

The legibility of prescription medication labelling in Canada: Moving from pharmacy-centred to patient-centred labels

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The legibility of patient-critical information on prescription labels has received little attention, and few standards exist nationally or internationally. Therefore, we were interested in developing such recommendations. Our first step was to highlight the degree to which labels follow existing general guidelines, which is reported in this study.

Peu de personnes se sont penchées sur la lisibilité des renseignements cruciaux destinés aux patients qui figurent sur les étiquettes d'ordonnance, et il existe peu de normes à leur endroit, que ce soit à l'échelle nationale ou internationale. Nous nous sommes donc intéressés à l'élaboration de recommandations à ce sujet. Notre première étape a consisté à déterminer dans quelle mesure les étiquettes suivent les lignes directrices générales existantes.

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ABSTRACT



Introduction: The legibility of medication labelling is a concern for all Canadians, because poor or illegible labelling may lead to miscommunication of medication information and poor patient outcomes. There are currently few guidelines and no regulations regarding print standards on medication labels. This study analyzed sample prescription labels from Ontario, Canada, and compared them with print legibility guidelines (both generic and specific to medication labels).

Methods: Cluster sampling was used to randomly select a total of 45 pharmacies in the tri-cities of Kitchener, Waterloo and Cambridge. Pharmacies were asked to supply a regular label with a hypothetical prescription. The print characteristics of patient-critical information were compared

against the recommendations for prescription labels by pharmaceutical and health organizations and for print accessibility by nongovernmental organizations.

Results: More than 90% of labels followed the guidelines for font style, contrast, print colour and nonglossy paper. However, only 44% of the medication instructions met the minimum guideline of 12-point print size, and none of the drug or patient names met this standard. Only 5% of the labels were judged to make the best use of space, and 51% used left alignment. None of the instructions were in sentence case, as is recommended.

Discussion: We found discrepancies between guidelines and current labels in print size, justification, spacing and methods of emphasis.

Conclusion: Improvements in pharmacy labelling are possible without moving to new technologies or changing the size of labels and would be expected to enhance patient outcomes. *Can Pharm J (Ott)* 2014;147:179-187.

Introduction

Patient-centred care is a professional obligation to take responsibility for an individual patient's needs. This includes making sure patients understand their medications and how to take them. In that regard, one area that has received

little attention is the legibility of medication labels.

The total number of people at risk of visual impairment in Canada is high and increases sharply with age. The 2006 Statistics Canada Participation and Activity Limitations Survey

KNOWLEDGE INTO PRACTICE



- We found discrepancies between current prescription medication labels and print guidelines.
- Designing labels according to print guidelines is needed to move from a pharmacy-centred approach to a more patient-centred approach.
- Improving legibility of prescription labels is a simple way to enhance patients' understanding of their medications.

(PALS) identified 816,250 Canadians aged 15 years and over as having a self-reported vision difficulty.¹ In the same year, Maberley et al.² estimated that 0.7% of the total population had visual impairment visual acuity less than 6/12, which means that the minimum size of letters that they can recognize is twice that which a person with normal vision can recognize) and 0.24% are legally blind (6/60 or less—the minimum size of letters that they can recognize is 10 times that which a person with normal vision can recognize).² These percentages rise to 9.8% of 75- to 84-year-olds and 18% of those 85 years and older, respectively.

Other measures of vision (besides visual acuity) are affected by aging in the absence of ocular disease. While high-contrast visual acuity is 2 times poorer in those aged 90 or older compared with younger adults, low-contrast acuity is nearly 4 times poorer.³ Contrast sensitivity and visual acuity for low contrast in low light are 6 times worse.³ The speed of reading is substantially slower in older adults and even among those who still have good high-contrast acuity.⁴ All these factors may affect the reading of print, as medicine labels may lose their contrast with time, and lighting in an individual's home may be less than optimal.

