BRIEFING

⟨**17**⟩ **Prescription Container Labeling.** This proposed new general test chapter provides information on prescription container labeling. On May 18, 2007, the USP Safe Medication Use Expert Committee established an Advisory Panel to (1) determine optimal prescription label content and format to promote safe medication use by critically reviewing factors that promote or distract from patient understanding of prescription medication instructions and (2) create universal prescription label standards for format/appearance and content/language.

In November 2009, the Health Literacy and Prescription Container Labeling Advisory Panel presented its recommendations to the Safe Medication Use Expert Committee, which then requested that USP develop patient-centered label standards for the format, appearance, content, and language of prescription medication instructions to promote patient understanding. Those recommendations formed the basis of this general test chapter.

(NSL: S. Becker) RTS—C85490

Add the following:

▲⟨17⟩ PRESCRIPTION CONTAINER LABELING

INTRODUCTION

Medication misuse has resulted in more than 1 million adverse drug events per year in the United States (*1*). Patients' best source (and often only source) of information regarding the medications they have been prescribed is on the prescription container label (*2–6*). Although other written information and oral counseling sometimes may be available (*2–4,6–13*), the prescription container label must fulfill the professional obligations of the prescriber and pharmacist. These obligations include giving the patient the most essential information needed to understand how to safely and appropriately use the medication and to adhere to the prescribed medication regimen (*2,3,13–15*).

Inadequate understanding of prescription directions for use and auxiliary information on dispensed containers is widespread (*2–12,14,16–18*). Studies have found that 46% of patients misunderstood one or more dosage instructions (*14*), and 56% misunderstood one or more auxiliary warnings (*17*). The problem of misunderstanding is particularly troublesome in patients with low or marginal literacy (*2,3,5,6,8,9,12,15,17*). In one study, patients with low literacy were 34 times more likely to misinterpret prescription medication warning labels (*17*). However, even patients with adequate literacy often misunderstand common prescription directions and warnings (*2,6,9,15,17*). In addition, there is great variability in the actual auxiliary warning and supplemental instructional information applied by individual practitioners to the same prescription. The specific evidence to support a given auxiliary statement often is unclear, and patients often ignore such information (*2,3,7,15,17,18*). The essential need for, and benefit of, auxiliary label information (both text and icons) in improving patient understanding about safe and appropriate use of their medications versus explicit simplified language alone require further study (*2–5,7,13–15,17–19*).

Lack of universal standards for labeling on dispensed prescription containers is a root cause for patient misunderstanding, nonadherence, and medication errors (*1–9,12,13,15,17,18,20*).

PRESCRIPTION CONTAINER LABEL STANDARDS TO PROMOTE PATIENT UNDERSTANDING

Organize the prescription label in a patient-centered manner: Information shall be organized in a way that best reflects how most patients seek out and understand medication instructions. Prescription container

labeling should feature only the most important patient information needed for safe and effective understanding and use (*2–5,7,6,11,13,14,16,18,20–23*).

Emphasize instructions and other information important to patients: Prominently display information that is critical for patients' safe and effective use of the medicine. Place at the top of the label the patient's name, drug name and strength, and explicit clear directions for use in simple language.

Other less critical but important content (e.g., pharmacy name and phone number, prescriber name, fill date, refill information, expiration date, prescription number, drug quantity, product description, and evidence-based auxiliary information) should not supersede critical patient information. Such less critical information should be placed away from dosing instructions (e.g., at the bottom of the label or in another less prominent location) because it distracts patients, which can impair their recognition and understanding (*2–6,11–16,18*).

Simplify language: Language on the label should be clear, simplified, concise, and familiar, and should be used in a standardized manner. Only common terms and sentences should be used. Do not use unfamiliar words (including Latin terms) or unclarified medical jargon.

Whenever available and appropriate to the patient context, standardized patient-centered translations of common prescribing directions to patients (SIG) should be used. Use of readability formulas and software is not recommended to simplify short excerpts of text like those on prescription labels. The principles established by Doak, Doak, and Root for maintaining simple language can facilitate the simplification process (*24*). Consumer feedback also should be sought (*2–6,9,12–15,17,18,25,26–28*).

