

HARVARD MEDICAL SCHOOL

*Program for the Analysis
of Clinical Strategies*



BRIGHAM AND WOMEN'S HOSPITAL

*Division of Pharmacoepidemiology
and Pharmacoeconomics*



A Joint Center of RAND Health
and The Agency for Healthcare
Research and Quality

Prescription Drug Labels: A Critical Review

11/29/06

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Today's Agenda

1. Brief description of current, highly-fragmented system of assembling labels
2. Results from our systematic literature review pertaining to the content and format for prescription drug labels
3. Evaluation of label variability in the community
4. Policy Implications

Rationale For High Quality Labels

Improve Adherence to Medications

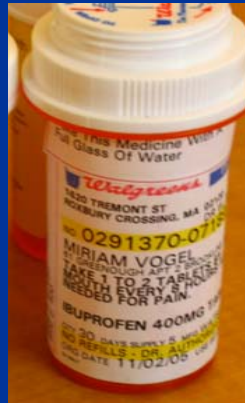
- Reduce confusion about medication regimen
- Enhance understanding about disease and indications
- Improve understanding about side-effects

Improve Quality and Decreasing Errors

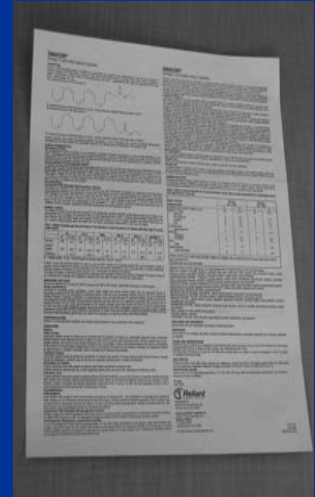
- Help patients follow instructions
- Help patients identify inappropriate prescription

What Constitutes the Label?

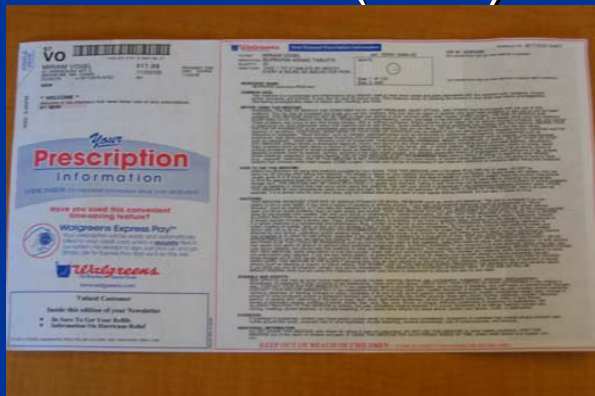
1) Container Label



3) Package Insert




















2) Consumer Medication Information (CMI)



4) Medication Guide



Labeling: A Fragmented System

| | State Law | FDA | Software Vendors | Pharmaceutical Manufacturers | Data Management Companies | Pharmacies |
|---|---|--|---|--|---|---|
| Container Label |  |  |  | | |  |
| Consumer Medication Information (CMI) | | |  | |  |  |
| Package Insert | |   | |   | | |
| Medication Guide | |   | |   | | |
|  = Content  = Format | | | | | | |

Literature Review: Evaluating Label Format and Content

METHODS

- Searched Medline
- Searched items related to two themes:
 - 1) *prescription drug labels*
 - 2) *doctor-patient communication about prescription drugs*
- Reviewed over 2000 articles and identified relevant articles from references and experts
- Included 104 articles that were targeted to our topic

CMI Format Associated with Readability and Understanding

No data linking CMI format to outcomes

Organization

- List format
- Headers
- Bullets
- White space
- Topics ordered logically

Print

- Typeface sans serif
- Large print (greater than 10 point font)

Language

- 6th grade level
- Short, simple sentences
- Less jargon
- Numbers vs. prose
- Unclear if icons are helpful

Container Label Format Associated with Readability and Understanding

No data linking Container Label format to patient outcomes

Organization

- Use of headers/sections
- Lists
- White space

Print

- Large font size
- Typeface sans serif

Surface Area

- New bottle shapes?