As a result, the legibility of medication labelling is indeed a concern, as poor or illegible labelling together with poor vision may lead to misunderstandings of how to take medication.^{5,6} Poor vision may also result in increased anxiety about taking medications and increased dependence on others for medication management.⁶ Additionally, older adults are at increased risk for medication mistakes because they take more medications than younger persons.⁷⁻⁹ An increase in the number of medications used is associated with increased medication mistakes¹⁰ and decreased medication recall.¹¹

Although there are guidelines for general print legibility from nongovernmental organizations (NGOs) and specifically for medication labels from some pharmaceutical and health organizations (Table 1), they may not be applied consistently to medication labels. For example, in Ontario, there are no legal requirements regarding the legibility of print, although the content of what must be included on the label is specified.¹²

Surprisingly, there has been a dearth of studies addressing this important issue. Latham et al.²¹ assessed 24 prescription labels from 6 pharmacy chains in the United Kingdom and compared them to the National Safety Patient Agency, UK, Design for Patient Safety guidelines.¹⁹ The investigators found that none of the labels met the guidelines. Chubaty et al.²² compared health information leaflets to guidelines from Canada, the United Kingdom and the United States and found that only 33% met guidelines.

We therefore sought to better understand these issues by analyzing and comparing a larger sample of current prescription labels from Ontario, Canada, to available print legibility guidelines (both generic and specific to medication labels) from different organizations worldwide. The purpose was to sample the range of print characteristics of medication labels and to determine the percentage of different labels that meet the guidelines, rather than to determine a strict percentage that a patient might encounter.

Methods

This study was reviewed and received clearance from the Office of Research Ethics at the University of Waterloo.

Pharmacy label collection

Cluster sampling was used to randomly initially select 50 pharmacies from a total of 127 pharmacies in the tri-cities of Kitchener, Waterloo and Cambridge, Ontario. This was considered a good percentage (39%) of the total sample and feasible to complete in the time available. Each city was divided into 6 clusters, 4 of which were randomly selected. We sampled proportionally according to the percentage of pharmacies in each city (27 from Kitchener, 10 from Waterloo and 13 from Cambridge). To obtain the desired 50, all independent pharmacies and at least one randomly selected pharmacy from each

TABLE 1 General print guidelines for people with vision loss and for prescription labelling

	General guidelines for print accessibility			Guidelines for legibility of prescription labelling				
	CNIB (Canada)	RNIB (UK)	ACB (US)	USP (US)	ASCP (US)	MPAG (Sweden)	NPSA (UK)	AFB (US)
Font style and point size	Sans-serif font Minimum 12, 14, 18 points	Sans-serif font Minimum 12, 14 points	Sans-serif font Minimum 18 points	Sans-serif font Minimum 12 points	Sans-serif font Minimum 18 points for vision loss	Times New Roman font 9 points or more	Font such as Arial Minimum 12 points	Sans-serif font Largest font possible, 18 points for vision loss
Case	Not all upper case	Not all upper case	Not all upper case	Sentence case	Sentence case	Avoid upper case	Avoid overuse of upper case	Not all upper case
Bolding	For emphasis	Use sparingly	Use bold	Use bold for emphasizing important information	Use bold for most important information		Use bold for most important information	Use bold for most important information
Italics	Not recommended	Italics harder to read	Do not use		Do not use			Do not use
Paper type	High contrast Nonglossy	High contrast Nonglossy	High contrast Nonglossy					

CNIB, Canadian National Institute for the Blind¹³; RNIB, Royal National Institute of Blind People¹⁴; ACB, American Council of the Blind¹⁵; USP, United States Pharmacopeia¹⁶; ASCP, American Society of Consultant Pharmacists¹⁷; MPAG, Medical Products Agency Guidelines (Sweden)¹⁸; NPSA, National Patient Safety Agency (UK)¹⁹; AFB, American Foundation for the Blind²⁰

pharmacy chain were invited to participate. Thus we ensured that the chains (including chains, food stores/mass merchandisers, banners and franchises) were represented and not excluded by random selection. However, they were not represented proportionally. This was in order to sample as widely as possible the range of labels that are available. A declining chain pharmacy was replaced by another of the same chain, in the same cluster or city or from another city (selected in this order). Similarly, a declining independent pharmacy was replaced by another randomly selected independent pharmacy from the same city or from another city if needed. Each participating pharmacist was contacted by a phone call, during which the purpose of the study was explained. This was followed by a more detailed letter of information, and pharmacists signed a consent form before taking part. There was no deception; that is, the pharmacists were told that the purpose was to study the legibility of the labels. They were asked to provide a regular sample prescription label based on the same fictitious prescription that was provided to

