

Institute for Safe Medication Practices

Principles of Designing a Medication Label

for Community and Mail Order Pharmacy Prescription Packages

There is an ever-present risk of medication errors in community pharmacy and ambulatory care practice, but this risk is even greater when pharmacy labels, which are provided to assist in patient care, are poorly designed. Standardized, and well thought drug labeling practices need to be a part of an overall strategy to improve medication adherence and reduce inadvertent medication errors. Based on ISMP's ongoing analysis of actual medication errors reported and a review of pharmacy-generated labels produced by a number of systems including a sample BPOC system, ISMP offers the following recommendations as a basic approach toward the prevention of errors related to label misinterpretation:

1. Label formats should include larger fonts, lists, headers, whitespace, simple language, and logical organization to improve readability and comprehension.¹
 - a. Minimum font size for patient name, generic drug name, and patient-specific dose should be 12 point or equivalent.² (A 1994 study of adults and seniors found more self-administration medication errors with 9 vs. 12 or 14 point font and *Courier* vs. Helvetica fonts.)
 - b. Use standardized font styles such as: Arial, Verdana, or their equivalent for all text and numbers. To improve typography, use larger, sans serif font. Do not use italic, oblique, narrow, or condensed type fonts.

- c. When applicable, use numeric vs. alphabetic characters when describing drug doses, concentrations, or frequencies.
- d. Use typographic cues (bolding and highlighting) for patient content only.
- e. Allow for horizontal text only.
- f. Maximize the amount of white space while managing the readability of the text. White space is often perceived by older patients as having greater readability.³
- g. Use thicker, denser lined letters where appropriate as they are easier to read.
- h. Consider enhancing the line spacing, making pharmacy labels easier to read.
- i. Use a white background color for labels for better visualization of text and bar codes (when applicable).
 - i. Use black ink for all bar codes.
- j. Organize the label content in a patient-centered manner, as below:
 - i. Group text into separate, conceptually-related sections (chunking) to facilitate search and acquisition of information for the patient.
 - ii. All provider directed content (Pharmacy logo, number, address, and phone number) should be placed away from dosage instructions and separated at the bottom of the label.⁴
 - iii. Provide pharmacy applied auxiliary labels in a consistent location for patient routine expectation.

2. Provide explicit instruction to improve patient comprehension, such as using - paced reading (see a-e below).⁵
 - a. Directions must contain specific dosing /interval times; ex: 'Take 2 tablets in the morning and take 2 tablets in the evening' NOT 'Take two tablets twice a day.'
 - b. Use numbers instead of text.
 - c. Avoid awkward terms such as 'twice'; instead use 'two' or '2.'
 - d. Use mixed case (upper and lower case letters).
 - e. Ensure that the application and printer support both upper and lower case fonts and any characters which drop below the lower line (example lower case y and g). This would include the ability to use mixed case fonts within a line or a format to support tall man lettering, when indicated. See <http://www.fda.gov/cder/drug/MedErrors/nameDiff.htm>.
 - f. Avoid use of dangerous drug name, dosage instruction, or unit of measure abbreviations.
 - i. To avoid confusion, never abbreviate drug names. Each drug field should contain a sufficient number of characters to prevent truncating drug names, whether single entity or multi-ingredient product. (The rise in acute liver toxicity has been attributed to patient inadvertent overdosing of acetaminophen.⁶ Consumers may be unaware that prescription labels indicating the drug abbreviation, APAP, is actually acetaminophen.)

ii. Avoid the use of all potentially dangerous abbreviations and dose expressions (see www.ismp.org/Tools/errorproneabbreviations.pdf)

including the following:

1. Do not use trailing zeros (e.g., 5 mg, never 5.0 mg).
2. Use leading zeros for doses less than a whole number (e.g., 0.3 mg, never .3 mg)
3. Spell out the word Units. Never use U, which easily can be mistaken as a zero, causing a 10-fold overdose
4. Abbreviate International Units as “units”
5. Include properly spaced commas for dose numbers expressed in thousands (e.g., 5,000 units).
6. Do not use M as an abbreviation for thousands (e.g., 5 M units), which has been mistaken as million. Use the word thousand for larger doses in the hundreds of thousands (e.g., 150 thousand rather than 150,000). Use the word million for doses expressed in millions (e.g., 1 million units) to avoid possible misplacement of commas and misreading the dose if the commas are not seen correctly with such large numbers.
7. Use standard metric abbreviations as follows:
 - a. m (lower case) = meter
 - b. kg = kilogram
 - c. g = gram

- d. mg = milligram
 - e. mcg = microgram (do not use the Greek letter μ as μg which has been misread as mg)
 - f. L (upper case) = liter
 - g. mL (lower/upper case) = milliliter (do not use cc which has been misread as U or the number 4)
- g. Simplify the language, avoiding unfamiliar words/medical jargon.
3. Drug names on label should be separate and distinct from all other information.
- a. List all generic names using lower-case letters as the primary drug nomenclature (unless employing tall man letters as a safety strategy), ensuring that each matches FDA-approved nomenclature. As appropriate, list associated brand names in a requisite field using all upper case letters (e.g., LASIX) to differentiate them from generic names. Trademark symbols (e.g., TM or ®) should not be used.
 - b. When the drug name, strength, dosage form, and dosage units appear together, avoid confusion by providing a space between them (e.g., propranolol20 mg has been misread as 120 mg and 10Units has been misread as 100 Units).
 - c. Do not include the salt of the chemical when expressing a generic name unless there are multiple salts available (e.g., hydroxyzine hydrochloride and hydroxyzine pamoate). If the salt is listed as part of the name (e.g., USP approved abbreviations such as K, Na, HBr, and HCl), it should

follow the drug name, not precede it (e.g., hydroxyzine HCl not HCl hydroxyzine).

