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Design and comprehensibility of over-the-counter product labels and leaflets- a narrative review

Introduction

Over-the-counter (OTC) availability of medicines supports consumer autonomy, enabling self-management of a variety of ailments by facilitating consumer access to medicines. However, OTC medicines must be supplied with appropriate medicine information to support treatment decision-making, alongside safe and effective use. Consumers obtain this information from health care professionals such as pharmacists [1-3], product labels [4, 5] and written medicine information leaflets (WMI) [1, 6].

Consumers use OTC labels (medicine information provided on the packaging) and WMI (leaflets provided with medicines, also referred to as Patient Information Leaflets) to further their understanding about a medicine's ingredients, relevant indication(s), directions for use and side effects [7], with similar information highly valued by consumers before starting an OTC medicine [1]. Consequently, OTC labels and WMI must deliver medicine information in an understandable manner.

Design and comprehensibility factors influence the degree to which medicine information is fit for purpose, and thus, are critical considerations in OTC label and WMI development. Various strategies have been implemented to ensure the quality of medicine information, such as OTC label standardisation in the United States (U.S.) [8] and mandatory consumer testing of all WMI in the European Union [9] to ensure usability. Similarly, a recent consultation paper published by the Therapeutic Goods Administration has proposed the introduction of a standardised OTC medicine label format in Australia [10]. This indicates that existing OTC labels may not be satisfactory and require improvements to better support safe and appropriate use. Due to increasing consumer self-management, a better understanding of specific factors such as design and comprehensibility in relation to OTC medicines information is critical to help ensure that future optimisation strategies address previously identified deficits and incorporate evidence-based recommendations.

Aim of the review

The aim of the review was to undertake an in-depth exploration of studies that have evaluated design and/or comprehensibility of OTC labels and WMI.

Methods

A narrative literature review was conducted using Medline, Embase, PubMed and International Pharmaceutical Abstracts database searches to identify relevant original research pertaining to OTC WMI and/or labels from 1987 to 2013. Relevant key terms and subject headings included: patient education, drug labelling, medicine information, health information, package insert, patient information leaflet, label, product label, packaging, over the counter medicine, over-the-counter, OTC, non-prescription drugs, readability, design, comprehension, understanding. Key author and reference list searching was also conducted to identify additional studies that met the inclusion criteria and key terms. The 'grey' literature (sourced primarily from government or organisation publications) was also searched for relevant publications.

Studies were included if OTC label or WMI comprehensibility and/or design aspects were evaluated. OTC labels and WMI included any labels or WMI currently available for an OTC product or developed specifically for research. Articles were excluded if they: were written in a language other than English; primarily examined pictograph understanding and use in OTC labels or WMI; examined consumer interpretation of OTC treatment benefits or harm only; explored consumer opinions on comprehensibility and/or design aspects alone; or if the study findings did not explicitly refer to OTC labels or WMI. Studies that fell within any of these categories were outside the scope of this review.

Specific study aspects that were extracted and reviewed for all included articles were: medicine information sources that were the subject of evaluation by the study authors (OTC labels, WMI or both), whether the evaluation primarily involved researchers or consumers, study objectives, study sample and sample size, study design, tools utilised and relevant outcome measures, key study findings relevant to the review aim and data generalisability. These study aspects were reviewed by one researcher, and a second researcher reviewed a proportion of the articles for accuracy of inclusion and review.

Results

A total of 35 studies were included in the review, which explored OTC medicine information design and/or comprehensibility through either researcher-orientated (n=8) or consumer-based (n=27) studies. Consumer comprehensibility studies were diverse in design with respect to participant demographics, sample size, questionnaire length and item types, amongst other study design factors. Study conclusions highlighted poor to adequate consumer understanding. Design influenced OTC label and WMI performance and generally improved consumer-related outcomes measured. Tables 1 and 2 highlight the studies included in the review. Further details regarding key study design aspects and findings can be found in the supplementary tables available as electronic material.

