Are Prescription Labels Usable? A Review and Analysis

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Abstract. There are approximately 400,000 adverse drug events per year in hospitalized patients which has resulted in more than $ 3.5 billion spent in subsequent recovery care. The present paper reviews the literature relating to the usability of information found on pharmaceutical labels. In particular, we examine the legibility and comprehensibility of the information provided on the labels. In addition, we highlight the differences in the physical makeup of medication that can be implemented to help users identify their medication. Finally, we provide recommendations for factors that should be examined in future research to improve the usability of pharmaceutical labels. Presently, the FDA has few standards and guidelines regarding the content and layout of a prescription label. We hope that the recommendations provided in this paper can lead to the development of standards for formatting and presenting information on prescription labels that will reduce the number of medical cases involving ingestion of the wrong medication.

1 Introduction

As technology encroaches upon traditional fields such as medicine, the need to assess the standards and regulations regarding usage, treatment, handling and management of medical products becomes essential. There are approximately 400,000 adverse drug events per year in hospitalized patients. These incidents have resulted in more than $3.5 billion spent in subsequent recovery care [1]. If these mistakes occur at high frequencies in professional settings such as in hospitals, then they are likely to occur in greater numbers in non-professional settings such as the home. As of today, the FDA has few explicit standards of how a prescription medication label should look and what information the label description should contain. Thus, the goal of this paper was to review the literature on the usability of information provided on prescription labels. We then identify factors that should be examined in future studies to aid the development of guidelines for pharmaceutical labels.

Under Title 21, the Food and Drug Administration (FDA) has listed guidelines for the labeling of substances and filling prescriptions. According to these guidelines, a label should be affixed to the package showing the pharmacy name and address, serial number, date of initial filling, the name of the patient, the name of the practitioner issuing the prescription, the directions for use and cautionary statements (if any, [2]). However, the guidelines do not attest to the effectiveness of the information being

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placed on the labels or provide specific guidance for how pharmacies should format the information.

The Institute of Safe Medication Practices (ISMP [3]) operates the ISMP Medication Errors Reporting Program (MERP), which is a confidential national voluntary reporting program that provides expert analysis of the systemic causes of medication errors and disseminates recommendations based on these findings. The ISMP provides examples of confusing and unclear labels on its website. To illustrate, a term that has been shown to confuse users is the word "twice." As such, the ISMP suggested that either the word "two" be utilized or the numeral "2" in the place of "twice" to avoid confusion. The FDA has provided some basic guidelines for the structure and content of medication labels. However, as will be shown below, these basic guidelines may not be enough to accommodate the various differences in users' abilities to see, read, comprehend and comply with the information that is contained in the label.

Avorn and Shrank [4] pointed out that the FDA admitted that the current labeling is poorly organized and filled with irrelevant information. Although in 2006, the FDA added some minor changes to the labeling of medication, it was not enough to ensure that patients understand the appearance and dosage of their medication based on the current prescription label. The new labeling regulations called for minor changes that the user may not notice or cannot readily see, such as a section that summarizes the risks and doses at the top of the label, as well as listing all of the risks together. In addition, there is a requirement for the manufacturer to submit an electronic copy of their package insert to the FDA so that it can be placed on the FDA's website. While these changes were made with good intentions, they still do not address the physical layout of the prescription label. As will be shown in the subsequent literature review, there is a need to redesign the current label standards to improve comprehension and identification of the patients' medicine.

2 Comprehension

A major problem with medical labels is that users do not understand all of the information conveyed on the label. For example, Patel, Branch, and Arocha [5] found that people were ingesting the wrong dose of their medication, either over or under dose, due to low literacy. Patel et al. sought to investigate errors in cognitive processes when individuals attempted to read and execute procedures found on pharmaceutical labels of children's medication. The participants were asked to read the labels of each medication and to calculate the dosage of the medication, if it were to be given to their youngest child. They were also asked to think aloud while they read the instructions. There were three different medication labels that were read and interpreted: The first label was from an oral rehydration therapy (ORT), the second label was from an over-the-counter (OTC) cough syrup for children, and the third label was taken from OTC antipyretic drops for children.

Patel et al. [5] found that the majority of the participants performed the task incorrectly. Either they miscalculated the dose or time of day to administer the medication.

