ORIGINAL INVESTIGATION

The Variability and Quality of Medication Container Labels

William H. Shrank, MSHS, MD; Jessica Agnew-Blais, BA; Niteesh K. Choudhry, MD, PhD; Michael S. Wolf, PhD, MPH; Aaron S. Kesselheim, MD, JD; Jerry Avorn, MD; Paul Shekelle, MD, PhD

Background: Medication errors occur frequently, and poor medication labeling is cited as a potential cause. We assessed the format, content, and variability of prescription drug container labels dispensed in the community.

Methods: Identically written prescriptions for 4 commonly used medications (atorvastatin calcium [Lipitor], alendronate sodium [Fosamax], trimethoprim-sulfamethoxazole [Bactrim], and ibuprofen) were filled in 6 pharmacies (the 2 largest chains, 2 grocery stores, and 2 independent pharmacies) in 4 cities (Boston, Chicago, Los Angeles, and Austin [Texas]). Characteristics of the format and content of the main container label and auxiliary stickers were evaluated. Labels were coded independently by 2 abstractors, and differences were reconciled by consensus.

Results: We evaluated 85 labels after excluding 11 ibuprofen prescriptions that were filled with over-the-counter containers that lacked labels printed at the pharmacy. The pharmacy name or logo was the most prominent item on 71 (84%) of the labels, with a mean font size of 13.6 point. Font sizes were smaller for medication instructions (9.3 point), medication name (8.9 point), and warning and instruction stickers (6.5 point). Color, boldfacing, and highlighting were most often used to identify the pharmacy and items most useful to pharmacists. While the content of the main label was generally consistent, there was substantial variability in the content of instruction and warning stickers from different pharmacies, and independent pharmacies were less likely to use such stickers ($P<.001$). None of the ibuprofen containers were delivered with Food and Drug Administration–approved medication guides, as required by law.

Conclusions: The format of most container labels emphasizes pharmacy characteristics and items frequently used by pharmacists rather than use instructions or medication warnings. The content of warning and instruction stickers is highly variable depending on the pharmacy selected.

Arch Intern Med. 2007;167(16):1760-1765

Author Affiliations: Division of Pharmacoepidemiology and Pharmacoeconomics, Brigham and Women's Hospital and Harvard Medical School, Boston, Massachusetts (Drs Shrank, Choudhry, Kesselheim, and Avorn and Ms Agnew-Blais); Institute for Healthcare Studies and Division of General Internal Medicine, Feinberg School of Medicine at Northwestern University, Chicago, Illinois (Dr Wolf); and Division of General Internal Medicine, Greater Los Angeles Veterans Affairs Healthcare System, Los Angeles, California (Dr Shekelle).

THE RECENT INSTITUTE OF Medicine report, "Preventing Medication Errors: The Quality Chasm Series," estimates that 1.5 million medication errors occur annually in the United States, most in the outpatient setting, generating costs of more than $3.5 billion.[1] The report identified poorly designed prescription drug labels as an important source of such errors. The United States Pharmacopeia reports that approximately one-third of errors it evaluates are, at least in part, because of confusion caused by the product labeling.[2]

When patients receive prescriptions at a pharmacy, there is commonly information affixed to the pill container (the "container label") and auxiliary leaflets, which may include official warnings from the Food and Drug Administration (FDA) or consumer medication information prepared by the pharmacy. Unlike the auxiliary leaflets, which patients can easily discard or ignore, the container label usually remains with the medication during the course of therapy. While patients ideally should receive information about their medications from physicians and pharmacists, there is considerable evidence that appropriate counseling about proper administration and adverse effects occurs infrequently.[3-5] Therefore, the container label may play an important role in the appropriate administration of prescription medication.