Give explicit instructions: Instructions for use shall clearly separate the dose itself from the timing of each dose in order to explicitly convey the number of dosage units to be taken and when (e.g., specific time periods each day such as morning and evening or at breakfast and dinner). Instructions should use numeric rather than alphabetic characters for numbers (e.g., write, ''Take 2 tablets in the morning and 2 tablets in the evening'' rather than ''Take two tablets twice daily'').

Whenever available, use standardized directions (e.g., write ''Take 1 tablet in the morning and 1 tablet in the evening'' or ''Take 1 tablet at breakfast and 1 tablet at dinner'' if the prescription reads b.i.d.). Vague instructions based on dosing intervals such as twice daily or 3 times daily, or hourly intervals such as every 12 hours, generally should be avoided because such instructions are implicit rather than explicit, they may involve numeracy skills, and patient interpretation may vary from prescriber intent. Although instructions that use specific hourly times (e.g., 8 a.m. and 10 p.m.) are more easily understood than implicit vague instructions, dosing by precise hours of the day is less readily understood and may present greater adherence issues than more general time frames such as in the morning, in the evening, after breakfast, with lunch, or at bedtime.

Ambiguous directions such as ''take as directed'' should be avoided unless clear and unambiguous supplemental instructions and counseling are provided (e.g., directions for use that will not fit on the prescription container label). A clear statement referring the patient to such supplemental materials should be included on the container label (*2–4,6,12–15,29*).

Include purpose for use: Determine what the patient prefers, and include the purpose of the medication on the label unless the patient prefers that it not appear. Confidentiality and FDA approval for intended use (e.g.,

labeled versus off-label use) may limit inclusion of the purpose on labels. Current evidence supports inclusion of purpose-for-use language in clear, simple terms (e.g., ''for high blood pressure'' rather than ''for hypertension'') (*2–4,13,14*).

Limit auxiliary information: Auxiliary information on the prescription container label should be evidence-based on simple explicit language that is minimized to avoid distracting patients with nonessential information. Most patients, particularly those with low literacy, pay little attention to auxiliary information. The information should be presented in a standardized manner and should be critical for patient understanding and safe medication use (e.g., warnings and critical administration alerts). Icons are frequently misunderstood by patients. In addition, icons that provide abstract imagery for messages that are difficult to visually depict may be ineffective at improving understanding compared with simplified text alone. Use only icons for which there is evidence that they improve patient understanding about correct use. Because of the limited space on the container, use only those icons shown in consumer testing to improve understanding beyond simple explicit text alone. Evidence-based auxiliary information, both text and icons, should be standardized so that it is applied consistently and does not depend on individual practitioner choice (*2–6,13–15,17–19*).

Address limited English proficiency: Whenever possible, prescription container labeling should be provided in an individual's preferred language. Otherwise there is a risk of misinterpretation of instructions by patients with limited English proficiency, that could lead to medication errors and adverse health outcomes.

Translations of prescription medication labels should be produced using a high-quality translation process. If a high-quality translation process cannot be provided, labels should be printed in English and translated by trained interpreter services whenever possible to ensure patient comprehension. The use of computer-generated translations should be limited to programs with demonstrated quality because dosage instructions can be inconsistent and potentially hazardous. Standardized translated instructions and technology advances are needed to ensure the accuracy and safety of prescription container labeling for patients with low English proficiency (*2,3,30,31*).

Improve readability: Labels should be designed and formatted so they are easy to read. Currently no strong evidence supports the superiority in legibility of serif versus sans serif typefaces, so simple uncondensed fonts of either type can be used (*2–4,20,22,2–37*).