While some of the participants were able to calculate the formulas correctly, they restricted or modified administering the medication in the belief that the prescribed amount was too much or too little. For the OTC cough syrup and OTC antipyretic drops conditions, educational level seemed to make no difference in performance. Education level was a major factor for participants in the oral rehydration therapy condition. Only participants with graduate degrees were able to interpret and administer all three stages of the medicine correctly. This finding suggests that there is an underlying literacy factor that needs to be taken into account in the design of medical labels to aid readability and comprehension.

The problem of medical labels being written at a level that is not comprehensible by a large portion of the general population has been documented in countries other than the United States. At the time of their study, Didonet and Mengue [6] found that the Brazilian medication label was written at a level which was higher than the reading level found in public journals and magazines. Using the Flesch Reading Index as a measure of reading level, they found that drug labels were more readable than scientific text but less readable than journalistic texts. In other words, drug labels were found to be difficult to read. Although the Brazilian government tried to address readability concerns two decades ago by passing legislation to improve drug labels, Didonet and Mengue found that drug labels written in accordance with the 1997 legislation did not differ significantly from the drug labels written in accordance with the 2003 legislation. Thus, the 2003 changes in legislation did not improve the readability of the labels. In pursuit of improving drug labels' readability, Didonet and Mengue suggested that medical companies should be obligated to fashion and format drug label text similar to the way in which non-scientific journal texts are written, because the material is intended for the general public.

Although there has been a greater push to get medical companies' compliance, this effort has resulted in the labels containing a lot of jargon aimed toward doctors and pharmacists, and not the end user [7]. In efforts to eliminate a user's reliance on text-dense material that may be riddled with high-level text, pictograms and icons have been studied to determine their effectiveness in relaying information [8, 9, 10]. Using pictorial cues on the labels may help individuals who have low literacy. The visual cues that pictures provide may also aid in identification of the medication inside the container or help point out critical differences between methods of administration (e.g., take the medication orally or have it injected) or side effects (e.g., motor impairments or drowsiness) of the medication. Plimpton and Root [11] concluded that good graphics could help improve comprehension relating to health care in low literacy adults. Thus, adults with low education may benefit significantly from using pictures or pictorial representation on medical labels.

Wolf et al. [12] showed that using pictorial cues could facilitate proper understanding and use of medicine. They compared two newly redesigned labels with a label that follows the current standards for drug warning labels. The two newly designed labels made use of simplified text as well as icons. Both versions used simplified text in which "simple" text was defined as using clearer, more explicit language. Moreover, the text of one version was accompanied by an icon that represented the warning. For example, the warning "shake well" was accompanied by an icon that depicted a

hand shaking a bottle. Wolf et al. found that when using the icons, participants frequently noticed the first two warnings on the label. In addition, simplified text labels were attended to more than text on traditional labels regardless of whether they were accompanied by icons. Based on their findings, Wolf et al. concluded that simple explicit language on warning labels can increase patients' understanding of the information on the label. More importantly, including simplified text and icons improved the participants' attention to the information on the label, which allowed for the correct interpretation.

Although pictorial cues such as icons can be helpful, they need to be tested for comprehensibility because some symbols and pictorial representations have to be learned. Ringseis and Caird [13] performed a three-phase study concerning the comprehensibility of pictograms on prescription warning labels. Their main objective was to determine how recognizable and understandable were 20 pharmaceutical warning pictograms. The pictograms were produced by a pharmaceutical company, Pharmex. The participants were shown only the pictogram, with the text that accompanied the warning label removed. Of the 20 labels shown, only four passed the American National Standards (ANSI) requirement for labels, which requires a comprehension level of 85%. In other words, 85% of the participants tested must be able to correctly interpret the pictograms' meaning. Seven of the pictograms passed the International Standards Organization (ISO) requirement where a 67% comprehension level is required. In a follow up study, Ringseis and Caird took 10 warning pictograms that did not meet the standards and redesigned them. For example, a warning pictogram with the intended meaning of "may impair driving" was originally depicted by a car. In the redesign, the new pictogram was a car with a slash through it. Of the 10 redesigned pictograms five of the labels passed the ANSI for the younger population, but only three passed for the older population. This study demonstrates that some pictograms have to be learned, taught, or explained to the user. Thus, the use of pictograms needs to be combined with training in order to be effective.

