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REVIEW

A narrative review on do's and don'ts in prescription label writing – lessons for pharmacists

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Abstract: Providing medicines information is a key role of a pharmacist. Miscommunication between pharmacist and patient may lead to adverse drug events or therapeutic failure. The aim of the review was to summarize the available research findings on factors that lead to poor communication between pharmacist and patient when providing written medicines information on dispensing and auxiliary labels and identify successful interventional approaches that help to alleviate these concerns. We selected articles available on PubMed, SAGE, and Google Scholar databases that are relevant to our objective. A total of 33 articles that matched the objectives of this review were retrieved and evaluated by all three authors. It was found that patient literacy levels, number of medicines dispensed, format and organization of the label, complexity of dosing instructions, precision of writing dosing instructions and use of icons, graphics and pictograms were aspects that were frequently used, and hence assessed by research groups on medicine label writing. Most studies reported that simple and straight forward instructions written legibly were better comprehended by patients. Based on our findings, we provide here useful tips for pharmacists on writing dosing instructions for patients. Finally, we spotlight crucial research gaps related to communicating written dosing instructions that need to be addressed in the future.

Keywords: dispensing labels, readability, comprehensibility, dosing instructions, medication safety

Introduction

Pharmacist is the link between the prescriber and the patient. Therapeutic intentions of the prescriber is usually written in the form of a medical prescription. The pharmacist will then dispense medicines according to the prescription, together with essential medicines information without which patients may misuse medicines leading to adverse drug events[1] or alternatively, therapeutic failure.[2] The waste of resources due to misuse of medication is costly to both the patient and the country, and costs millions in expenditure.[3] Further, it has also been reported that patient knowledge concerning patient-centered contents of medication labels is significantly associated with quality of life among older adults.[4] The pharmacist, therefore, is the community pivotal point for providing correct, comprehensible and readable medicines information to patients in order to facilitate proper use of medicines.[5]

Medicines information may be written or verbal. Written forms may be presented in the form of dispensing labels, auxiliary labels, manufacture labels and even patient information leaflets. However, it is clear that there are weak links in the communication chain between health care professionals and patients. First, some or all of the

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important information may not be communicated to patients at all.[6,7] Research has shown that only 35% of patients receive information about their medicines from their primary care provider, 46% from pharmacist, while 32% received from neither.[8] Second, some information even if delivered by the health care professional may be incomprehensible to the patient depending on the educational standards and their cognitive ability, which in turn may be due to health-related or other factors. Consequently, patients may find it difficult to read, understand or even recall the information provided.[9] The level of understanding of prescription label instructions vary, and ranged from 53% to 89% in some studies conducted in the USA.[10] It is also known that poor readability significantly affects comprehensibility and medication recall.[11] Hence, practicing pharmacist may find it useful to know the factors that hinder effective communication of medicines information in order to improve the process.

The depth of information to be provided greatly depends on the type of medicine. As far as the patient is concerned, he/she needs to have minimum data such as the name, strength, frequency, duration, route of administration and important cautionary information on their medicines. Hence, dispensing labels which contain dosing instruction on correctly administering medicines and auxiliary labels to warn patient on important cautionary information about the medicine are key essentials.

Shrank et al[12] and Bailey et al[13] conducted two systematic reviews, both aimed at summarizing best practices in written prescription medication information and instructions to patients using related articles published from 1990 to 2015. These reviews also included physician–patient communication about medications and were not specifically focused on communication between patient and pharmacist. The role of the pharmacists in providing medicines information is different to that of the prescriber in many ways. The pharmacist is the last health care professional to care for patients at the outpatient setting, and is expected to transcribe the medical terminology on the prescription to simple instructions for the patient to follow. In that, the pharmacist is expected to ascertain the patient's level of comprehension through a brief interview and adjust the level of communication accordingly. The pharmacist may even be the only health care professional encountered by a patient when purchasing over-the-counter medication at the pharmacy. Hence, this review aims to focus exclusively on patient and label-specific factors that lead to patient misunderstanding of the prescription instructions and auxiliary labels, given by pharmacists, and identify successful interventions that helped to improve this issue. As this review aims to collate studies that support a non-controversial aspect in patient communication, a narrative review approach was deemed appropriate.

Methods

Information was searched by a research pharmacist (reviewer 1) and a senior academic pharmacist (reviewer 2) using electronic resources, PubMed, Google Scholar and SAGE in April 2017. Search terms used were "drug dosing instructions", "prescription medication label", "prescription labels" and "dispensing labels". All types of research designs except opinions and editorials published from year 2000 to April 2017 were included. The first reviewer read the titles and the abstracts and selected articles for review using the following inclusion and exclusion criteria.

Inclusion criteria

- Articles written in English language.
- Articles published in year 2000 and after.
- Articles including studies that focused on communication with patients.
- Articles including studies related to dispensing/prescription labels or auxiliary labels for prescription only medicines.