[INSERT TABLE 1]

[INSERT TABLE 2]

Researcher evaluation of OTC labels or WMI

a. Comprehensibility

Comprehensibility evaluation was solely conducted by researchers in 5 identified studies (1 study explored OTC labels; 4 remaining studies examined OTC WMI). A wide range of reading grade levels were ascertained to be required to read OTC labels [11]. Poor OTC WMI readability was determined by researchers using readability formulae [12-15]. For instance, mean reported reading grade levels determined using the Simplified Measure of Gobbledygook ranged between 10.5 [15] and 12.7 [12]. Consumers therefore required near completion of a secondary level of education to adequately comprehend information contained in WMI.

b. Design

Most OTC WMI utilised bullet points and headings [18], identified as elements of good information design by the author. However, in some WMI, deviation from good information design principles was evident through the use of small font size and a single column format with lengthy sentences [18]. Other unfavourable design characteristics identified in the studies included:

- use of all upper case lettering for parts of OTC labels [16] and WMI [18];

- minimal use of bullet points in indications and warning sections in OTC labels [17];
- lack of bolding (for emphasis) of OTC label warnings information [16] and indications [17];
- hyphenation of precautions/warnings information in OTC labels [16, 17];
- consistent use of small font size for warnings information and indications on OTC labels, despite increases in packaging size [16]

Impact on measured consumer-related outcomes

a. Study design and outcome measures of consumer-orientated studies

A range of study designs have been used to ascertain the impact of OTC medicine information on consumer-related outcomes. Sampling frames differed, ranging from mainly younger [20, 26, 33, 36, 39-41], older [27, 42, 43, 45], or both younger and older consumers [29, 31, 37]. Other studies attempted to include demographically diverse participants [24, 25, 34, 44]. Aside from age, specific consumer samples of females [25, 26] and parents/caregivers [22, 28], reflective of the target consumer population, were recruited to test OTC labels for an emergency contraceptive and OTC paediatric products, respectively. Overall, sample sizes varied considerably between studies of various designs, ranging from less than 100 consumers [23, 29, 33, 37, 39, 41- 43, 45], between 100 and 500 consumers (inclusive) [20, 22, 24, 26, 28, 30, 31, 36, 38, 40, 44], to larger sample sizes exceeding 500 consumers [8, 19, 21, 25, 32, 34].

OTC labels or WMI studies exploring comprehensibility aspects measured specific consumer-related outcomes, such as the ability to locate and understand medicine information [27, 29, 44, 45] (treated as two separate and distinct outcome measures), answers given in response to a structured questionnaire [8, 20-22, 24-26, 30-34, 37-41, 43] and other endpoints such as determining the appropriateness of a product for use [19] or an appropriate dose/dosage regimen [23, 28].

Questionnaires developed to evaluate consumer understanding of OTC labels and/or WMI, and their administration, differed between studies. Open ended questions were used in user testing studies to elicit understanding [27, 29, 44]. Some OTC label comprehensibility studies included a large proportion of questionnaire items with dichotomised answers (e.g. yes/no or true/false answers) [20, 21, 24-26] (the FDA study questionnaire [35] allowed the additional option for consumers to state that they did not know the

answer). Other questionnaire item types included: multiple choice questionnaire items [25, 26, 33-35], single questionnaire items with multiple correct answers [27, 34], and items that measured consumer responses using Likert scales [38-40]. During administration, consumers were occasionally required to answer questionnaires without the OTC label present [20, 24, 31, 39, 43] (or part of the questionnaire without the OTC label present [35]).

The process of user testing (developed by Sless and colleagues for application in written medicine information development [46]) has been used to measure consumers' ability to locate and understand medicine information in OTC labels [27, 29] and WMI [44, 45]. User testing has effectively emphasised the role of information design in the usability of medicine information, whether used as a tool during the development [27, 29] and/or diagnostic testing of developed OTC medicine information [27, 29, 44, 45].

b. Findings- comprehensibility of OTC labels or WMI

Findings from OTC label studies that explored comprehensibility aspects ranged from relatively adequate consumer understanding [21, 25, 26, 29, 30, 34, 41] of key medicine information, through to identification of significant consumer misunderstanding that resulted in inappropriate actions reported by consumers [22, 23, 28].

Variability in consumers' ability to interpret specific medicine information was observed in OTC WMI studies [32, 33], where some key points of information were better understood by consumers than other points. Redeveloped WMI yielded improvements in consumers' ability to determine the maximum daily dose, where 9.4% versus 84.9% of consumers could correctly nominate the maximum daily dose for paracetamol when using the existing WMI and redeveloped WMI, respectively [32]. Doses were correctly understood by more than 90% of consumers using the redeveloped WMI for both ibuprofen and paracetamol, which could be associated with tabulation of dosage information [32]. Similarly, tabulation of dosages according to age on an OTC paracetamol label may have helped consumers determine an appropriate dose [23].