3 Legibility

Comprehension deals with the user's ability to understand the information that is being presented, such as understanding how often to take the medication. Legibility deals with the perception of the information, that is, whether the user is able to see or read the information being presented. Identification of medicine requires that patients correctly perceive the medicine and the information about the medicine they are taking. This requires that patients identify the medicine's correct name as well as that the pill in the container is the correct medication that was prescribed for them to consume. Therefore, in addition to comprehending how to take their medicine, legibility and/or the ability for participants to see the information on the labels should be taken into take into account. The physical makeup of the label is important because it is usually the only visual representation that the user has of what is inside the bottle. Therefore, the label should be legible and the information on the label should be scannable so that it can be quickly referenced.

One major concern when it comes to legibility is font size. A user cannot read what they cannot see. Bernardini, Ambrogi, Fardella, Perioli, and Grandolini [14] investigated the font size issue in regards to the patient package leaflet in Europe. The leaflet used a size 9 font, and 63% of their participants complained about not being able to read the information because the font size was too small. Wogalter and Vigilante [15] noted that some elderly users have to squint or use a magnifying glass in order to read a prescription label. They found that the use of small font sizes for prescription labels used by elderly adults had the effect of reducing their recall of the information in the label as well as their understanding of that information.

Shrank, Avron, et al. [16] examined font size in regards to the variability and quality of medication labels. They conducted a review of multiple databases in order to gather information that would assist in the facilitation of reading and understanding various prescription labels by consumers. They searched databases such as Medline and the Cochrane Database in order to locate articles that related to the content and format of prescription labels. They found that the use of more white space and simpler language improved legibility, and recommended that these factors be incorporated in the design of medical labels to facilitate comprehension and readability. Additionally, other factors they identified for improving legibility included larger font sizes for the header, lists of ingredients, and names of the medication.

Wallace et al. [17] investigated the readability of prescription inhalers for asthma patients and also found font size to be an important factor. Many labels for these medications were in a font size of 9.2, which made these medications more difficult to read. Thus, Wallace et al. recommended use of larger font sizes. Skelly and Schmuck [18] found that patients in an outpatient facility had less difficulty reading items that were written in a size 14 font. Thus, the use of 14 point font may help with the legibility of prescription labels. Shrank, Agnew-Blais, et al. [7] examined the pharmaceutical labels from six different pharmacies located in four major cities across the country. They noted the size of various attributes (e.g., pharmacy logo, drug name and medication instructions) located on prescriptions labels and found that the largest item was the pharmacy logo, with a mean font size of 13.6. The medication instructions had a mean font size of 9.3 and 8.9 for the drug name. This finding points to the need to prioritize information on the label for the end user.

There have also been studies that addressed issues regarding the legibility of text on the current pharmaceutical label. Filik, Purdy, Gale, and Gerrett [19] found that consumers have difficulty with drugs that sound alike and that are spelled alike. They used various methods such as bolding, red color coding, underlining and utilizing brackets in order to improve legibility. They also used a different type of font known as tall man lettering to try to facilitate legibility. Tall man lettering is a technique used to point out a distinction between words that look alike. Upper case lettering is used in conjunction with lower case letters to signify a distinction between two different words that look alike and sound alike [20]. Filik et al. [19] found that tall man lettering was by far a more effective strategy than color coding if the participants are

made aware of the purpose of such lettering. Tall man lettering can make similarly spelled drug names less confusing by distinguishing the area of the word that is different. It brings attention to the differences, especially in high risk drug names. The FDA and the Institute of Safe Medication Practice have identified medications that are confusing either due to sound-alike or look-alike qualities. For example, Dopamine and dobutamine are commonly confused words. Tall man lettering would distinguish the two words by highlighting the area of the word that helps distinguish the differences between the words. In this case "amine" is the same in both words, and therefore those letters remain in regular text while the first half of the words is presented in tall man lettering: DOBUTamine DOPamine. If tall man lettering can help users with identifying the medicine's name, then including pictures of what the medication looks like should also reduce ambiguity relating to identifying the correct drug.

In summary, there have been many studies on the legibility and comprehensibility of medical labels, specifically pharmaceutical labels [5] and drug warning labels [12]. These studies showed that medical labels are not written in manner that aids users (patients) in taking their medication. An area that has not been examined, though, is whether the current text description of the medication itself allows users to correctly identify their medication. This issue is important because information on labels can serve as a safety check for drug consumption errors.