Exclusion criteria

- Articles that focused on manufacture labels, patient information leaflets and product information leaflets.
- Articles that focused on non-prescription medicines; off-label indications; devices; biologics; chemotherapy; herbal, dietary and non-medicinal preparations and investigational medicines.
- Opinions and editorials.

Cited references of selected articles were also included where relevant. A second reviewer went through the same process to endorse the selection of articles. Discrepancies were resolved through discussion among the two reviewers until 100% agreement was reached. A critical appraisal of articles was not performed using a formal checklist, but reviewers used self-judgment to appraise the studies before selection.

Results

A total of 33 articles that matched the objectives of this review were retrieved and evaluated by all three authors (Table 1). The findings of factors that lead to poor communication between pharmacist and patient when providing medicines information on dispensing/prescription labels and auxiliary labels, and interventions that were used to alleviate these

Table 1 Summary of studies reviewed

Author	Summary of the process	Summary of findings	Year of publication
Davis et al[10]	Focus: The usefulness of explicit language to communicate dose and frequency of medicines in improving comprehension among patients Design: Cross-sectional study using structured interviews Study setting and participants: Three hundred and fifty-nine adults in three primary health care settings Study process: Assessed the correct understanding of 10 dispensing instructions on labels based on patients' verbatim responses	• Patient understanding of prescription label instructions ranged from 53% to 89% • Explicit time periods or precise times were more easily understood than stating times per day or hourly intervals • Low level of literacy was related to misinterpreting of instructions	2009
O'Hare et al[11]	Focus: Assess ability to read and recall dispensing labels related to eye drops among glaucoma population Design: Cross-sectional study using a questionnaire Study setting and participants: Two hundred glaucoma patients in a tertiary care hospital Study process: Patients' ability to read standard and large font medication labels and their ability to recall the treatment regimen were assessed	• 12% of the gluocoma patients were unable to read standard pharmacy labels and 5.5% were unable to read the larger font labels • 32% found it difficult to recall the dosing regimen accurately • Inability to read standard labels was associated with difficulty in recalling dosing instructions	2009
Shrank et al[12]	Focus: Evidence-based information on optimal content and format of prescription labels that improves readability, understanding and medication use Design: Systematic review Articles included: 105	• Patients desired to know about a drug's indication, expected benefits, duration of therapy and adverse effects • Labels with larger fonts, lists, headers and white space, using simple language and logical organization improved readability and comprehension • Evidence on the use of pictographic icons in helping patients and the link between labels and medication adherence was not adequate	2007
Bailey et al1[13]	Focus: Review of best practices related to communication of written prescription medication information and instructions to patients which included labels, leaflets, brochure/pamphlet, medication guides, medication inserts and drug inserts Design: Systematic review Article included: 31	• Best practices were concluded to be use of plain language, improved formatting and use of explicit instructions • Usage of icons in communication was indecisive based on the available evidence	2015
Davis et al [14]	Focus: Patients' capabilities on comprehending and demonstrating instructions stated on container labels of prescription medicines Design: Cross-sectional study using structured interviews Patients and study setting: Three primary care clinics using 395 English-speaking patients Study process: Patients' understanding of information on five container labels, and their ability to demonstrate dosage instructions of one of the labels was assessed	• Low level of literacy and the number of medicines in a prescription were related to misunderstanding the instructions on dispensing labels • Although most patients were able to read label instructions, they were less able to correctly demonstrate the number of pills to be taken	2006
Davis et al[15]	Focus: Patients' ability to correctly interpret commonly used prescription medication warning labels Design: Structured interviews with literacy assessment Study setting and participants: 251 patients in one public hospital and a primary care clinic Study process: Patients were asked to interpret eight commonly used prescription medication warning labels, and the accuracy was determined by an expert panel	• Multistep instructions were more difficult to interpret • Patients with low literacy were 3.4 times less likely to interpret prescription medication warning labels correctly	2006

(*Continued*)

Table 1 (*Continued*)

