reduce repetition (Aus); condense Section 2 (UK) • Content clarification: NSAID (UK); appropriate action to be taken if some rarer side effects experienced

	Label		Leaflet	
	Voltaren®	Voltarol®	Voltaren®	Voltarol®
	regarding dosage (Aus); "store below 30°C" (UK)		• Content clarification e.g. allergic reaction (UK), NSAID (UK)	(UK); ingredients (UK)
Wording	• Reword dosage • Simplify pregnancy warning • Reword and combine statements regarding prolonged use and not exceeding stated dose (UK)	• Plain English (Aus)	• Reword advice regarding avoiding concomitant use with other NSAIDs- delete reference to arthritis • Clearly specify maximum duration of continuous use consistently (in days) • Simplify headings (Aus)	• Plain English (Aus)

N.B Suggestions were proposed by participants in both Australian and UK groups, unless specified otherwise

*Aus = Suggestions proposed only by participant(s) in Australia

**UK = Suggestions proposed only by participant(s) in the United Kingdom

Discussion

When labels and leaflets for OTC diclofenac were evaluated by consumers, their usability varied depending on the key clinical point required to be found and understood. Although some WMI aspects were appreciated, consumers felt improvements were needed to improve factors such as design, grouping of information, and content. When using an OTC NSAID such as diclofenac, key information such as the directions for use, contraindications to use, and when to stop taking diclofenac or when to seek medical advice should be effectively communicated to consumers. Although many of these points were well found and understood in this study, not all participants correctly understood the dosage or that two OTC NSAIDs should not be used in combination, which is concerning in terms of OTC medication safety. OTC medication safety concerns associated with suboptimal WMI are further amplified if pharmacists do not provide appropriate advice to consumers purchasing the product from pharmacies.

Dosage information on the Australian Voltaren® label caused some confusion for a few Australian and UK participants. Although all participants could locate the dosage, significant misunderstanding of the dosing interval on the Voltaren® label as 1 hour instead of 8 hours, similarly identified in a recent study,[32] poses a serious medication safety concern. The wording of instructions and the complexity of the prescribed dosage regimen can impact people's understanding of dosages.[33] Consumers read OTC labels to obtain information regarding directions for use,[34] and dosage is seen as a very important point of information needed prior to OTC medication use.[35] Simple rewording of the dosing interval to "every 8

hours" on the Voltaren® label, in addition to ensuring that the dosage regimen presented in both the label and leaflet are the same, may help resolve this misunderstanding.

Participants in all groups were unable to locate the appropriate information in both leaflets to best respond to the scenario regarding whether the Nurofen® Cold and Flu product could be used together with diclofenac. Consumer difficulty in using leaflets has been previously reported,[36] where previous studies involving consumer evaluation of leaflets for OTC NSAID ibuprofen have also highlighted problematic areas impairing usability.[37,38] Consumers do not often refer to the active ingredient in medicines and can have limited understanding of the differences between active ingredients found in common OTC analgesics,[39] which could explain participants trying to look for reference to cold and flu or the brand name Nurofen® in the Voltaren® and Voltarol® leaflets. Participants' inability to find the reference to NSAIDs situated under the instruction that Voltaren® is not to be used concomitantly with arthritis medicines[21] may be attributable to inappropriate signposting of this information in the leaflet. As NSAIDs are not solely used in the management of arthritis, this may pose a medication safety issue if consumers use the leaflet to try and find this information when using NSAIDs bought without a prescription. Mention of anti-inflammatories in multiple locations within a single lengthy Voltarol® leaflet section may have contributed to difficulty in finding and/or understanding the most relevant information for the scenario. This also corresponds to consumer suggestions to condense this section. As consumers do not always discuss their OTC medication use with health care professionals,[40] this reiterates the importance for manufacturers to re-evaluate how best to convey this information in their WMI.

A notable difference between the performance of the Voltaren® and Voltarol® leaflet was that many participants were unable to find the maximum treatment duration using the Voltaren® leaflet. Participants primarily referred to the "How to take Voltaren® Rapid 25" section, which specified that it should not be used for longer than a few days at a time in general.[21] However, use of up to 7 days was located in the "What Voltaren® Rapid 25 is used for" section.[21] As the more cautious statement regarding restricting use to a few consecutive days was found by participants, potential clinically significant repercussions of not locating the maximum use of 7 days are minimized. However, consideration should be made to consistently communicating and grouping relevant information together to ensure consumers can locate and appropriately understand information like treatment duration.