4 Properties of Medicine

Generally, when a prescription is filled, the medication is repackaged by hand by the pharmacist and given a new label. The label will contain the patient's name, medication name, and dose of the medication, in addition to a description of the medication and its use [21]. However, problems can arise in this process such as that the medication may be put in the wrong bottle or the pharmacist can place the wrong label on the bottle. Hence, a disparity in the description of the pill and its physical appearance may arise. This problem may not be detrimental for some consumers, especially if the mistake is caught before the pill is ingested. In order for users to accomplish this identification task, though, patients must know what their medication looks like. However, individuals who are taking the medication for the first time usually do not know what the pill should look like and therefore may not question whether they are taking the correct pill. On the other hand, if an individual has taken the medication before, they are likely to be alarmed if the medication looks different than it did in the past, whether the change in the medicine's appearance be a change in color or shape. Based on a literature review, there are four distinct ways that medication varies [22].

1. Shape: compare Figure 1A with Figure 1C
2. Size: compare Figure 1B with Figure 1D
3. Color: compare Figure 1C with Figure 1D
4. Imprints: writing (alpha, numeric, symbol or a combination of any of these)

Fig. 1. Illustration of Medicine and their Properties

Thus, use of pictures of the actual medication on the label may benefit the patients by allowing them to take advantage of a coding mechanism in identifying their medicine. Tylenol (see Figure 1A) is different from Metformin (see Figure 1B). However, they are both white and relatively the same size and only differ by the imprints.

Upon first glance, it is common to dismiss most pills as being the same. To the untrained eye, many pills look very similar. However, after close analysis there are slight deviations in their appearance, such as in their shape or color (see Figures 1C and 1D). The variations are applied intentionally to help medical professionals identify the different types of medicine. Hence, there is reason to pay close attention to the deviations that are present among the pills. Companies, such as the makers of Prevacid, have intentionally used different colors to denote a difference in the dosage. For example, the 15 mg capsule of Prevacid is denoted by a pink and turquoise capsule while the 30 mg capsule is denoted by a pink and black capsule. This distinction is very helpful for the pharmacies to decipher the two dosages. The use of color coding is commonplace in human factors [23] and has been successfully used to aid people with quick and easy identification of items. Here, it is applied to medicine, but the colors used have not been taken advantage of to help patients self-identify their medication to avoid or reduce the medical frequency of errors by highlighting these differences on a label.

5 Recommendations for Future Research

Based on the literature review provided, we recommend examining the following factors in future research to help improve the usability of the information being presented on pharmaceutical labels.

- **Determine a way to simplify instructions.** Patients with low literacy are able to read simple instructions such as "take two tablets by mouth 2 times daily." However, actually demonstrating the daily dosage posed a challenge to patients with low literacy. These findings demonstrate a disconnect in a person's ability to read, comprehend, and carry out simple instructions located on medication labels. Future research should examine how best to simplify instructions for taking medicine that are put on the prescription labels.
- **Identifying the best symbols to use for warnings.** It is clear from the studies reviewed in this paper that many symbols have to be learned. However, certain symbols may be easier to learn and identify than others. Future research should examine what properties of symbols or global symbols are more intuitive than others in order to facilitate the learning and interpretation of the symbols. Additionally, symbols should be researched for comprehensibility before being implemented and used.
- **Determine the effectiveness of using pictures to help users identify their medicine.** While there was an abundance of research on comprehension of pharmaceutical label warning signs, there has not been any research on consumers' recognition of medication. As illustrated in the paper, though, there are many properties of the medicine itself that can be used to help users distinguish between their various medications. Future research should identify the most promising dimensions to use for the coding of the medicine.
- **Determine the best layout of the information.** Where the information about the medicine is printed is important in determining whether users will see and attend to the information. When considering the optimal placement of information, it is necessary to look at how the information will be processed at various locations on the label. For example, English speakers and readers may be able to process information effectively if key information is presented at the top or left locations of the label. This is because this population reads from left to right and top to bottom. However, people from other cultures may not be inclined to read in this spatial pattern. For example, in Hebrew, text is read from right to left first, and in Chinese, text is read top to bottom first. Thus, the optimal location of information may be different for people who speak different languages. How to best place information for different populations of users, then, is another area in need of future research.

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