Author	Summary of the process	Summary of findings	Year of publication
Wolf et al[16]	Objective: Nature and reasons for misunderstanding common dosing instructions on drug container labels by patients Design: In-person cognitive interviews Study setting and participants: 395 patients in three primary care clinics Study process: Patients were asked to read and demonstrate dosage instructions of five commonly used prescription medications	• Misunderstanding dosage instructions on labels was common • Limited literacy was associated with misunderstanding dosing instructions • Instruction presentation in labels was awkward, vague and unnecessarily difficult	2007
Wolf et al[17]	Focus: Reasons for misunderstanding prescription drug warning labels (PWLs) among adults with a low level of literacy Design: Structured interviews Study setting and participants: 74 patients with reading ability of sixth-grade level or less attending a primary care clinic Study process: Patients were asked to interpret and comment on eight commonly used PWLs, which was assessed by an expert panel	• Patients with low levels of literacy were less able to correctly interpret the PWLs than those with higher levels of literacy • Reasons for difficulty in interpreting were found to be: – Use of multiple-step instructions – Difficulty reading the text – Use of icons and color – Clarity of message	2006
Bailey et al [18]	Focus: To determine the level of adult understanding of dosage instructions for a liquid medication commonly prescribed for children Design: Structured interviews Study setting and participants: 373 adults attending a family medicine clinic serving a lower income population Study process: Patients were asked to read a prescription label for amoxicillin and demonstrate the method of administration. The recorded responses were evaluated by a blinded panel of experts	• Nearly a quarter of patients misunderstood instructions on amoxicillin • Issues related to dosage measurement and frequency of use were commonly misunderstood • Limited literacy was significantly associated with misunderstanding and could contribute to racial disparities	2009
Masland et al[19]	Focus: Effect of limited English and other factors on understanding prescription among five ethnic groups Design: Controlled analysis of a self-reported survey Study setting and participants: 48,968 participants belonging to five ethnic groups who responded to California's 2007 Health Interview Survey and had received a prescription in the past year Study process: Participants were asked questions about the ease of understanding prescription label information and ease of speaking the English language. Multivariate logistic regression was done after controlling for bilingual doctor, education level, medications for chronic conditions, disability, years in USA, citizenship and sociodemographics	• Among all participants who had limited English proficiency, 25% found it difficult to understand prescription bottle labels compared to only 5% among those who were proficient in English • Limited English literacy hindered prescription understanding for most ethnic groups • Education and ethnicity also affected prescription understanding	2011
Bailey et al[20]	Focus: Compare the efficacy of multilingual Rx instructions (the Concordant Rx instructions) against standard, language-concordant Rx instructions in improving understanding of treatment instructions Design: Randomized, experimental study Study setting and participants: 202 non-English-speaking adults from nine clinics and community organizations Study process: Participants were asked to review labels on bottles with either Concordant Rx or standard instructions which were assigned randomly. Proper demonstration of instructions and times per day participants took medicine for a multidrug regimen was assessed	• Concordant Rx instructions were better understood and correctly demonstrated than standard instructions	2011

(*Continued*)

Table 1 (*Continued*)

Author	Summary of the process	Summary of findings	Year of publication
Tai et al[21]	Focus: Effectiveness of an educational intervention on understanding prescription (Rx) labels and functional health literacy (FHL) among geriatrics Design: Experimental, before and after study Study setting and participants: Adults aged over 55 years attending senior and community centers and taking two or more prescription medicines daily. Study process: Modified LaRue Tool (MLT) was used to test understanding of prescription labels before and after an educational intervention (one-on-one education provided by student pharmacists). Correlated FHL was also analyzed. Outcomes were compared between current and redesigned Rx labels	• Older adults understood the redesigned prescription and showed improved FHL after the educational intervention • Those using redesigned labels showed a higher comprehension compared with those using current Rx labels	2016
Shrank et al[22]	Focus: Assessing the format, content and variability of prescription drug container labels dispensed in community pharmacies Design: Observational study Study setting and participants: Six pharmacies in four cities; 85 labels were evaluated Study process: Hypothetical prescriptions for four commonly used medicines were used to assess the quality of prescription labels and auxiliary labels that resulted	• The main label was found to be generally consistent • Substantial variability was observed in the content of instruction and warning stickers among pharmacies • The pharmacy name or logo was more prominent than medication instructions	2007
Wallace et al[23]	Focus: Assessing the format, content and readability of medication container labels and auxiliary labels (stickers) for prednisolone and amoxicillin for children Design: Observational study Study setting and participants: Labels of 40 containers dispensed from 20 pharmacies Study process: All labels were assessed against the presence and rank order of seven US Food and Drug Administration (FDA)-required label items, presentation, content and presentation of auxiliary warning labels. Reading grade level (RGL) of labels was assessed using the Lexile Analyzer	• Labels met the minimum FDA-required labeling standards • Information about the pharmacy was more prominently displayed than medication instructions and patient information	2010
Leat et al[24]	Focus: Comparison of the legibility of current prescription medication labels against an improved prototype labels, developed based on current guidelines for legibility Design: Observational study Study setting and participants: Three groups including older adults with normal vision, and older and younger patients with impaired vision (total, N = 71) participated Study process: Patients were asked to read and rank current prescriptions from pharmacies and prototype labels. Accuracy and speed of reading were assessed	• Both current and prototypes were read with high accuracies were high (75%–100%) • There were no significant differences in reading accuracy among the different label types and participants groups. • Prototypes were read faster than current labels • Largest print option and numbers written in highlighted uppercase words were preferred by patients	2016
Leat et al[25]	Focus: Assessing if sample prescription labels adhered to print legibility guidelines Design: Observational study Study setting and participants: 45 pharmacies in three cities selected through cluster sampling Study process: Hypothetical prescription was produced to pharmacies and the resulting label was compared with recommended guidelines	• Most (90%) labels were consistent with the guidelines for font style, contrast, print color and nonglossy paper • Less than half (44%) of the medication instructions met the minimum guideline for font size, especially the drug and patient name	2014