Insight was gained into consumers' perceptions of the usability of the WMI via qualitative feedback. For instance, consumers found the Voltaren® label pregnancy warning confusing, despite almost all participants being able to find and understand it. This pregnancy warning is a mandated warning for inclusion on the labels of OTC NSAIDs in Australia.[41] Accordingly, due to its widespread use, it may be beneficial for regulators to consider simplifying this advisory statement, as suggested by both Australian and UK groups. Regarding the Voltaren® leaflet, in many instances, this qualitative feedback supported the quantitative user testing findings. Perceived shortcomings and subsequent suggestions for improvement in the present study were comparable to those reported by Pires and Cavaco[20] for a package insert for an OTC diclofenac product. Although use of some bolding is advocated,[11,28,42] the extensive bolding used in the Voltaren® leaflet was negatively viewed by the participants. Interestingly, although it appears that the Voltaren® leaflet has adhered to the recommendation that instructions should be bolded, as stipulated in Australian WMI leaflet development guidelines,[11] the large number of instructions contained in the leaflet itself

have led to extensive bolding. Therefore, this emphasizes the importance of involving consumers in evaluating WMI to ensure that the implemented design principles have the intended effect on the target audience. In addition, the importance of consistent use of effective design and simple language to communicate information is reiterated in the suggested improvements of larger font and better bolding across all of the study OTC labels and leaflets, among other suggestions. Label and leaflet formatting consistencies should also be used to support optimal grouping of information that complements how consumers navigate medicine information.

Overall, when interpreting the present study findings, regulatory influences and WMI quality drivers should be taken into account. The requirement for leaflets to be evaluated with consumers in the EU[12] may explain why the Voltarol® leaflet performed better when user tested in both countries. However, based on the present study, both leaflets did not meet the criteria for satisfactory user testing as implemented in the EU[12] (i.e. 16/20 participants able to find and understand the key information for each UTQ item). Furthermore, certain key clinical points were not well communicated by the Voltaren® WMI, when user tested in both Australia and the UK. This suggests that key clinical points that are not effectively communicated will still be problematic when WMI is used by consumers in different contexts. With many pharmaceutical companies operating internationally, usability of OTC WMI developed in-house must be maximized from the outset, which may promote positive flow-on effects for high quality OTC WMI internationally.

This study has some limitations. User testing was utilized in this study primarily as a diagnostic tool to identify problem areas in the labels and/or leaflets and to compare them across the WMI studied. In that context, it is standard practice to use groups of 10

participants. However, this group size does not provide an indication of the proportion of consumers within the general population that would be affected by the identified WMI usability deficiencies. As this was not the aim of the present study, additional research may be beneficial to provide further insight. Also, as user testing is an iterative process,[10] future work should examine redeveloping the leaflets and testing them in a second round of user testing with demographically matched groups to improve their quality. In addition, as a shorter UTQ was used, additional items could be included in future user testing studies to evaluate whether other key information is also adequately communicated by the diclofenac WMI.

Conclusions

To the best of our knowledge, this is the first study to user test Australian and UK OTC medicine information available for different brands of a similar product in both countries. Labels and/or leaflets did not adequately communicate all key clinical points that were evaluated as part of the user testing questionnaire. The misunderstanding of the Voltaren® dosage, together with many participants being unable to determine that two OTC NSAID-containing products should not be used together, could lead to unsafe self-medication. The information accompanying the UK Voltarol® product performed better overall than its Australian Voltaren® counterpart when user tested in both countries. Inconsistencies exist within the information provided with each product and between the two products. Thus, it is clear that improvements to these OTC labels and leaflets are needed, as seen from the degree of consistency between both perceived and actual usability. Both the qualitative and quantitative findings are useful for manufacturers responsible for developing WMI to action the necessary improvements to optimize the quality of these OTC WMI sources and apply the learnings to WMI sources for other OTC products. Consumer testing of existing and future OTC labels and leaflets via user testing can assist in the development of usable product-specific OTC medicine information sources. With respect to the broader potential impact of this research, this comparative study reinforces the importance of user testing and highlights that there are opportunities to better engage in international harmonization to improve the quality of WMI. As user testing does not seek to determine the proportion of the broader population impacted by WMI aspects denoting poorer usability, future research

is still needed to explore such prevalence to further support best practice in WMI development.

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