Labels are only effective if patients are able to read and understand them. Nearly half of all US adults have difficulty understanding and using health information in general; this problem of poor health literacy has been linked to higher rates of

hospitalization and emergency service use.[6] Health literacy challenges often arise when patients attempt to read prescription drug labels, especially container stickers with essential medication instruction and warning information.[7,8] In particular, patients with less education and elderly patients frequently report having difficulty reading and understanding prescription labels.[7-9]

Certain characteristics of container labels improve readability and understanding,[10] including larger font,[11,12] boldfacing and use of white space to emphasize important details,[13] and organization of items consistent with the schema that patients use to process prescription information.[14] Medical education guidelines explicitly suggest that font size must be 12 point or larger to optimize patients' ability to read health information.[15] The human factors' literature suggests that all print on a label should be oriented in the same direction for a given task.[16] While the FDA has limited standards for the content of drug labels[17] and state boards of pharmacy provide additional content-related regulations, there are few regulations guiding the format of container labels.

Several studies have evaluated specific features of container labels, but little is known about national variations in the type and quality of information they contain. We sought to describe the characteristics of the content and format of information printed on prescription drug container labels and to evaluate variability in labels affixed by different pharmacies in 4 geographically diverse cities.

METHODS

SELECTION OF STUDY PHARMACIES

We identified pharmacies in 4 cities in the United States, representing geographically diverse metropolitan areas: Los Angeles, Boston, Austin (Texas), and Chicago. In each city, collaborating local physicians identified a purposeful sample of 6 pharmacies, including the 2 largest chain pharmacies in each area, 2 grocery store pharmacies, and 2 independent pharmacies.

SELECTION AND PRESCRIPTION OF STUDY DRUGS

We chose 4 commonly prescribed medications to use in our study sample: (1) the lipid-lowering agent atorvastatin calcium (Lipitor; Pfizer Inc, New York, New York), the top-selling medication in the United States[18]; (2) the osteoporosis medication, alendronate sodium (Fosamax; Merck & Co, Inc, Whitehorse Station, New Jersey), a medication with specific administration directions (patients must take with 6-8 oz [180-240 mL] of water and avoid reclining or eating for 30 minutes after consumption); (3) the antibiotic combination trimethoprim-sulfamethoxazole (Bactrim); and (4) ibuprofen, a nonsteroidal anti-inflammatory and analgesic agent. The FDA recently required all ibuprofen prescriptions to be dispensed with an FDA-approved medication guide,[19] an auxiliary leaflet providing additional information about medication risks.

Collaborating physicians in each city wrote identically worded prescriptions for each drug for a female patient (1 in her 30s, 1 in her 40s, 1 in her 50s, and 1 in her 60s). Prescriptions were purchased without insurance.

IDENTIFICATION OF CONTAINER LABEL VARIABLES

We identified relevant components of the container label content and format for larger analysis by evaluating a preliminary sample of container labels obtained from 1 city. Three clinicians (W.H.S., N.K.C., and A.S.K.) and a health literacy expert (M.S.W.) assessed items on the label to create an inclusive list.

Relevant format variables included the font type and size of each content item, the use of color, the use of boldfacing or highlighting, and the placement or orientation of warning and instruction stickers. For stickers that used more than 1 font size, we determined the font size by averaging the smallest and largest font sizes observed.

Content-related variables included items specifically required to be placed on each container label by the FDA: drug name, patient name, physician name, pharmacy name, "Rx number" (a serial number), instructions, and refill status.[17] Other variables identified through the preliminary analysis included quantity of pills dispensed, pharmacy telephone number, pharmacy address, pharmacist name or initials, patient address, original prescription date, fill date, manufacturer name, discard date, physician telephone number, and pill description. The inclusion and order of these items on the labels were evaluated along with the presence and content of auxiliary labels or warning stickers.

ABSTRACTION AND ANALYSIS OF CONTAINER LABEL INFORMATION

Information was abstracted from the container labels independently by 1 trained abstractor (J.A.-B.) and the lead investigator (W.H.S.). Variables on the container labels were coded as to their contents and format and compared between both abstractors. Disagreements were resolved by consensus between the abstractors.

The data were evaluated descriptively. Differences in font size and presence of warning and instruction stickers by type of pharmacy were examined using analysis of variance, with significance at $P < .05$. This study received an exemption from the West Los Angeles Veterans Affairs institutional review board.