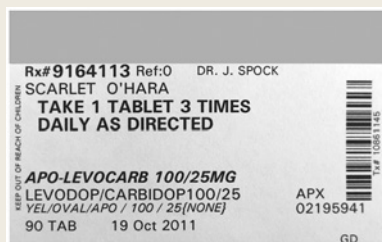
them. They were also asked to provide a large-print label, if possible. An example of a regular-print label is shown in Figure 1, which shows the prescription information.

Label analysis

The print characteristics of patient-critical information were compared against the recommendations for print accessibility by nongovernmental organizations and for prescription labels by pharmaceutical and health organizations (Table 1). For the purpose of this study, the patient name, instructions and trade and generic drug names were included as patient-critical information.²³

First, the type of print of patient-critical information was identified as being either sans-serif or serif font. A serif font is one where the letters have small flourishes at the end of their strokes, whereas sans-serif fonts (without serifs) have simpler letters without these flourishes (Figure 2). As most of the guidelines are not specific and suggest clear, nondecorative, plain fonts such as Arial or Verdana (Table 1), the

FIGURE 1 Example of a regular-print prescription label, showing the prescription information*



*The pharmacy logo and identifying information have been covered.

typeface was analyzed by comparison with printed fonts from Microsoft Word.

The print size of each patient-critical piece of information was recorded. Since print sizes change with font style, and also because most recommendations suggest Arial or similar, we determined the size by comparing with printed samples of Arial font in different point sizes (points are a common measure of print size). This was done by holding up the label and printouts against a light or by measuring with a ruler. The 3 labels that did not use Arial font were written in capital letters, so the heights were compared from the lowest point to the highest point of the letters. One of these labels was printed in Telidon dot font (in which the width is greater than the height); thus, comparing by height alone would not be representative. We therefore took an average of the height and the width compared with the Arial samples for this particular label. Any information (other than the pharmacy information and logo) was noted if it was larger than the instructions.

Components that were bolded were noted (excluding the pharmacy information and logo) for the following components: prescription number, patient name, instructions, trade drug name, generic drug name, strength, physician name, dosage form, pharmacist initials and refills. Bolding was defined as print of the same size that was composed of thicker strokes than the standard print. The number of patient-critical pieces of information (as defined above) that were bolded was calculated as a percentage of the total pieces of information that were bolded for each label. The percentage of patient-critical information that was highlighted was similarly determined. Highlighting was defined

FIGURE 2 Illustration of serif and sans-serif fonts

Times New Roman is a common serif font

Arial is a common sans-serif font

as there being a background colour (including grey) behind the line of print.

Left justification of the patient-critical information was noted if present. Information printed in italics was also recorded. Spacing was measured subjectively by judging whether the information could have been spaced out better without changing the print size. The print colour (excluding pharmacy information and logo) was noted, as well as whether it was high contrast or not. High contrast was defined as the print being black against a white background. The paper finish (glossy or nonglossy) was defined as whether the paper background noticeably showed any specular reflections or not. Descriptive analyses were undertaken for the sample label analysis. We planned to have all these print characteristics remeasured for 20% of the labels by a second investigator who was not informed of the first results.

Results

Sample labels

Of the total number of 96 pharmacies contacted, 45 pharmacies provided us with labels (response rate: 47%): 25 from Kitchener, 9 from Waterloo and 11 from Cambridge. Sixteen (35.6%) were chains and food stores/mass merchandisers, 14 (31%) were banners and franchises²⁴ and 15 (33.3%) were independents. Forty-one pharmacies indicated which dispensing software program they used, as follows: Kroll 44% ($n = 18$), Nexsys 34% ($n = 14$),¹⁴ Assyst Rx, Health Watch and Connexus 5% ($n = 2$ each)² and Other 7% ($n = 3$).³ Only 3 pharmacists were able to supply a large-print version, 2 of which were from the same pharmacy chain.