- d. Include both the brand name and the generic name on the label. If state law prohibits printing the BRAND name when the specific BRAND is not dispensed then the term “used for” may be inserted before the BRAND name.
 - e. All combination products should include the BRAND name on the label. If a product contains two ingredients they should both appear in the generic name field. If the product contains greater than two generic ingredients then the two primary ingredients should be placed in the generic field accompanied by the phrase “and others” at the end of the 2 generic names. If one of the ingredients is acetaminophen, consider applying an auxiliary label that states; ‘This product contains acetaminophen.’
 - f. Do not include an abbreviation of the manufacturer’s name as part of the drug name on the same line of text (e.g., tramadol hcl acetaminophen par, where PAR is the name of the manufacturer, not an additional ingredient or drug-name suffix).
 - i. Should be written as:
tramadol 37.5 mg acetaminophen 325 mg
manuf: Par used for ULTRACET
4. Include the condition for which the drug was prescribed if requested by the patient and if the condition is indicated on the prescription.

5. Label should include a clearly-visible second patient identifier, preferably their date of birth, but also could use the current address.
6. Provide a written description of medication and picture of medication, if possible.

ISMP additional/future recommendations

1. Use a standard icon system for signaling and organizing auxiliary warnings and instructions.
 - a. Consider well placed sparing use of easily understood pictograms to increase likelihood of reading.
 - b. Ensure that warnings and alerts are applied consistently and not practitioner dependent.
2. The purchase receipt should include the second patient identifier, preferably date of birth, and/or patient address.
3. When affixing labels to a manufacturer-supplied bottle, do not cover medication name and strength on original label.
4. If a picture of medication can not be included on the label, refer patient to Web sites that provide pictures of medications, such as:
www.mypillbox.org/mypillbox.php; www.healthline.com; www.webmd.com.
5. Use the largest font size label will allow, minimum of 18-point type for people with low vision.⁷ Most standard prescription label size will not accommodate the required labeling information in 18-point type. Therefore, the American Foundation for the Blind recommends that pharmacies:⁷
 - a. Provide "duplicate labels" (prescription and auxiliary) printed in a minimum of 18-point type on paper stock.
 - b. If pictograms are used, these should also be provided in "large print" format and high contrast (saturated black on white background).

- c. The "duplicate labels" should be matched in some way to the prescription container, such as by using a large-print number or colored sticker on both the duplicate label and the corresponding medication container.
 - d. Use sans serif, standard font (not narrow or condensed), such as Arial, Verdana, or obtain APHont™ (pronounced Ay'-font). APHont™ was developed specifically for low vision readers and embodies characteristics that have been shown to enhance reading speed, comprehension, and comfort for large print users. Available free at:
www.aph.org/products/aphont.html.
 - e. If the pharmacy offers prescription label information in large print, this should be prominently posted at the prescription counter or communicated directly to each patient.
6. Use "tall man" letters (e.g., hydrOXYzine and hydrALAZINE) to help distinguish look-alike products on screens to minimize the risk of selecting the wrong product when medication names appear alphabetically in drug profiles. Establish and disseminate a list of products for which tall man letters are used, specifying which letters are affected, to ensure standard application for all uses. <http://www.fda.gov/cder/drug/MedErrors/nameDiff.htm>.

References

- 1) 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.
- 2) Shrank WH, Agnew-Blais J, Choudhry NK, et al. The variability and quality of medication container labels. *Arch Intern Med.* 2007;167:1760-1765.
- 3) Wogalter M., Vigilante W. Effects of label format on knowledge acquisition and perceived readability by younger and older adults. *Ergonomics.* 2003;46(4):327-344.
- 4) Cohen MR, ed. Medication Errors. 2nd ed. Washington DC: American Pharmacists Association. 2007. 222-223.
- 5) Wolf M, Davis T, Shrank W, et al. To err is human: Patient misinterpretations of prescription drug label instructions. *Patient Education and Counseling.* 2007;67(3):293-300.
- 6) Larson AM, Polson J, Fontana RJ, et al. Acetaminophen-induced acute liver failure: results of a United States multicenter, prospective study. *Hepatology.* 2005;42:1364-1372. Available on the Intranet at: <http://www3.interscience.wiley.com/cgi-bin/fulltext/112161379/HTMLSTART>. Accessed 24 Nov 2008.
- 7) American Society of Consultant Pharmacists Foundation/American Foundation for the Blind. Guidelines for prescription labeling and consumer medication information for

people with vision loss. 2008. Available on the Intranet at:

<http://www.afb.org/Section.asp?SectionID=3&TopicID=329&DocumentID=4064>.

Accessed 24 Nov 2008.