RESULTS

A total of 96 prescriptions were filled, 24 each for ibuprofen, alendronate, trimethoprim-sulfamethoxazole, and atorvastatin. Almost half (n = 11) of the pharmacies substituted over-the-counter ibuprofen for the prescription written and did not create a patient-specific pharmacy label, leaving 85 labels for evaluation.

FORMAT OF LABELS

The order of presentation of FDA-required container label items was quite consistent. The pharmacy was listed first on all labels; the Rx number was listed either second (57 labels [67%]) or third (28 labels [33%]). Physician name was frequently listed third (34 labels [40%]) or fourth (26 labels [31%]), as was patient name (20 [24%] third or 50 [59%] fourth). Instructions were generally fifth (76 labels [89%]), drug name was generally sixth (75 labels [88%]), and refill status was typically seventh (79 labels [93%]).

There was substantial variation in the font size of different items. The largest item on 71 (84%) of the labels was

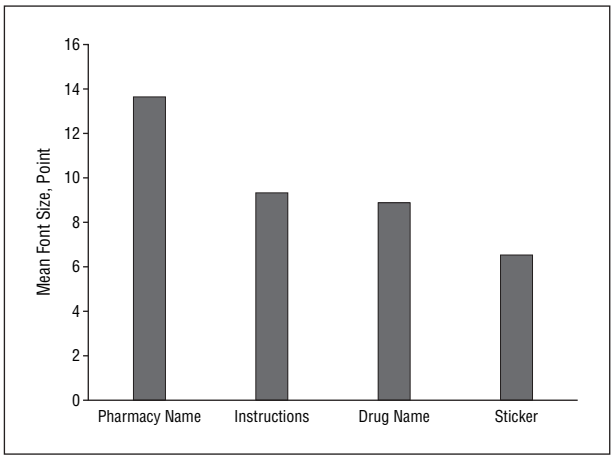

Figure. Mean font size of container label components.

the pharmacy logo. The mean font size was 13.6 point for the pharmacy logo, 9.3 point for medication instructions, and 8.9 point for drug name. Auxiliary instructions and warning stickers were a mean 6.5-point font (**Figure**).

Use of color, boldface, or highlights in the label also showed variation. Items related to the pharmacy were the only items presented in color on the labels we evaluated. The pharmacy logo was presented in color on 82 (96%) of the labels, and color was also occasionally seen in the pharmacy slogan (12 labels [14%]), telephone number (16 labels [19%]), and address (16 labels [19%]). Auxiliary warnings and instruction stickers were presented in a variety of colors, of which the most common were yellow (54 labels [64%]), red or red outlines (39 labels [46%]), pink (16 labels [19%]), and blue (11 labels [13%]). Items that were most commonly boldfaced were the pharmacy name/logo (81 labels [95%]), Rx number (80 labels [94%]), and pharmacy telephone number (75 labels [88%]). The most commonly highlighted items were Rx number (70 labels [82%]), refill status (37 labels [44%]), quantity (23 labels [27%]), and pharmacy telephone number (15 labels [18%]) (**Table 1**).

In addition, we found that warning stickers frequently were not oriented in the same direction as the main container label, and 70 containers (82%) required the reader to tilt the bottle sideways to read the warning stickers. When comparing font sizes of label components by type of pharmacy (chain, grocery store, and independent), statistically significant differences were seen between font sizes, but the magnitude of those differences was small (**Table 2**).

CONTENT OF LABELS

Certain label items were present on all the labels we evaluated, including all items required by the FDA. Other items, such as the drug manufacturer, the physician's telephone number, a description of the appearance of the pill, and the pharmacist's name, appeared inconsistently (**Table 3**).

The content of the warning and other special instruction stickers on the labels varied considerably. For each of the 4 drugs we evaluated, between 7 (8%) and 21 (25%) containers did not include any warning or instruction stickers. Among those that did include a warning, there was substantial variability in the content of the stickers.