Consumer misunderstanding of medicine information impacted the appropriateness of actions imperative in self-management, such as caregivers' determination of the appropriateness of a product for a child [22]. Lokker *et al.* [22] demonstrated that an overall mean of 51% of caregivers (determined across caregiver

exposure to 4 different OTC labels) nominated that they would administer an OTC paediatric cough/cold medicine to a child less than 2 years, despite the label stating the need for medical advice from a doctor prior to use in this age group. Moreover, consumer understanding of dosage information proved problematic, where only 40% of caregivers were able to determine an appropriate dose of paracetamol for a child under their care [28], despite having access to the label.

c. Impact of design on consumer-related outcomes and OTC label or WMI performance

OTC label and WMI design had an intrinsic impact on performance-based consumer outcome measures. Small font size and/or minimal white spacing between letters (generally regarded as the antithesis to good information design) impacted the ability of older consumers to read OTC labels [42]. Specifically, an ill-positioned page break led to 63% of consumers being unable to locate information pertaining to action required in the event of overdose in the existing ibuprofen OTC WMI [32], reinforcing the negative impact of suboptimal OTC WMI design.

OTC label design affected the time taken for consumers to complete questionnaire items [8, 37, 41] regarding specific information on OTC labels. One label format that these studies explored was the Food and Drug Administration (FDA) Drug Facts label: the legislated, standardised OTC label format utilised in the U.S. since 1999 [8]. Design improvements evident in the Drug Facts label format, such as clearer headings and increased white spacing [8, 37, 41], may have played an important role in the format supporting improved time taken to complete the relevant questionnaire(s) [8] (compared to corresponding older label formats), and in particular, for younger consumers [37, 41].

Optimisation of medicine information design improved performance with respect to consumer-related outcome measures. Larger font sizes appeared to contribute to improved consumer medicine knowledge with respect to OTC label use [31, 38]. User testing applied iteratively, in tandem with good information design, improved OTC label performance [27, 29]. Improved usability could be attributed to design changes such as information ordering, use of headings and improved spacing [27, 29].

With respect to OTC WMI, good information design, such as adequate spacing and appropriate use of bolding and bullet points is a potential contributor to superior WMI performance in user testing studies [44,

157 45]. Further improvements made such as the use of ‘plain English’ and the ensuing reduction in medical

158 jargon inclusion should also be considered as contributors to WMI improvement [44].

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Discussion

OTC labels and WMI studies have elucidated a broad range of issues, highlighting the intrinsic relationship between information design and consumers' ability to use and understand medicine information. As a result, information design is a critical consideration in OTC label and WMI development. Accordingly, routine implementation of good information design should not be compromised and should be balanced with legislative requirements.

When examining the improvements seen in the performance of the standardised OTC FDA Drug Facts label format [8, 37, 41], it must be noted that good information design initiatives have also been integral and are inherent in this standardised design format. As a result, standardisation alone cannot completely account for, nor be dissociated from, the impact that application of good information design has on label performance. Further studies are required to determine the impact of label standardisation on OTC label usability and usefulness, particularly in light of proposed OTC label standardisation in Australia [10].

Upon examination of mean reported reading age/reading grade levels of existing OTC WMI [12-15] (as determined through the use of readability formulae), these were higher than the 6^{th} to 8^{th} reading grade level recommended for written medicine information [47], potentially impairing OTC WMI usefulness. However, readability formulae have inherent limitations as comprehensibility markers, which include: a disregard for wording and presentation of information, potential inflation of reading grade levels with frequent polysyllabic word use [48], and their indirect measure of consumer understanding that does not determine if the information has appropriately communicated its intended meaning to consumers [49]. Consequently, these findings should be interpreted with care, and further work is required to explore the role and comprehensibility of OTC WMI with consumers.

Consumer misunderstanding of existing OTC medicine information [22, 23, 28] highlights the importance of well-designed, consumer-focussed studies to evaluate its performance, where consumer misunderstanding has also been noted in the literature for dosage instructions in general [50] and prescription medicine labels specifically [51-54]. 'User testing', arguably the gold standard method used in performance-based medicine information testing [55], has not been routinely used in the published literature when testing OTC medicine information. Differences may also be seen between various regulatory contexts. For example, in

Australia, adherence to 'user testing' guidelines for label [56] and WMI [46] development remains largely unknown, as opposed to the European Union where WMI performance testing with consumers is legislated [9]. Moreover, OTC label and WMI performance in light of benchmark performance standards inherent in 'user testing' is also unknown. Thus, comments on the comprehensibility of existing OTC medicine information cannot be satisfactorily made as per the literature identified in this review, due to the inability to source and include published manufacturer-conducted comprehension studies. This is a limitation of the review which could be addressed in future work.