(*Continued*)

Table 1 (*Continued*)

Author	Summary of the process	Summary of findings	Year of publication
Zargarzadeh and Law[26]	Focus: Measuring the preference of patients, pharmacists and physicians on content, convenience and cosmetic appearance when designing prescription labels Design: Interviews (patients), discussions at professional meetings (pharmacists and physicians), survey Study setting and participants: 444 patients, 115 pharmacists and 69 physicians Study process: Preferences were asked from participants between labels A and B, designed based on published literature and previous experiences. A survey instrument was used to compare current labels with labels A and B	• Most patients (82.8%), pharmacists (76.4%) and physicians (75.3%) preferred new labels over existing ones and over half of them preferred label B • Modifications to all three parameters, content, convenience and cosmetic appearance, were endorsed by the participants	2011
Kebodeaux et al[27]	Focus: Patient expectations for prescription label content and formatting and their preferences to United States Pharmacopeia (USP) Chapter 17 Standards[46] for prescription container labeling Design: Focus group discussions Study setting and participants: Adult patients taking at least two chronic prescription medications and able to manage their own medicines Study process: Five focus groups (17 total participants) were conducted in St Louis in 2014. To ensure consistency of interpretation, a constant comparative analytic framework approach was used	• Patients' perceptions and expectations on prescription content, formatting container labeling were generally consistent with published USP Chapter 17 guidelines • Patients perceived having the pharmacy phone numbers, white space and highlighting as important	2016
Chan and Hassali[28]	Focus: Impact of improved labels with enlarged font and pictograms on adherence, comprehension and preferences of patients on long-term medication Design: Three-arm, randomized controlled trial Study setting and participants: Outpatient pharmacy of a general hospital on patients using long-term medication Study process: Three groups of patients were randomly allocated with standard (n = 35), font-enlarged (n = 40) or pictogram-incorporated (n = 35) labels. Adherence, comprehension using a structured questionnaire and preferences were scored. Patients were interviewed by telephone after 4 weeks	• Comprehension and adherence did not significantly change after adjusting for age in the three groups ($p = 0.573$ and 0.069, respectively) • Pictogram-incorporated label over font-enlarged label was preferred by elders and those with a number of morbidities	2014
Shrank et al[29]	Focus: Improving medication adherence with the new "Target label" Design: Observational study Study setting and participants: Patients with one of nine chronic diseases who were dispensed prescriptions at a selected pharmacy chain (N = 23,745) and a matched sample (N = 162,368) who were dispensed prescriptions at other community pharmacies Study process: The impact of the new "Target label" was assessed in the two cohorts	• No significant change was observed in utilization of health services due to the implementation of the new prescription drug label at the selected pharmacy chain	2009

(*Continued*)

Table 1 (*Continued*)

Author	Summary of the process	Summary of findings	Year of publication
Wolf et al[30]	Scope: Effectiveness of standardized, patient-centered label (PCL) instructions against typical instructions on comprehension of prescription drug use Design: Cross-sectional study using structured interview Study setting and participants: 500 patients from two academic and two community primary care clinics Study process: Patients were given one of either instructions written as times per day (once, twice and three times per day), instructions with explicit timing (morning, noon, evening and bedtime) (PCL) or PCL depicting dose and timing graphically (PCL + Graphic)	• PCL format was more correctly interpreted compared to standard instructions • Graphic aids (PCL + Graphic) reduced rates of correct interpretation compared to PCL instructions • Patients with low literacy levels were more able to interpret PCL	2011
Wolf et al[31]	Scope: Effectiveness of a patient-centered drug label with Universal Medication Schedule (UMS), in comparison to a standard label, on proper medication use and adherence Design: Two-arm, multisite patient-randomized pragmatic trial Study setting and participants: 845 English- and Spanish-speaking patients with diabetes/hypertension attending one of eight community health centers Study process: PCLs developed according to evidence-based practices, including UMS, were used. Proper use of a multidrug regimen and adherence to medication were measured by self-report and pill count at 3 and 9 months	• PCLs were slightly better in promoting proper use of their drugs in the first and at 9 months • The effect was significant for English-speaking patients • Intervention did not improve medication adherence • The PCLs benefited patients with medications to be taken ≥2 times a day	2016
Sahm et al[32]	Focus: Comparing PCL instructions against standard instructions on knowledge and comprehension of prescription drug use Design: Observational study Study setting and participants: 94 patients attending an outpatient clinic Study process: Patients were given either standard prescription instructions written as times per day (usual care), PCL instructions with explicit timing, standard intervals with mealtime anchors (both PCL) or PCL instructions with a pictorial (PCL + Graphic) for interpretation	• PCL instructions were better interpreted than standard instructions • PCLs were better interpreted than PCL + Graphic • There was a relationship with instruction type and health literacy • Patients with limited health literacy better interpreted PCL labels than the standard labels	2012
Web et al[33]	Focus: Use of patient-centered warning labels Design: Ten face-to-face cognitive interviews Study setting and participants: Participants were from a general internal medicine clinic and four adult education classes Study process: Participants were asked regarding the comprehension of the 10 most commonly used drug warning labels for revising text and icons	• Participants felt most of icons were confusing • Five of the warning labels reached a set standard of >80% comprehension	2008
Sundar et al [34]	Study focus: Effectiveness of prescription warning labels (PWLs) in communicating warning information Design: Observational study Study setting and participants: Participants were categorized into two groups: young adults and those above 50 years Study process: Patients were asked to interact with the prescription vials that had PWLs and their recognition memory was tracked	• Participants were often failed to attend to the PWLs • Older participants were less attentive and did not perform the memory test as well as the young adults	2012