The most common sticker affixed to atorvastatin labels, present on 19 of the prescriptions, was a warning about grapefruit juice consumption. A smaller fraction included a warning about pregnancy, and less than 20% included directions about taking with food, taking with water, following directions precisely, and checking with a physician before starting other medications (**Table 4**).

Fourteen of the containers for alendronate included stickers with directions instructing the patient not to lie down for 30 minutes after administration. Other warnings concerning drug interactions, swallowing the medication whole, and pregnancy were present on less than one-third of the labels (Table 4).

Containers for trimethoprim-sulfamethoxazole had less variation. Twenty (83%) containers included stickers suggesting the medication should be taken with water, 19 (79%) warned about excessive sunlight, and 14 (58%) recommended finishing all the medication. Warnings about pregnancy and dizziness were less frequent (Table 4).

Ibuprofen containers included a broad range of warnings, but no warning was present on more than half of the prescriptions filled. Examples of warnings included the following: take the medication with water and/or food, avoid antacids and alcohol, and watch for potential drowsiness or dizziness (Table 4). None of the ibuprofen prescriptions were accompanied by FDA-approved official medication guides, as required by law.

When the results were stratified by pharmacy of origin, warnings and other informational stickers were ob-

Table 1. Frequencies That 85 Label Items Were Highlighted, Boldfaced, or Presented in Color[a]

Label Item	Highlighted	Boldfaced	Presented in Color
Refill status	37	18	0
Prescription No.[b]	70	80	0
Pharmacy telephone number	15	75	16
Pharmacy address	3	21	16
Pharmacy name/logo	3	81	82
Pharmacist name/initials	13	0	0
Patient No.	6	62	0
Patient address	3	0	0
Original date	6	4	0
Fill date	3	11	0
Drug name	6	64	0
Quantity	23	15	0
Patient telephone number	0	3	0
Store number	0	17	0
Pharmacy slogan	0	0	12
Manufacturer	2	15	0
Instructions	0	46	0
Physician name	0	26	0
Discard date	0	4	0
Pharmacy e-mail address	0	0	3
Pill description	3	0	0
Brand name	0	2	0

[a] Data are given as number of labels.
[b] A serial number.

Table 2. Mean Characteristics of 85 Labels by Type of Pharmacy

Characteristic	Grocery Store	Chain Pharmacy	Independent Pharmacy	*P* Value[a]
Instruction font size, point	9.7	9.8	8.5	<.001
Drug name font size, point	9.3	9.1	8.3	<.001
Warning sticker font size, point	6.0	6.7	7.0	.01
Logo font size, point	15.3	12.4	13.3	.04
No. of warning stickers	1.5	1.5	0.6	<.001
No. of instruction stickers	1.0	1.2	0.7	.09

[a] Results from an analysis of variance.

served less often in independent pharmacies than in chain or grocery store pharmacies (Table 2). We also found that prescriptions filled in larger bottles received significantly more warning labels than those filled in smaller bottles, although only a small amount of the variance was explained by this association (Pearson correlation=0.36, $P<.01$).

Table 3. Contents of the 85 Labels

Item	No. (%) of Labels Containing the Item
Refill status	85 (100)
Prescription No.[a]	85 (100)
Pharmacy telephone number	85 (100)
Pharmacy address	85 (100)
Pharmacy name	85 (100)
Patient name	85 (100)
Fill date	85 (100)
Drug name	85 (100)
Quantity	85 (100)
Any type of stickers	72 (85)
Discard date	65 (76)
Manufacturer	65 (76)
Warning stickers	60 (71)
Instruction stickers	53 (62)
Patient address	48 (56)
Original date	44 (52)
Description of pill	24 (28)
Pharmacist name/initials	37 (44)
Pharmacist in charge name	15 (18)
Physician's telephone number	11 (13)

[a] A serial number.

COMMENT

This is the first study, to our knowledge, that assesses the variability of the content and format of prescription drug container labels. Although FDA-required items were present on every label, there was marked inconsistency with regard to other types of information. We found substantial discrepancies in the presence of warning or other important instruction labels. Some containers lacked warnings altogether and in other cases warnings were placed sporadically. Warnings or instructions were frequently printed in a small font, smaller than many elderly patients can read even with the assistance of refractive glasses.[20] Instead, the labels emphasized items that identify the pharmacy, while less attention was called to medication warnings.

