

**HARVARD MEDICAL SCHOOL**

*Program for the Analysis  
of Clinical Strategies*



**BRIGHAM AND WOMEN'S HOSPITAL**

*Division of Pharmacoepidemiology  
and Pharmacoeconomics*



# Prescription Drug Labels: An Issue of Health Literacy

William Shrank MD MSHS

# Agenda

1. What is a label?
  - Description of current, highly-fragmented system of assembling labels
2. What should be the format and content of labels?
  - Results from our systematic literature review pertaining to the content and format for prescription drug labels
3. Are Labels Patient-Oriented?
  - Evaluation of label quality and variability in the community
4. An evaluation of a natural experiment

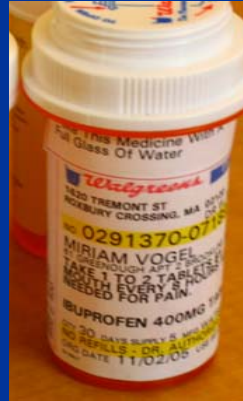
- Funding for this work:
  - ACP Foundation Prescription Drug Labeling Project
  - Robert Wood Johnson Foundation
- Disclosures:

Research funding from (no consulting)

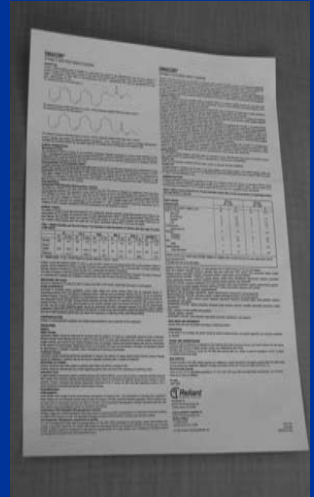
  - CVS Caremark
  - Express Scripts
  - Aetna

# What is the “Label”?

1) Container Label



3) Package Insert



2) Consumer Medication Information (CMI)



4) Medication Guide




















For today's purposes ...  
Focus on Labels Aimed at Patients

- Sticky label
- Consumer Medication Information (CMI) Leaflet
- Medication Guide
- Not Package Insert

**A SYSTEM TO PROVIDE  
INFORMATION TO PATIENTS**

# Labeling in the US: A Fragmented System

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

# What is the optimal format and content of labels?

## Systematic Review of the Literature

- 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 and Container Label Format Associated with Readability and Understanding

## Organization

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

## Print

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

## Language

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

**NO data linking format to outcomes**

# 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

# Are Labels Patient-Oriented?

An evaluation of label quality and variability in the community

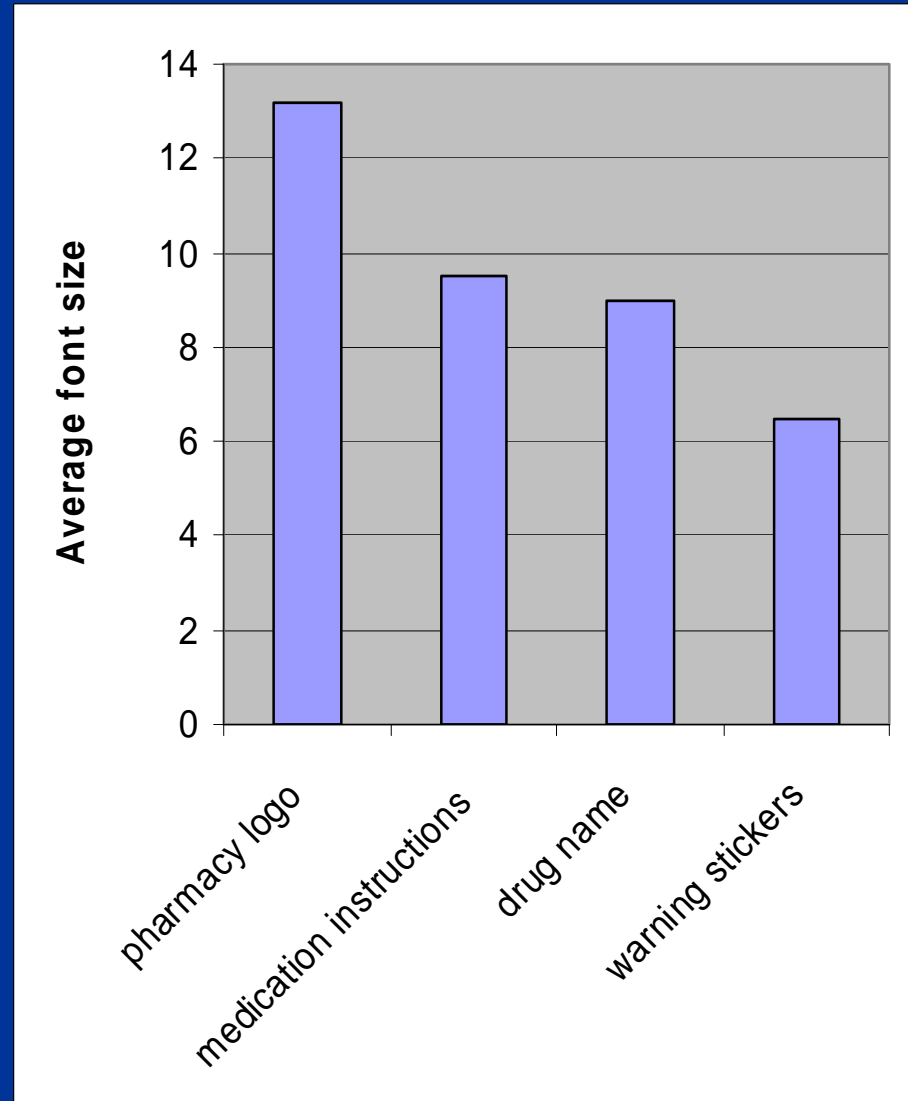
<b>What Drugs:</b>	Identically written prescriptions of: atorvastatin alendronate, TMP/SMX, ibuprofen
<b>Where:</b>	Boston, Los Angeles, Chicago, Austin
<b>What Pharmacies:</b>	6 pharmacies in each city: 2 Independents, 2 chain drug stores, 2 grocery stores
<b>Label Sample:</b>	Filled a total of 96 prescriptions.
<b>Final Sample:</b>	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: Pharmacy-related 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)

# Did the New label at Target Improve Outcomes?

## Sample:

- Continuously enrolled adults in 2 large insurers – over 5 million patients
- Patients with 1 of 9 chronic diseases

## Methods:

- Time trend analysis
- Compared patient adherence and rates of physician and ER visits and hospitalizations before and after implementation of the new label in Target users and concurrent controls



# Did the New Label at Target Affect Adherence?

# Did the New Label at Target Affect Health Services Utilization?

Outpatient Visits

ER and Inpatient Visits

Preliminary Findings

# 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) May not be easy to stimulate massive changes
  - Need to think about outcomes evaluation
- 5) Potential benefit of standards for drug label formatting and contents(i.e. Nutrition Facts and Drug Facts)