(*Continued*)

Table 1 (*Continued*)

Author	Summary of the process	Summary of findings	Year of publication
Mohan et al[35]	Focus: Assess the improvement in understanding by using an evidence-based bilingual prescription container label Design: Qualitative study, focus group discussions and one-on-one interviews Study setting and participants: Latino (N = 30) and non-Latino patients (N = 18) attending two clinics caring for low-income patients and pharmacists (N = 9) of a university pharmacy Study process: Several prototypes of labels were developed in English only and in bilingual form (English and Spanish). An image of the drug, an icon to show its purpose, was included with instructions presented in a table. Participants were asked to critically review the designs and compare them and reformat labels without illustrations and standard labels	• Labels with patient-relevant content, highlighted key information and drug indication icons were preferred • Instructions using the 4-time-of-day table together with plain-language text were also preferred as opposed to either one alone • Warnings were preferred on the main label instead of auxiliary labels • Pharmacists and Latino patients preferred having instructions on the label in both languages, Spanish and English	2013
Chuang et al[36]	Focus: Preference and comprehension levels of having pictographs to illustrate medication use instructions among patients with low-literacy levels and medical staff Design: Survey Study setting and participants: 250 patients with low-literacy levels and 250 members of the medical staff in a teaching hospital Study process: Three sets of pictographs in four medication instruction categories were used in a survey among participants	• Preference among medical and patients differed • Significant differences in ability to comprehend pictographs relate to medication administration time of day and medication administration associated with meals were also observed between the two groups	2010
Wolf et al[37]	Focus: Improve patient comprehension by using "enhanced print" drug auxiliary warnings against the current standard Design: A three-arm, cross-sectional evaluation Study setting and participants: 500 adult patients at two academic and two community health primary care clinics Study process: Consecutively assigned to receive one of standard warning, drug warnings with text rewritten in plain language (simplified text), or plain language and icons (simplified text + icon). Correct interpretation of nine drug warning labels was assessed by a blinded reviewer panel	• Simple, explicit language on warning labels improved patient comprehension • Ions were useful for adults with lower literacy skills	2010
Emich et al[38]	Objective: Compare the effectiveness of a yellow/black label + written warning (already in practice) on driving-impairing medicines (DIMs) against a new rating model, with and without side-text Design: Cross-sectional questionnaire study Study setting and participants: 298 participants attending community pharmacies (30% response rate) Study process: Patients who were dispensed DIM for the first time were asked to respond to a written questionnaire comparing the three types of warning labels. The estimated level of driving risk rated by patients and intention to change driving behavior after seeing the warning label were assessed	• The yellow/black label was found to be less effective than the new rating model in both estimating risk and intention to change driving behavior • Side-text the new model further	2014

(*Continued*)

Table 1 (*Continued*)