The results of the label analysis are shown in Table 2. Over 90% of labels followed the guidelines for font style, contrast, print colour and nonglossy paper. Ninety-three percent (42 labels) used Arial or a sans-serif font resembling Arial, while 4.4% (2 labels) used a font resembling Univers 65 bold. One label (2.2%) was printed with a dot matrix printer, which created a low-contrast result, and

TABLE 2 Comparison of the print of sample prescription labels with print recommendations for prescription labels

Characteristic	Recommendations by guidelines	Number (%) of sample prescription labels that followed guidelines (total <i>n</i> = 45)
Serif	Sans-serif	45 (100)
Font style	Arial	42 (93) Arial or resembling Arial 2 (4) Univers 65 Bold 1 (2) Telidon dot
Contrast	High contrast	44 (98)
Print colour	Black	44 (98)
Paper	Nonglossy	43 (95)
Case	Sentence case	0% instructions 20 (44) drug name 26 (58) patient name
Bolding	For emphasis	20 (44) bolded instructions, drug name and patient name
Alignment	Left justification ^{20,23,24}	23 (51)
Spacing	25%-30%, ²² or 40% of the text size or 1.5 × spacing ²⁰	2 (4) made the best use of spacing
Highlight	For emphasis	13 (29) used highlighting: 2 (4) highlighted the patient name, 11 (24) used grey highlighting, none highlighted drug name or instructions.

the font resembled Telidon. The instructions on all the labels were printed in upper case. For the drug and patient names, 58% and 44% of labels were printed in upper case, respectively.

The majority (95.6%) of the labels used bolding for emphasis of some text on the label, but it was not always the patient-critical information that was bolded. Forty-four percent of the labels bolded all patient-critical information, 84.4% bolded the instructions and 84.4% bolded either the generic or trade drug name (note that these were not the same labels that made up the percentages), while 55.6% bolded the patient name. About half (51.1%) of the labels were left-justified (as opposed to right justified or centred). Just 5% of the labels made the best use of spacing, using either the recommended spacing of 25%-30%²² or 40% of the print size or 1.5 spacing between lines.²⁰ Highlighting was used in 29%¹³ of the labels, but only 4.4%² used yellow highlighting. The rest used some form of grey highlighting. Highlighting was mainly used to emphasize information other than the patient-critical information. Only 2 highlighted the patient name and none highlighted the drug name or directions. Of the 13 labels that used highlighting, 10 highlighted the prescription number and refills. The use of italics was found

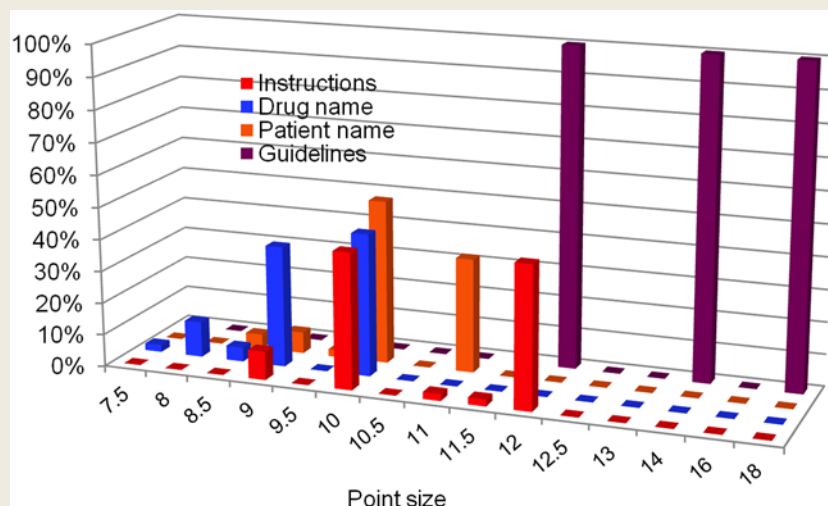
in 82.2% of the labels for information other than the pharmacy logo.

Print size is shown graphically in Figure 3 for the 3 most important components. Forty-four percent of the instructions on the labels met the minimum guideline of 12-point type. None of the labels used 14-point type or larger. None of the drug names or patient names were 12-point type or larger. The prescription number was larger than the instructions for 13 labels (29%). The prescription number and the patient name were larger than the instructions for 2 labels (4.4%). The rest of the labels had the instructions as the largest component.