These findings underscore the need to further evaluate how to best communicate medication information to patients through medication labels. Poor container label construction may adversely affect patient safety and adherence to instructions by increasing patients' difficulty identifying and comprehending important messages about their drugs. We found numerous examples in which important critical warnings regarding potential adverse effects on the container label were omitted. Extensive data about medication safety are gathered by manufacturers and the FDA before approval of all drugs; careful attention is paid to every indication and warning listed on the official product description, a multipage review of indications, data, and warnings intended to educate physicians about the medication.[21] However, there is no system to assess which warnings or instructions would be the most relevant to communicate directly to patients and to include on the container label. More attention must be paid to identifying key messages for patients for particular drugs and ensuring that these messages are communicated to patients in a legible and understandable manner.

One strategy that may help to optimize the utility of container labels would be the development of national standards for their format and content. Precedents for such national standards exist for other types of labels under FDA jurisdiction. To simplify the process of identifying nutrition information about food purchased at grocery stores, the FDA has required a uniform label, called Nutrition Facts.[22] Similarly, the FDA has required that packaging for all over-the-counter drugs include a standardized drug facts label to simplify the process of identifying instruction and safety information about medications purchased without a prescription.[23] Both of these developments have been widely hailed as beneficial to consumers. Standard formatting for prescription drug labels, the most complex products under the jurisdiction of the FDA, could simplify access to medication information. The extent to which standardized patient-oriented labels could improve medication safety is unclear and requires further research. However, standardized labels would be consistent with widespread efforts to improve patient safety by developing standardized processes in health care,[24,25] and labeling improvements and specific standards have been called for in 2 recent Institute of Medicine reports[1,26] focusing on medication safety.

While there are some existing standards promulgated by the FDA, our results showed varying compli-

Table 4. Contents of Auxiliary Label Stickers Applied to Containers, by Drug[a]

Content	No. (%) of Labels for Each Drug
Alendronate Sodium (Fosamax) (n=24)	
Do not take with other medicines without checking with your doctors or pharmacist.	5 (21)
Do not use if pregnant or if you suspect you are pregnant or you are breastfeeding.	6 (25)
Do not take antacids within a half hour before or after taking this medicine.	6 (25)
Do not take with aspirin, ibuprofen, or naproxen without consent from your doctor.	4 (17)
Medication should be taken with plenty of water.	8 (33)
Take with 8 oz of water at least 30 min before first food, beverage, or drug of the day. Do not lie down.	14 (58)
Take on an empty stomach.	1 (4)
Take exactly as directed, do not discontinue or skip doses unless directed by doctor.	3 (12)
Do not chew or crush, swallow whole.	2 (8)
Do not lie down until after first food of the day.	1 (4)
Ibuprofen (n=13)	
Do not take with aspirin or products containing aspirin without consulting your doctor.	2 (15)
May cause drowsiness or dizziness.	4 (31)
Do not take medication in third trimester of pregnancy.	3 (23)
Alcohol may intensify effect, use care using machines.	5 (38)
Do not take with antacids.	1 (8)
Take with food.	5 (38)
Take with a small meal or snack if stomach upset occurs.	3 (23)
Take with plenty of water.	2 (15)
Atorvastatin Calcium (Lipitor) (n=24)	
Do not take with grapefruit juice.	19 (79)
Do not take other medications without checking with doctor or pharmacist.	3 (12)
Do not use if pregnant, suspect you are pregnant, or are breastfeeding.	10 (42)
This medication may be taken with or without food.	4 (17)
Take exactly as directed, do not discontinue or skip doses unless directed by doctor.	1 (4)
Take with 8 oz of plain water at least 30 min before first food, beverage, or drug of the day. Do not lie down for 30 min.	1 (4)
Trimethoprim-Sulfamethoxazole (Bactrim) (n=24)	
Do not take if you are pregnant or are breastfeeding.	9 (38)
Avoid prolonged or excessive exposure to direct or artificial sunlight while taking this medication.	19 (79)
May cause dizziness.	1 (4)
Take with plenty of water.	20 (83)
Finish all medication unless directed by a doctor.	14 (58)