Author	Summary of the process	Summary of findings	Year of publication
Cardarelli et al[39]	Focus: Evaluate the effectiveness of adding color-specific symbols to the standard label on medication bottles on the ability of older patients to match their medication with the indication Design: Focus group discussion, before and after interventional study Study setting and participants: Patients aged 65 years and above. Two phases: focus group discussions among 25 patients (Phase I); pre- and post-identification tests among patients (Phase II) (N = 100) Patients were a convenience sample attending a family medicine clinic Study process: Focus group was used to obtain consensus on color labeling for 19 indications. Patients were asked to identify the indication for their own medicines before and after adding the color symbol when placed in front of participants and then at a distance of 2 feet	• Participants appreciated the new system and found the colors and symbols easy to understand and relevant • The new system of labeling improved the ability of participants to match their medication to the appropriate medical indication at a distance of 2 feet	2011
Shiyanbola et al[40]	Objective: To explore the perspectives of patients and pharmacists on five newly designed PWLs, and examine if there were similarities and differences between patients' and pharmacists' perspectives Design: Semistructured face-to-face interviews Study setting and participants: Patients who took prescription medication from an ambulatory setting and pharmacists dispensing in an ambulatory setting Measurements: Explored patients' and pharmacists' feedback on five newly designed PWLs. The patient and pharmacist perspectives on the words (content), picture and color (cosmetic appearance) and placement of warning instructions on the pill bottle (convenience) were based on a label redesign framework. Qualitative content analysis was done	Patients and pharmacists had different preferences for PWL design changes to improve understandability. Pharmacist preferences did not always correspond with patient preferences. However, patients and pharmacists generally agreed on the preferred location of the PWL on the pill bottle and the use of color for drawing patients' attention.	2017
Shiyanbola et al[41]	Focus: Patient feedback on five newly designed PWLs Design: In-depth semistructured face-to-face interviews Study setting and participants: Adult patients (N = 21) speaking English and on at least one prescription medication Study process: Feedback was obtained on different variations of five commonly used PWLs – Take with Food, Do not Drink Alcohol, Take with a Full glass of Water, Do not Chew or Break and Protect from Sunlight	• Patients had positive opinion on the redesigned PWLs but suggested further improvements to the content and design to improve clarity and comprehensibility	2016
Shiyanbola et al[42]	Focus: Assess how underserved populations attend to PWL instructions, the importance attributed to PWL by them and challenges faced in interpreting the information on PWLs Design: Semistructured interviews Study setting and participants: 103 adults who had used prescription medication were able to understand English and represented a population which included racial and ethnic minorities, individuals with low income and/or older adults Study process: Participants were asked regarding the information they would like to have related to eight different prescription bottles with an attached PWL, including other questions to assess their views on importance of PWLs and the challenges with understanding PWLs. Those who attended to the warning labels were also noted	• Most participants with limited level of literacy and those currently not taking medications overlooked the warning labels • Most agreed that warning instructions are extremely important • Participants also preferred the pharmacist to help them understand PWLs • Participants believed that the graphics made the label information easy to understand	2014

problems were categorized as "patient-related factors" and "medication label-related factors" and are summarized in the following section.

Patient-related factors

Patient literacy levels and language barriers

Studies on readability and comprehensibility of dispensing labels or auxiliary labels reflect various factors that lead to poor communication. Among them, low level of literacy among patients was a major contributing factor.[10,14–17] Davis et al[14] reported that low literacy rates were independently correlated to misunderstanding of written dosing instructions. In their study, patients with low level of literacy were found to be 3.4 times less likely to correctly interpret prescriptions and medication warning labels.[15] Bailey et al[18] found that low literacy rates was a risk factor for misunderstanding dosing instructions which also differed among different races. A large study by Masland et al[19] among 48,968 participants found that among all participants who had limited English proficiency, 25% found it difficult to understand prescription bottle labels compared to only 5% among those who were proficient in English. The study concluded that prescription instructions must be compatible with patients' educational level and culture. Bailey et al[20] reported that using concordant prescription instructions can help to improve safe medication use among limited English proficient patients.

Age of patients

Tai et al[21] reported that age is a common significant predictor of prescription label comprehension and simple educational interventions such as one-on-one education provided on critical elements of the label could significantly improve the level of comprehension of prescription labels.

Medication label-related factors

Number of medicines dispensed

Taking a larger number of prescribed medicines was associated with poor patient comprehension of prescription labels.[14] Patients were more likely to misinterpret dosing instructions when the number of medicines in a prescription was high. The authors of this study related this finding to high complexity of dosing instructions leading to confusion.[14] In addition, the consistency of dosing instructions provided also varied among pharmacists in the community.[22] This implies that pharmacists generally do not adhere to standard guidelines for providing vital medicines information that needs to be communicated to patients.

Format and organization of instructions

The format of the prescription label, the organization, spacing, headers, font style and font size, are critical features for promoting readable and understandable dosing instructions.[20] Most prescription labels emphasized less important information and gave little prominence to vital dosing instructions. Pharmacy name and logo were prominent in most labels while medication instructions, medication name, warning instructions and stickers were in smaller fonts.[12,22,23] Although larger fonts were readable by most patients,[11,24] nearly half of the labels did not comply with the minimum standard guidelines of 12-point font size specified for vital medicines information.[12,25,26] It was interesting to note that medication labels with better content and cosmetic appearance were preferred by the majority of physicians (75.3%), pharmacists (76.4%) and patients.[26] Leat et al[24] emphasize on the improvements to the label by including larger print size, a consistent layout with left justification and using upper case with highlighting for emphasizing of numbers in the instructions. A focus group including 17 participants revealed the importance of including pharmacy phone numbers, white space and highlighting in dispensing labels.[27] On the contrary, Chan and Hassali[28] used medicine labels with larger fonts but found no significant change in comprehension and medication adherence.