Label Content: Literature Review Findings

Patients prefer:

- ✓ Directions – Avoid vague terminology
- ✓ Benefits of the medication (Indication)
- ✓ Warnings and possible side effects
- ✓ Suggested responses to side effects (e.g., when to call doctor or stop taking medication)
- ✓ Duration of therapy

Methods for Measuring Container Label Variability in Format and Content

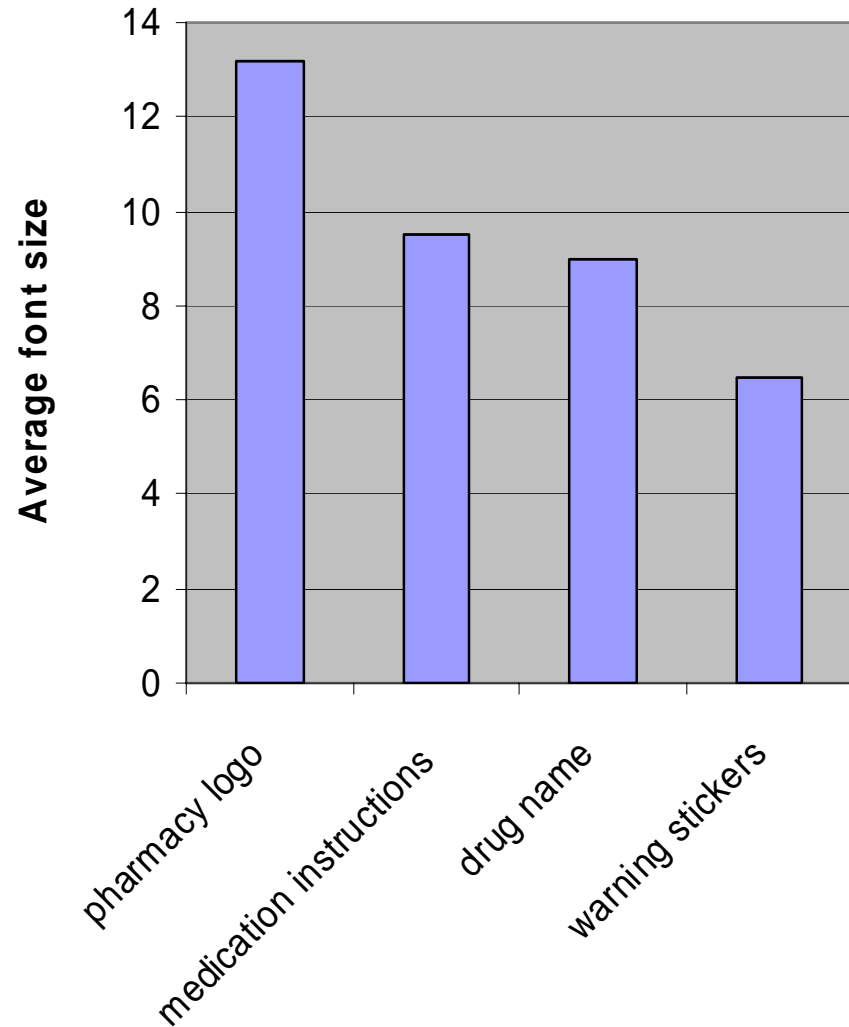
| | |
|-------------------------|---|
| What Drugs: | Identically written prescriptions of: atorvastatin alendronate, TMP/SMX, ibuprofen |
| Where: | Boston, Los Angeles, Chicago, Austin |
| What Pharmacies: | 6 pharmacies in each city: 2 Independents, 2 chain drug stores, 2 grocery stores |
| Label Sample: | Filled a total of 96 prescriptions. |
| Final Sample: | Received 11 over-the-counter ibuprofen bottles |

A total of **85 labels** for evaluation

Container Label Format Variability: Preliminary Findings

Font Size:

Pharmacy
name/logo most
prominent



Container Label Format: Items Emphasized

- **Color:** Only pharmacy-related items in color
 - Pharmacy logo 96%,
 - Pharmacy slogan 14%, phone number 19%, address 19%
- **Bold font:** Items used by pharmacists or identifying the pharmacy
 - Rx# 88%, Pharmacy logo 85%, Pharmacy phone 79%
- **Highlighted:** Items used by pharmacists
 - Rx# 82%, Refill status 44%, Quantity 20%

Container Label Content Variability:

Items present on main container label

| Item | Percent of labels containing item |
|----------------------|-----------------------------------|
| Any type of stickers | 84.7 |
| Discard date | 78.8 |
| Manufacturer | 71.8 |
| Warning stickers | 70.6 |
| Instruction stickers | 62.3 |
| Patient address | 56.5 |
| Original date | 50.6 |
| Description of pill | 28.2 |
| PIC name | 17.6 |
| Pharmacist name | 25.9 |
| Doc phone # | 9.4 |

Container Label Content Variability: Warning Stickers

atorvastatin

| Warning stickers (n=24) | Number (%) of stickers with warning |
|--|-------------------------------------|
| Number of bottles with stickers | 19 (79.2) |
| 1. Do not take with grapefruit juice. | 19 (79.2) |
| 2. Do not take if pregnant, suspect you are pregnant, or are breastfeeding. | 10 (41.7) |
| 3. This medication may be taken with or without food. | 4 (16.7) |
| 4. Do not take with other medications without checking with doctor or pharmacist. | 3 (12.5) |
| 5. Take exactly as directed, do not discontinue or skip doses unless directed by a doctor. | 1 (4.2) |
| 6. Take with 8 oz of plain water at least 30 minutes before first food/beverage/drug of the day. Do not lie down for 30 minutes. | 1 (4.2) |

alendronate

| Warning stickers (n=24) | Number (%) of stickers with warning |
|---|-------------------------------------|
| Number of bottles with stickers | 19 (79.2) |
| 1. Take with 8 ounces of water at least 30 minutes before first food/beverage/drug of the day. Do not lie down. | 14 (58.3) |
| 2. Medication should be taken with plenty of water. | 8 (33.3) |
| 3. Do not use if pregnant or if you suspect you are pregnant or breastfeeding | 6 (25.0) |
| 4. Do not take antacids within ½ hour before or after taking this medicine. | 6 (25.0) |
| 5. Do not take with other medicines without checking with your doctor or pharmacist. | 5 (20.8) |
| 6. Do not take with aspirin, ibuprofen, or naproxen without consent from your doctor. | 4 (16.7) |
| 7. Take exactly as directed, do not discontinue or skip doses unless directed by doctor. | 3 (12.5) |
| 8. Do not chew or crush, swallow whole. | 2 (8.3) |
| 9. Take on an empty stomach. | 1 (4.2) |
| 10. Do not lie down until after first food of the day. | 1 (4.2) |

trimethoprim-sulfamethoxazole

| Warning stickers (n=24) | Number (%) of stickers with warning |
|--|--|
| Number of bottles with stickers | 22 (91.7) |
| 1. Take with plenty of water. | 20 (83.3) |
| 2. Avoid prolonged or excessive exposure to direct/artificial sunlight while taking this medication. | 19 (79.2) |
| 3. Finish all medication unless directed by a doctor. | 14 (58.3) |
| 4. Do not take if you are pregnant or breastfeeding. | 9 (37.5) |
| 5. May cause dizziness. | 1 (4.2) |

ibuprofen

| Warning stickers (n=13) | Number (%) of stickers with warning |
|--|--|
| Number of bottles with stickers | 10 (77.0) |
| 1. Alcohol may intensify effect use care using machines. | 5 (38.46) |
| 2. Take with food. | 5 (38.46) |
| 3. May cause drowsiness or dizziness. | 4 (30.7) |
| 4. Do not take medication in 3 rd trimester of pregnancy. | 3 (23.1) |
| 5. Take with a small meal or snack if stomach upset occurs. | 3 (23.1) |
| 6. Do not take with aspirin or products containing aspirin without consulting your doctor. | 2 (15.3) |
| 7. Take with plenty of water. | 2 (15.3) |
| 8. Do not take with antacids. | 1 (7.6) |

FDA-Approved Medication Guides

**None of the ibuprofen
prescriptions were accompanied
by a Medication Guide**

Policy Implications

- 1) Fragmented system of creating labels
- 2) Formatting of labels are not patient-oriented
 - There is some evidence to direct us in improving label formatting (more would help)
- 3) Variability in contents of warnings and instructions
 - Data exists to guide appropriate contents
- 4) Potential benefit of standards for drug label formatting and contents(i.e. Nutrition Facts and Drug Facts)

The Right Time for Change

- IOM Report focusing on medication errors
- Recent standardization successes of container labels:
 - Food (Nutrition Facts)
 - OTC drugs (Drug Facts)
 - Medication Guides
- Medicare Modernization Act
- An important time for physicians and other key stakeholders to take a position on this topic

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