Optimize typography by using the following techniques:

- High-contrast print (e.g., black print on white background).
- Simple, uncondensed familiar fonts with sufficient space within letters and between letters (e.g., Times Roman or Arial).
- Sentence case (i.e., punctuated like a sentence in English: initial capital followed by lower-case words except proper nouns).
- Large font size (e.g., minimum 12-point Times Roman or 11-point Arial) for critical information. Note that point size is not the actual size of the letter, so two fonts with the same nominal point size can have different actual letter sizes. X-height, the height of the lower-case x in typeface, has been used as a more accurate indicator of apparent size than point size. For example, for a given point size, the x-height and apparent size of Arial are actually bigger than those for Times Roman. Do not use type smaller than 10-point Times Roman or equivalent size of another font. Older adults often experience declines in visual acuity.

- Adequate white space between lines of text (25%–30% of the point size).
- White space to distinguish sections on the label such as directions for use versus pharmacy information.
- Horizontal text only.

Other measures that can also improve readability include the following:

- If possible, minimize the need to turn the container in order to read lines of text.
- Never truncate critical information.
- Highlighting, bolding, and other typographical cues should preserve readability (e.g., high-contrast print and light color for highlighting) and should emphasize patient-centric information or information that facilitates adherence (e.g., refill ordering).
- Limit the number of colors used for highlighting (e.g., no more than one or two).

REFERENCES

1. IOM (Institute of Medicine). *Preventing Medication Errors*. Washington, DC: National Academies Press; 2007.
2. IOM. Standardizing medication labels: confusing patients less [workshop summary]. Washington, DC: National Academies Press; 2008.
3. Wolf MS, Parker RM for the ACPF Medication Labeling Technical Advisory Board. Improving prescription drug container labeling in the United States: a health literacy and medication safety initiative [white paper]. 2007. Available at: http://acpfoundation.org/files/medlabel/acpfwhitepaper.pdf. Accessed 09 August 2010.
4. Shrank W, Avorn J, Rolon C, et al. Effect of content and format of prescription drug labels on readability, understanding, and medication use: a systematic review. *Ann Pharmacother.* 2007;41 : 783–801.
5. Wolf MS, Davis TC, Bass PF, et al. Improving prescription drug warnings to promote patient comprehension. *Arch Intern Med.* 2010;170 : 50–56.
6. Wolfe MS, Davis TC, Shrank W, et al. To err is human: patient misinterpretations of prescription drug label instructions. *Patient Educ Counsel.* 2007;67 : 293–300.
7. Shrank WH, Agnew-Blais J, Choudhry NK, et al. The variability and quality of medication container labels. *Arch Intern Med.* 2007;167 : 1760–1765.
8. Shrank WH, Avorn J. Educating patients about their medications: the potential and limitations of written drug information. *Health Affairs.* 2007;26 : 731–740.
9. Shillinger D. Misunderstanding prescription labels: the genie is out of the bottle [editorial]. *Ann Intern Med.* 2006;145 : 926–928.
10. Tkacz VL, Pruchnicki MC. Health literacy in pharmacy. *Am J Health-Syst Pharm.* 2008;65 : 974–975.
11. Shrank WH, Patrick A, Gleason PP. et al. An evaluation of the relationship between the implementation of a newly designed prescription drug label at Target pharmacies and health outcomes. *Med Care.* 2009;47 : 1031–1035.
12. Davis TC, Federman AD, Bass PF III, et al. Improving patient understanding of prescription drug label instructions. *J Gen Intern Med.* 2009;24 : 57–62.
13. National Association of Boards of Pharmacy. Report of the Task Force on Uniform Prescription Labeling Requirements. 2009. Available at: http://www.nabp.net/news/assets/08TF_Uniform_Presc_Labeling_Req.pdf. Accessed 09 August 2010.
14. Davis TC, Wolf MS, Bass PF III, et al. Literacy and misunderstanding prescription drug labels. *Ann Intern Med.* 2006;145 : 887–894.
15. Institute for Safe Medication Practices. Principles of designing a medication label for community and mail order pharmacy prescription packages. 2008.

Available at: http://www.ismp.org/tools/guidelines/labelFormats/comments/default.asp. Accessed 09 August 2010.