Of the 3 large-print labels, all used a sans-serif font, 2 of which resembled Univers 65 Bold and 1 of which resembled Arial. The large-print labels were nonglossy and the print was of high contrast. Two of the large-print labels had 13.5-point print for the instructions. All 3 large-print labels were written in upper case and were not left-justified. All 3 labels had bolding but it was not used to strictly highlight the patient-critical information. None of the large-print labels had highlighting.

When the print characteristics for 10 labels (22%) were rechecked by the second investigator, there was 100% agreement (Kappa = 1.0) for all

FIGURE 3 Print sizes of sample labels for instructions, drug name and patient name compared with guidelines from various nongovernmental organizations



Guidelines considered from USP, United States Pharmacopeia¹⁶; ASCP, American Society of Consultant Pharmacists¹⁷; NPSA, National Patient Safety Agency (UK)¹⁹; AFB, American Foundation for the Blind²⁰; CNIB, Canadian National Institute for the Blind¹³; RNIB, Royal National Institute of Blind People¹⁴; ACB, American Council of the Blind.¹⁵

parameters except for spacing and contrast, for which there was 90% agreement (Kappa = 0.78).

Discussion

We found that current medication labels do conform to guidelines regarding sans-serif font, style, high contrast and nonglossy paper. However, they have several deficiencies that could lead to confusion and poor patient outcomes. The medication label can be thought of as an extension of pharmacist's care and, as such, should meet the individual needs of patients, many of whom have visual impairment.

Our findings are consistent with the results of Latham et al.²¹ Sans-serif fonts may be more legible by allowing improved horizontal movement, which is important for adults with low vision.²⁵ Use of high-contrast and nonglossy paper is important for older adults, considering the loss of low-contrast acuity, low-lighting visual acuity and the increased sensitivity to glare with age.³ Widespread implementation of these printing options should be straightforward. However, some pharmacists may tape the label to the vial, which would effectively turn a nonglossy label into a glossy version. Thus, the percentage of glossy labels in practice may be higher than documented here. There was one label that had

low contrast attributable to use of a dot-matrix printer, which could easily be updated.

More discrepancies between guidelines and current labels were found in print size, spacing and methods of emphasis such as bolding or highlighting patient-critical information. This was similar to Latham et al.'s study²¹ using UK labels, which found discrepancies in print size, centre justification, bolding, highlighting and branding. Similarly, Chubaty et al.²² found that only one-third of medication information leaflets met print-size recommendations, and only 19% used appropriate spacing.

Recommendations suggest the use of sentence case (where you only capitalize the first letter of the first word in a line or heading—just as you would in a sentence), and none of the labels met this criteria for the instructions. The use of capital letters may reduce the clarity of the label and is considered to be particularly difficult to read by those with visual impairments.²⁶ The various nongovernmental organizations (Table 1) support limited use of capital letters, although not all stress this strongly (e.g., CNIB). It has largely been assumed, rather than demonstrated, that sentence case is more legible.^{26,27} It was suggested that capital letters are less visually pleasing and harder to read due to the block appearance, which eliminates the unique shape

of each word.²⁷ However, the use of capital letters may result in faster reading when comparing equivalent size in point print in sentence case for both people with and without visual impairment.²⁶ The optimum use of sentence case versus capitals is, therefore, still not confirmed.

Bolding was used in 95.6% of the labels, but was not used to strictly emphasize the patient-critical information, as recommendations would suggest. All of the labels that used bolding had at least one of the patient-critical components bolded; however, none of the labels bolded only the patient-critical information. Similarly, highlighting was found in some of the labels for the prescription number and refills section, which is not considered to be the most important information for the patient. Furthermore, use of grey highlighting lowers the contrast of the print. It may be more beneficial to limit bolding and highlighting to patient-critical information. If bolding and highlighting capabilities exist within the software used by pharmacists, this could be easily achieved.

It is noteworthy that neither italics nor underlining is recommended as a method for emphasis by common guidelines,^{13-15,17,20} yet 82% of the labels used italics in some form or another. The guidelines that mention italics suggest avoiding their use completely, and so it may be best practice to only use italics for information that is not critical to patients.