Complexity of dosing instructions

Common sense dictates that and many have confirmed the importance of providing fairly simple and lucid dosing instructions when dispensing any medication.[12,13,29] Labels with multistep instructions,[15,17] ambiguous instructions[16] and imprecise instructions were often regarded by patients as complex.[10,13] Multistep instructions were found to be difficult for all patients irrespective of the literacy levels.[15] Even a simple multistep instruction such as "take with food at night" was more difficult to comprehend than a single-step instruction such as "take with food".[15]

Precision of dosing instructions

Labels with precise wording were more comprehensible to patients. Interestingly, a dosing instruction given as "take one tablet twice a day" or "take one tablet 12 hourly" was more difficult to understand than "take one tablet each in the morning and night".[10] Interventions to support best practices in writing dosing frequencies are numerous. Wolf et al[30] developed and tested the effectiveness of patient-centered labels (PCLs), one written with explicit timing (morning,

noon, evening and bed time) and another with explicit timing accompanied with graphics, against a standard label with dosing instructions written as once, twice and thrice per day ("times per day" approach). They reported that PCLs were more likely to be correctly interpreted than standard labels, especially by patients with low level of literacy.[30] Further, a subsequent, improved version of the PCL developed using evidence-based information by the same group of researchers also showed improvement in proper use of medicines.[31] A similar study by Sahm et al[32] also supported this finding. Another study by Davis et al[10] where mock medicine labels were prepared with dosing frequencies specified in "times per day" approach (e.g., three times a day), hourly intervals (e.g., every 8 hourly), time periods (morning, noon and night) and specific times (e.g., 8 am, 12.00 noon and 8 pm) reported that dosing instructions stated in time periods and specific times were more likely to be correctly interpreted. Bailey et al[20] used standard instructions (e.g., TAKE TWO TABLETS TWICE DAILY) written in uppercase lettering and "times per day" approach, against concordant instructions (e.g., Take 2 pills in the morning and 2 pills at bedtime) using explicit and simpler terms, lower and upper case lettering and numeric characters. Patients having concordant instructions understood dosing instructions and accurately dosed their medication better than those who received standard instructions. Hence, pharmacists must try to specify "time periods" instead of "times per day" and "specific times" instead of "hourly intervals", when writing medicine frequencies.

Use of icons, graphics and pictograms

The use of icons, pictograms and graphics in labels received mixed responses from patients. According to some reviewers, icons, pictographs and prescription warning labels were frequently misunderstood by patients.[12,33] Prescription warning labels were also given less attention by older patients[34] and they preferred warnings to be given in the main label and not in auxiliary labels.[35] There was variability in comprehending pictographs among patients as well as medical staff.[36] Davis et al,[15] for instance, summarized common misinterpretations of pictographic drug warning labels. Chan and Hassali[28] found no significant change in comprehension of information nor improved medication adherence due to pictograms. However, Wolf et al[37] noted that icons or pictograms were useful, particularly for the low literates. The latter author also studied the usefulness of auxiliary labels where patient-centered auxiliary labels were prepared using clear, concise and explicit language. Patient-centered icons were included after considering patient feedback and following guidelines established by the International Organization for Standardization for the Development and Testing of Universal Icons.[37] Auxiliary labels with simplified text only, and simplified text with icons, were more likely to be correctly interpreted compared with standard auxiliary labels. Between the two, labels with simplified text supported by icons were better interpreted than simplified text alone.[37] A study by Emich et al[38] also supports this claim where acceptability of three types of warning labels were assessed among patients taking driving-impairing medicines. Among three types of labels, a conventional yellow/black label, label with a rating model (risk level of driving) and a label with rating model accompanied with side-text, patients preferred the latter. Auxiliary labels attached to more prominent places of the label were better received by patients.[37] Addition of a color code to represent the indication of the medicine was also found to significantly improve the ability to accurately match their medication to indications.[39] Shiyanbola et al[40] redesigned patient warning labels using feedback from pharmacists and patients, on words (content), picture and color (cosmetic appearance) and placement of warning instructions on the pill bottle (convenience). They found that preferences of patients on design changes to improve understandability of warning labels were not always similar to that of the pharmacist, indicating differences in patient's perspective to health care professionals. Both groups agreed on the preferred location of the warning label on the medicine pack and the use of color for drawing patients' attention. Another study by Shiyanbola et al[41] describes the outcome of a qualitative study using different variations of the five most commonly used warning labels: "Take with Food", "Do not Drink Alcohol", "Take with a Full glass of Water", "Do not Chew or Break" and "Protect from Sunlight". While appreciating the efforts, patients demanded further improvements to the content and design of the warning label to enhance clarity and understandability,[41] depicting the importance patients place on clarity of information provided through warning labels. The same research group investigated perception on warning labels among an undeserved population and found that most rated the warning instructions to be extremely important and thought the graphics made the label information easy to understand. However, those who were currently not on medication and those with limited health literacy overlooked warning labels.[42] Moreover, these participants preferred to be counseled by pharmacists on the important facts about the warning labels.[42]