On close examination, significant heterogeneity can be seen in studies evaluating OTC label and WMI design and comprehensibility. Specific study design factors inevitably impact the ensuing interpretation of consumer comprehensibility study findings. Acquired knowledge as an outcome measure, as opposed to actual understanding, may not adequately explore consumers' ability to utilise and apply information in a relevant context. For instance, in studies which required consumers to answer either a part or the entire questionnaire with the OTC label absent [20, 24, 31, 35, 39, 43], the impact of memory recall on study findings and their interpretation must be considered. Furthermore, tools developed and used to measure these consumer-related outcomes impact the confidence in the conclusions drawn. The inclusion of questionnaire items with essentially dichotomised answers [20, 21, 24-26] or multiple choice questionnaire items [25, 26, 33-35] measuring consumer knowledge and/or understanding may be suboptimal in determining actual consumer understanding. Correct answers nominated by chance alone cannot be eliminated, unless consumers' reasoning underpinning the nominated answers were recorded and analysed. Accordingly, multiple choice questions are not advocated for extensive use in label comprehension studies by the FDA [57], where questions allowing consumers to volunteer and elaborate on their own understanding have been favoured. Moreover, OTC label comprehension studies with a narrower focus, either through minimal questions posed to consumers [22, 30], testing of one aspect of the label alone [19, 23, 28], or developed labels that included minimal medicine information [39], offers limited insight into consumer understanding of OTC labels as a complete medicine information source and does not allow for in-depth analysis of label performance. Therefore, developed questionnaires used to ascertain OTC medicine information performance should reflect core medicine information required to be

understood and applied at any stage throughout the treatment continuum, to allow for sound measurement of the purported consumer-related outcomes.

When considering the present review, the choice of conducting a narrative review, as opposed to a systematic review of the literature, has allowed for a wider scope of literature to be reviewed. However, it is important to acknowledge that in future, a systematic review to specifically focus on certain areas of OTC medicine information design and comprehensibility research, may be considered. Moreover, as this review did not examine the impact of design and comprehensibility of OTC labels and WMI on actual patient adherence and other health outcomes in OTC self-management, this provides grounds for future work to ensure safe and appropriate consumer use of OTC medicines globally.

Conclusion

Suboptimal OTC label and WMI design and comprehensibility has been noted in both researcher-centred evaluation and consumer-orientated studies. Findings indicate that information design influences effective consumer use of OTC labels and WMI, where adherence to good information design improves label and WMI performance. Comprehensibility of OTC labels and WMI differs between studies. Large variation in sampling frames, sample sizes, tools and outcome measures were seen in consumer- orientated studies evaluating OTC labels and WMI. Subsequently, emphasis on well- designed consumer-orientated studies is necessary to ascertain actual consumer comprehensibility of OTC labels and WMI, reflected in appropriate measures and tools developed to specifically evaluate these outcomes in a satisfactory manner.

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Conflicts of interest

David K Raynor is the co-founder and academic advisor for Luto Research Ltd, a company that provides performance-based user testing services for health information.

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tables

Click here to download table: OTC label and leaflet literature review- Table 1 and 2 FINAL 140614.docx

1 **Table 1- Researcher evaluation studies of OTC labels or WMI included in the review (n=8)**

Label/WMI study	Author; Year; Country	Study title
Comprehensibility		
Label	Holt (1990); USA [11]	OTC labels: can consumers read and understand them?
WMI	Auta (2011); Nigeria [12]	Readability of over-the-counter medicine information leaflets in Nigeria
WMI	Bradley (1994); UK [13]	Readability of patient information leaflets on over-the-counter (OTC) medicines
WMI	El-Ibiary (2007); USA [14]	Health literacy and contraception: a readability evaluation of contraceptive instructions for condoms, spermicides and emergency contraception in the USA
WMI	Stevens (2007); USA [15]	Are instructions for over-the-counter nicotine replacement therapy products readable?
Design		
Label	Sansgiry (1997); USA [16]	Readability of over-the-counter medication labels
Label	Sansgiry (2003); USA [17]	Manufacturers' compliance with the US Food and Drug Administration's over-the-counter human drugs: labeling requirements
WMI	Twomey (2001); UK [18]	An analysis of patient information leaflets supplied with medicines sold by pharmacists in the United Kingdom