16. Shrank WH, Gleason PP, Canning C, et al. Can improved prescription medication labeling influence adherence to chronic medications? An evaluation of the Target pharmacy label. *J Gen Intern Med.* 2009;25 : 570–578.
17. Davis TC, Wolf MS, Bass III, et al. Low literacy impairs comprehension of prescription drug warning labels. *J Gen Intern Med.* 2006;21 : 847–851.
18. Webb J, Davis TC, Bernadella P, et al. Patient-centered approach for improving prescription drug warning labels. *Patient Educ Counsel.* 2008;72 : 443–449.
19. Wolf MS, Davis TC, Tilson HH, et al. Misunderstanding of prescription drug warning labels among patients with low literacy. *Am J Health-Syst Pharm*. 2006;63 : 1048–1055.
20. Morrow DG, Leiter VO, Andrassy JM, et al. The influence of list format and category headers on age differences in understanding medication instructions. *Exp Aging Res.* 1998;24 : 231–256.
21. Miselli M. What information for the patient? Large scale pilot study on experimental package inserts giving information on prescribed and over the counter drugs. *BMJ.* 1990;301 : 1261–1265.
22. Bernardini C, Ambrogi V, Fardella G, et al. How to improve the readability of the patient package leaflet: a survey on the use of colour, print size and layout. *Pharmacol Res.* 2001;43 : 437–444.
23. Morrow D, Leirer V, Altieri P. List formats improve medication instructions for older adults. *Educ Gerontol.* 1995;21 : 151–166.
24. Doak C, Doak L, Root J. Suitability assessment of materials [instrument] in *Teaching Patients with Low Literacy Skills.* Philadelphia: Lippincott; 1996.
25. Bower AB, Taylor VA. Increasing intention to comply with pharmaceutical product instructions: An exploratory study investigating roles of frame and plain language. *J Health Commun.* 2003;8 : 145–156.
26. Gramling R, Irvin JE, Nash J, et al. Numeracy and medicine: key family physician attitudes about communicating probability with patients [letter]. *J Am Board Fam Pract.* 2004;17 : 473.
27. Morrow DG, Hier CM, Menard WE, et al. Icons improve older and younger adults' comprehension of medication information. *J Gerontol B Psychol Sci Soc Sci.* 1998;53 : 240–254.
28. Mazzullo JM III, Lasagna L, Griner PF. Variations in interpretations of prescription instructions. The need for improved prescribing habits. *JAMA.* 1974;227 : 929–931.
29. Holt GA, Dorcheus L, Hall EL, et al. Patient interpretation of label instructions. *Am Pharm.* 1992;NS32 : 58–62.
30. Bailey SC, Pandhit AU, Curtis L, et al. Availability of prescription labels: a multi-state pharmacy survey. *Med Care.* 2009;47 : 707–710.
31. Sharif I, Tse J. Accuracy of computer-generated, Spanish-language medicine labels. *Pediatrics.* 2010;125 : 960–965.
32. Wogalter MS, Vigilante WJ Jr. Effects of label format on knowledge acquisition and perceived readability by younger and older adults. *Ergonomics.* 2003;46 : 327–344.
33. Zuccollo G, Liddell H. The elderly and medication label: do it better. *Age Aging.* 1985;14 : 371–376.
34. Filk R, Purdy K, Gale A, et al. Drug name confusion: evaluating the effectiveness of capital (''tall man'') letters using eye movement data. *Soc Sci Med.* 2004;59 : 2597–2601.
35. Smither JA, Braun CC. Readability of prescription drug labels by older and younger adults. *J Clin Psychol Med Sett.* 1994;1 : 149–159.

36. Poole A. Which are more legible: serif or sans serif typefaces? 2004. Available at: http://www.alexpoole.info/academic/literaturereview.html. Accessed 09 August 2010.
37. Arditi A. Making text legible: designing for people with partial sight. 2009. Available at: http://www.lighthouse.org/accessibility/design/accessible-print-design/making-text-legible/. Accessed 09 August 2010.▲*USP35*