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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.

26 **Aim of the review**

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

29 **Methods**

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

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

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

52 **Results**

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

61 [INSERT TABLE 1]

62 [INSERT TABLE 2]

63 Researcher evaluation of OTC labels or WMI

64 a. Comprehensibility

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

72 b. Design

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

- 77 • 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

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

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

114 b. Findings- comprehensibility of OTC labels or WMI

115 Findings from OTC label studies that explored comprehensibility aspects ranged from relatively adequate
116 consumer understanding [21, 25, 26, 29, 30, 34, 41] of key medicine information, through to identification
117 of significant consumer misunderstanding that resulted in inappropriate actions reported by consumers
118 [22, 23, 28].

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

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

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

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

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

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

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

155 With respect to OTC WMI, good information design, such as adequate spacing and appropriate use of
156 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].
159

160 Discussion

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

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

172 Upon examination of mean reported reading age/reading grade levels of existing OTC WMI [12-15] (as
173 determined through the use of readability formulae), these were higher than the 6th to 8th reading grade
174 level recommended for written medicine information [47], potentially impairing OTC WMI usefulness.

175 However, readability formulae have inherent limitations as comprehensibility markers, which include: a
176 disregard for wording and presentation of information, potential inflation of reading grade levels with
177 frequent polysyllabic word use [48], and their indirect measure of consumer understanding that does not
178 determine if the information has appropriately communicated its intended meaning to consumers [49].

179 Consequently, these findings should be interpreted with care, and further work is required to explore the
180 role and comprehensibility of OTC WMI with consumers.

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

187 Australia, adherence to 'user testing' guidelines for label [56] and WMI [46] development remains largely
188 unknown, as opposed to the European Union where WMI performance testing with consumers is legislated
189 [9]. Moreover, OTC label and WMI performance in light of benchmark performance standards inherent in
190 'user testing' is also unknown. Thus, comments on the comprehensibility of existing OTC medicine
191 information cannot be satisfactorily made as per the literature identified in this review, due to the inability
192 to source and include published manufacturer-conducted comprehension studies. This is a limitation of the
193 review which could be addressed in future work.

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

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

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

223 **Conclusion**

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

232

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234 None.

235

236 **Conflicts of interest**

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

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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
<i>Comprehensibility</i>		
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?
<i>Design</i>		
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
<i>Comprehensibility (which may have incorporated an examination of the impact of information design, where applicable)</i>		
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
<i>Design (and comprehensibility where relevant, as explored in some studies)</i>		
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

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.