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5 **Table 2- Consumer evaluation studies of OTC labels and/or WMI included in the review (n=27)**

Label/WMI study	Author; Year; Country	Study title
Comprehensibility (which may have incorporated an examination of the impact of information design, where applicable)		
Label	Brass (2008); USA [19]	Can consumers self-select for appropriate use of an over-the-counter statin? The self evaluation of lovastatin to enhance cholesterol treatment study
Label	Catlin (2012); USA [20]	The Influence of need for cognition and principal display panel factors on over-the-counter Drug Facts label comprehension
Label	Ciociola (2001); USA [21]	A study of the nonprescription drug consumer's understanding of the ranitidine product label and actual product usage patterns in the treatment of episodic heartburn
Label	Lokker (2009); USA [22]	Parental misinterpretations of over-the-counter pediatric cough and cold medication labels
Label	Patel (2002); Africa, Canada [23]	Errors in interpreting quantities as procedures: the case of pharmaceutical labels
Label	Proprietary Medicines Association of Australia (1992); Australia [24]	Making medicine labels work: the impact of changing the design and content of labels
Label	Raymond (2002); USA [25]	Comprehension of a prototype over-the-counter label for an emergency contraceptive pill product
Label	Raymond (2009); USA [26]	Comprehension of a prototype emergency contraception package label by female adolescents
Label	Rogers (1995); Australia [27]	Designing better medicine labels: Report to PHARM
Label	Simon (1997); USA [28]	Over-the-counter medications: do parents give what they intend to give?
Label	Sless (date not found); Australia [29]	Medicine labelling for consumers
Label	Wilke (2011); Germany [30]	Does package design matter for patients? The association between package design and patients' drug knowledge
Label	Wogalter (2003); USA [31]	Effects of label format on knowledge acquisition and perceived readability by younger and older adults
WMI	Fuchs (2007); Germany [32]	Inappropriate dosage instructions in package inserts
WMI	Lee (2012); South Korea [33]	Examining the readability of two package inserts for self-medication in South Korea
Both label and WMI	Friedman (1997); USA [34]	Healthcare decisions and product labeling: results of a consumer comprehension study of prototype labeling for proposed over-the-counter cholestyramine
Design (and comprehensibility where relevant, as explored in some studies)		
Label	FDA (1999); USA [8] (a copy of a questionnaire used in the study can be accessed online [35])	Over-the-counter human drugs; Labeling requirements; Final rule
Label	Hellier (2010); UK [36]	Merits of using color and shape differentiation to improve the speed and accuracy of drug strength identification on over-the-counter medicines by laypeople
Label	Mendat (2005); USA [37]	Age differences in search time for two over-the-counter (OTC) drug label formats
Label	Murty (2007); USA [38]	Consumer comprehension of OTC medication labels and the scope for improvement in font size
Label	Sansgiry (1995); USA [39]	The effect of label content and placement on consumers' understanding of OTC product label information
Label	Sansgiry (2001); USA [40]	Effect of package design on evaluation of OTC medication information
Label	Shaver (2003); USA [41]	A comparison of older vs. newer over-the-counter (OTC) nonprescription drug labels on search time accuracy
Label	Watanabe (1994); USA [42]	The ability of the geriatric population to read labels on over-the-counter medication containers
Label	Wogalter (1996); USA [43]	Facilitating information acquisition for over-the-counter drugs using supplemental labels
WMI	Aslani (2010); Australia [44]	Investigating Consumer Medicine Information (I-CMI) project
WMI	Dickinson (2001); UK [45]	Patient information leaflets for medicines: using consumer testing to determine the most effective design

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Design and comprehensibility of over-the-counter product labels and leaflets- a narrative review

Impact of findings on practice statements

1. Good information design and clearer wording contributes to improved performance (usability) of over-the-counter (OTC) medicine information labels and leaflets.
2. 'User testing' of OTC written medicine information leaflets with consumers is uncommon in the published literature. This may potentially contribute to poor performance of available labels and leaflets.
3. There is a need to ensure that the tools used to evaluate OTC medicine information measure the intended consumer outcomes relevant to OTC label and leaflet performance and usability.
4. Performance evaluation of OTC labels and leaflets must be a consumer-centred process to ensure that consumers can effectively find and understand information to facilitate safe and effective self-management.