Discussion

The foregoing is a narrative review of the currently available data and factors that affect the readability and comprehensibility of medicine labels written by pharmacists. We noted that 1) patient literacy levels, 2) age, 3) number of medicines dispensed, 4) format and organization of the medicines label, 5) complexity of dosing instructions, 6) precision of writing dosing instructions and 7) the use of icons, graphics and pictograms were aspects that were frequently assessed by research groups on medicine label writing. In general, our review findings support the notion that instructions written in a simple and straight forward manner were better comprehended by patients.

Effective communication may not always ensure medication adherence among patients. From the available and reviewed data, it is difficult to conclude whether readability and comprehensibility of dosing instructions are directly related to medicines adherence. Shrank et al,[29] for instance, recently evaluated the effect of a number of improved features of labels on medication adherence. For this purpose, he incorporated flattened bottles with larger space to present the information and used larger font with more white space to improve prominence of the content as well as logical representation of information preferred by patients through evidence-based information. The new label also included a pocket to store medicines information. Interestingly though, the results from this study did not reveal a significant change in medication adherence of the participants due to the improved format of the presentation.[29] Chan and Hassali also concluded that improved medicine labels do not affect medicine adherence.[28] Moisan et al[43] conducted face-to-face interviews among 325 participants and found 38.8% were not able to read all the prescription labels and 67.1% did not fully understand all the information. However, the two variables were not directly related to adherence after adjusting for several factors such as gender, age, living alone or not, having help of caregiver when taking medication, assistance of a pill organizer, financial capability to procure his medicine during the previous month, attitude and efficacy of medication used, self-perception of status of health, satisfaction of information provided by health care professionals and complexity of the treatment.

However, Shanika et al[44] used improved dosing instructions as a part of their intervention which resulted in better medication adherence. Odegard and Gray[2] conducted their study on poorly controlled diabetes patients and listed "ability to read prescription labels" as one barrier for medication adherence among paying for medications, remembering doses and obtaining refills.[2] Wolf et al[31] used a patient-centered drug label strategy to find that there were significant benefits to medication adherence among patients with limited literacy. These data clearly indicate that medication adherence is a complex, multifactorial issue and other unaddressed or unknown factors may have affected the result of the foregoing studies.

A few important gaps were identified on the practice of writing dosing instructions and related research. One important observation was that pharmacists in general do not appear to use a standard set of guidelines when providing medicines information. A universal approach and format on writing dosing instructions, taking into consideration the abovementioned findings, would be immensely helpful in the provision of complete, consistent and comprehendible instructions to patients. Most medicine labels are hand-written, especially in the South East Asian countries, but not many studies have assessed the legibility of dosing instructions written by pharmacists. Given the issues related to illegible prescriptions, legibility of hand-written dosing instructions is undoubtedly a problem worth further study. Finally, except for a very few studies,[45] most workers have used mock dispensing labels and artificial situations to assess the readability and comprehensibility of dosing instructions. There is a need, therefore, for more research that measure the readability and comprehensibility of information related to patients' own medications in real life.

There are some limitations in this communication that needs to be acknowledged by the readers. Articles used in this narrative review were not obtained using a systematic process. We used only PubMed, SAGE and Google Scholar to extract our findings, hence there is a chance that some relevant studies not indexed in these search engines may have been missed. A critical appraisal of articles was not performed using a formal checklist, but reviewers used self-judgment to appraise the studies before selection. However, we have taken care to present an unbiased view of the studies accessible through the method we used.

Conclusion

To conclude then, providing clear, readable and comprehensible prescription labels is a crucial and a key role of the pharmacist. Our review highlights key factors that need to be considered when writing dispensing labels, such as patient literacy levels, age, number of medicines dispensed, format and organization of the medicines label, complexity of dosing instructions, precision of writing dosing instructions and the use of icons, graphics and pictograms when writing

prescription labels. We also emphasize do's and don'ts related to such key factors as lessons for pharmacists when writing dispensing labels. There is a surprising lack of standardization when writing dosing instructions to the public by pharmacists, and hence propose the need for universal guidelines.

Disclosure

The authors report no conflicts of interest in this work.

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