[a]For alendronate, 19 of 24 bottles (79%) had stickers; for ibuprofen, 10 of 13 bottles (77%); for atorvastatin, 19 of 24 bottles (79%); and for trimethoprim-sulfamethoxazole, 22 of 24 bottles (92%). Details about drug manufacturers are given in the "Selection and Prescription of Study Drugs" subsection of the "Methods" section.

ance with even these few government regulations. We found all FDA-required items on every label, although in different orders and emphasized to varying degrees. However, the prescriptions we filled for ibuprofen did not include even 1 medication guide, even though they are required by law.

Our study assessed 4 commonly prescribed medications in 4 diverse metropolitan centers. This work should be replicated more broadly by assessing other medications in other geographic areas, including rural ones. Even so, the present findings are relevant to millions of patients, residing in these and other metropolitan areas, who use these common medications. Some variation in the warnings placed on the container labels may have been because of variability in patient age, which may have led to appropriate variability in warnings regarding pregnancy. Future studies should evaluate the extent to which pharmacies tailor warning information to individuals, and providers (physicians, pharmacists, nurse practitioners, or insurers) should consider the extent to which such patient-level variability might be warranted. In addition, we did not systematically collect information about the presence or content of patient counseling received at the pharmacies and did not account for the possibility that labels may not have included particular warnings if they were communicated in person. However, the prescriptions were frequently purchased and picked up by someone other than the patient, and qualitative feedback from medication purchasers suggests that limited counseling was offered, consistent with recent evidence about the frequency and quality of counseling offered by pharmacists.[27]

With passage of the Medicare prescription drug benefit, the federal government has become the largest purchaser of prescription drugs in the nation. As a result, it has an even larger responsibility to help improve the safety and appropriate administration of medications for Medicare beneficiaries. Federal standards for the content and format of container labels may help to meet this responsibility. Substantial research has been performed that can guide the development of an "evidence-based" prescription drug label that is easier to read and understand, although additional research is needed to better understand how labeling improvement affects medication-taking behavior.[10] Further dialogue is necessary to establish which groups, including the FDA, manufacturers, pharmacies, and physicians' organizations, would be best suited to develop and implement improved patient-oriented labeling.

Accepted for Publication: April 11, 2007.
Correspondence: William H. Shrank, MSHS, MD, Division of Pharmacoepidemiology and Pharmacoeconomics, Brigham and Women's Hospital, Harvard Medical School, 1620 Tremont St, Ste 3030, Boston, MA 02120 (wshrank@partners.org).
Author Contributions: *Study concept and design:* Shrank, Avorn, and Shekelle. *Acquisition of data:* Shrank and Shekelle. *Analysis and interpretation of data:* Shrank, Agnew-Blais, Choudhry, Wolf, Kellelheim, Avorn, and Shekelle. *Drafting of the manuscript:* Shrank. *Critical revision of the manuscript for important intellectual content:* Agnew-Blais, Choudhry, Wolf, Kesselheim, Avorn, and Shekelle. *Statistical analysis:* . *Obtained funding:* Shrank and Shekelle. *Administrative, technical, and material support:* Agnew-Blais, Choudhry, Wolf, Kesselheim, Avorn, and Shekelle. *Study supervision:* Shrank, Avorn, and Shekelle.
Financial Disclosure: None reported.
Funding/Support: This study was supported by a grant from the American College of Physicians Foundation Prescription Drug Labeling Project.

Role of the Sponsor: The funding body had no role in data extraction and analyses, in the writing of the manuscript, or in the decision to submit the manuscript for publication.

Additional Contributions: Neil Wenger, MD, Isabelle Hovermen, MD, and Patrick Fahey, MD, provided assistance in acquiring the prescriptions.

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