Print size was an area for potential improvement for all labels in our study. Only 47% of labels met the 12-point font size guideline for instructions, with a mean font size of 10.9 points. Two of the large-print labels met the 12-point guideline at 13.5-point print for instructions. All other essential components of the labels were below the guideline of 12-point font size (the most frequent guideline), with both the American Society of Consultant Pharmacists and the American Foundation for the Blind recommending 18-point font size for those with vision loss. This is important, because the larger the font size, the greater the percentage of the population that would be able to read it properly. As 18-point font size may not be feasible with the current standard label size, a compromise of 14- or 16-point font size might be possible. Perhaps a medication label guideline should specify that print should be made as large as possible, depending on the amount of text that is required, with a minimum font size of 12 points for patient-critical information (Table 1).

MISE EN PRATIQUE DES CONNAISSANCES



- Nous avons relevé des écarts entre les étiquettes actuelles des médicaments sur ordonnance et les lignes directrices publiées.
- Il est nécessaire de concevoir les étiquettes conformément aux lignes directrices de manière à passer d'une démarche axée sur la pharmacie à une approche axée sur le patient.
- Une manière simple de renforcer la compréhension du traitement par les patients consiste à améliorer la lisibilité des étiquettes d'ordonnance.

Print may also be made more legible with better use of spacing and minimal distracters.²⁸ Pharmacy-centred information such as the logo, address and contact information is also important but may be distracting and can use up valuable space on the label.²⁸ Most labels in our study did not use space on the label optimally, and our impression was that pharmacy logos were the largest and most eye-catching feature. Consistent with our findings, Shrank et al.²⁹ showed that 84% of pharmacies in several large cities in the United States displayed the pharmacy logo as the most prominent feature. Those investigators also noted that the mean print size for the logo was larger than the mean print sizes for any of the other components. A parsimonious way to increase space on the label for patient-critical information is to decrease the size of the pharmacy logo. Improved use of spacing, larger font size and bolding for emphasis for patient-critical information could then easily be achieved for most labels. Although Shrank et al. suggest that there is little direct evidence that improved labels increase safety or adherence in studies that have been conducted so far and that many errors are due to lack of comprehension rather than legibility, they do mention that improving the label format can increase legibility and understanding.³⁰⁻³² Prescription labels often serve as the only or "last line" source of medication instructions,²⁸ so it is generally agreed that labels should be as clear and legible as possible (Box 1).³³

Limitations

One limitation of this study is that the sample of prescription labels was taken from a group of medium-sized cities in Ontario and therefore may not be fully generalizable to all of Ontario or Canada. A second limitation is that our

BOX 1 Action items for pharmacists

- Ask patients whether they have difficulty reading the medication label.
- Print a large print label if your software allows.
- Know the capabilities of your label printing software, so you can modify it for patients.

sampling ensured that chains were represented, but not proportionally. We were more interested in assessing the range and percentage of different labels that meet the guidelines rather than in determining the strict likelihood that a patient would encounter a particular size of print on a label. Third, we cannot be sure whether the failure to follow guidelines is due to the software capabilities or the choice of each pharmacy. We attempted to contact the software suppliers, with little success. Further study is required to determine this. Last, it is possible that the pharmacists modified the way that they printed the labels, as they knew we were studying label legibility, even though we specifically asked

them not to do this. However, we think this is unlikely, as only 3 provided a large-print label. If pharmacists had been trying to influence the appearance of the results, it might have been expected that more would provide large-print labels. Also, in many cases the pharmacist printed the label while the researcher was waiting, so probably would not have taken the time to modify the print characteristics.

Conclusion

This study demonstrates discrepancies between print guidelines and certain print characteristics in many medication labels, in particular for font size, use of case, bolding, justification and spacing. These are characteristics that might be modified, and result in greater legibility, without moving to new technologies or even larger labels. Changes in the printing software may be needed to move from a pharmacy-centred approach to a more patient-centred approach. Additionally, the development of Canadian guidelines or regulations for print characteristics on medication labels may assist more patients to read the important information independently and may increase their health and safety. ■

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