

**HARVARD MEDICAL SCHOOL**

*Program for the Analysis  
of Clinical Strategies*



**BRIGHAM AND WOMEN'S HOSPITAL**



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# Patient Medication Information: The Physician's Perspective

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# What the Physician Wants...

- The content should be consistent
  - When 5 patients are prescribed a medication, all should receive the same essential content
- The format should be easy to read
  - Standards can help
- There is a clear expectation about how this information is delivered
  - And the doctor likely does not want to be part of it...

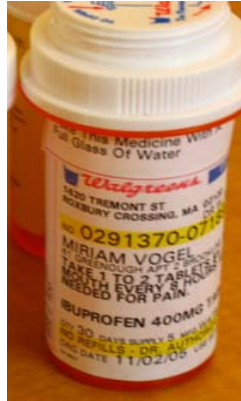
# Why does PMI matter?

- Doctors don't talk to patients much about their medications (Tarn, Archives 2006)
- Patients often do not remember what was discussed (Fletcher)
- Pharmacists often do not as well (Svarstadt)
- The label could be an important source of information – Stays with the medication

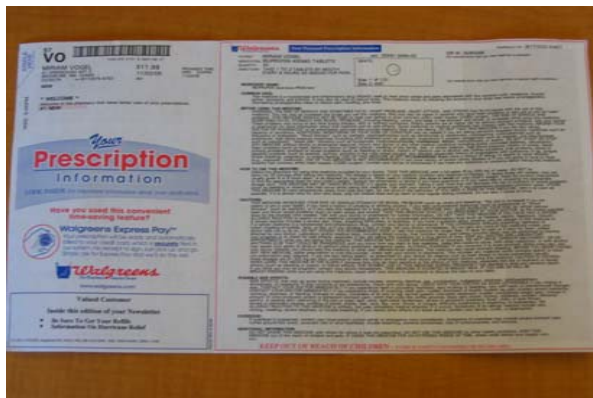
We must think about PMI as a safety net  
for medication education

# What is the “Label”ing?

1) Container Label



2) Patient Medication Information (PMI)



3) Package Insert



4) Medication Guide

**Medication Guide**  
**Cordarone® KOR-DU-RÖN Tablets**  
 (amiodarone HCl)

**Do not** read the Medication Guide that comes with Cordarone Tablets before you start taking them, and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking with your doctor about your medical condition or your treatment.

**What is the most important information I should know about Cordarone Tablets?**  
 Cordarone Tablets can cause serious side effects that can lead to death, including:

- lung damage
- liver damage
- worse heart/beat problems

Call your doctor or get medical help right away if you have any symptoms such as the following:

- shortness of breath, wheezing, or any other trouble breathing, coughing, chest pain, or spitting up blood
- nausea or vomiting, passing stool more or dark colored urine, feel more tired than usual, your skin and whites of your eyes get yellow or pale, stomach pain
- heart pounding, skipping a beat, feeling very fast or very slow, faint, light-headed or lightheaded

**Because of these possible side effects, Cordarone Tablets should only be used in adults with life-threatening heart/beat problems called arrhythmias, for which other treatments did not work or were not tolerated.**

**Cordarone® KOR-DU-RÖN Tablets**  
 (amiodarone HCl)  
 PI 8046-1

**What you may still have side effects after stopping Cordarone Tablets because the medicine stays in your body months after treatment is stopped.** Tell all your healthcare providers that you take or took Cordarone Tablets. This information is very important for other medical treatments or surgeries you may have.

**What are the most important information I should know about Cordarone Tablets?**  
 Cordarone is a medicine used in adults to treat life-threatening heart/beat problems called arrhythmias, for which other treatment did not work or was not tolerated. Cordarone Tablets have not been shown to help people with the heart/beat problems they experience. Treatment with Cordarone Tablets should be started as a hospital to monitor your condition. You should have regular check-ups, blood tests, chest x-rays, and eye exams before and during treatment with Cordarone Tablets to check for serious side effects. Cordarone Tablets have not been studied in children.

**Who should not take Cordarone Tablets?**  
 Do not take Cordarone Tablets if you:

- have certain heart conditions (heart block, very slow heart rate, or slow heart rate with dizziness or lightheadedness)
- have an allergy to amiodarone tablets, or any of the other ingredients in Cordarone Tablets. See the end of the Medication Guide for a complete list of ingredients in Cordarone Tablets.

**What should I tell my doctor before starting Cordarone Tablets?**  
 Tell your doctor about all of your medical conditions including if you:

- have liver problems
- have or had thyroid problems
- have blood pressure problems
- are pregnant or planning to become pregnant. Cordarone can harm your unborn baby. Cordarone can also in your body for months after treatment is stopped. Therefore, talk with your doctor before you plan to get pregnant.
- are breastfeeding. Cordarone passes into your milk and can harm your baby. You should not breast feed while taking Cordarone. Also, Cordarone can stay in your body for months after treatment is stopped.

**Tell your doctor about all the medicines you take including prescription and over-the-counter medicines, vitamins and herbal supplements.** Cordarone Tablets and certain other medicines can interact with each other causing serious side effects. Sometimes the dose of Cordarone Tablets or other medicines must be changed when they are used together. Especially, tell your doctor if you are taking:

- antibiotic medicines used to treat infections
- depression medicines
- blood thinner medicines
- HIV or AIDS medicines
- cimetidine (Tagamet®), a medicine for stomach ulcers or indigestion
- insulin medicines
- diuretic medicines
- cyclosporin, an immunosuppressive medicine
- dextromethorphan, a cough medicine
- medicines for your heart circulation, or blood pressure
- water pills (diuretics)
- high cholesterol or bile medicines
- narcotic pain medicines
- St. John's Wort.


















**Know the medicines you take.** Keep a list of them with you at all times and show it to your doctor and pharmacist each time you get a new medicine. You may not need any more medicines while you are taking Cordarone Tablets unless you have talked with your doctor.

**How should I take Cordarone Tablets?**  
 • Take Cordarone Tablets exactly as prescribed by your doctor.

**What are the possible or important side effects of Cordarone Tablets?** For more information, if you get serious side effects during treatment with Cordarone Tablets you may need to stop Cordarone Tablets, have your dose changed, or get medical treatment. Talk with your doctor before you stop taking Cordarone Tablets.

Shrank, Avorn. Health Affairs 2006  
 Avorn, Shrank. NEJM, 2006

# Labeling in the US: A Fragmented System

	State Law	FDA	Software Vendors	Pharmaceutical Manufacturers	Data Management Companies	Pharmacies
Container Label						
Patient Medication Information (PMI)						
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

# 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



# Variability in Label Delivery

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 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)

# The “Delivery System”?

- NONE of the ibuprofen prescriptions were delivered with a Medication Guide, as required by law
- It is not enough to encourage new sources of PMI delivery → we must be very clear about who is responsible and how the labels will get to the patient

# Metrics for Measuring Quality

1) Readability - simplicity

2) Rate of delivery

3) Coordination between labeling components

1) Consistency

– can be solved with better standards

# Defining the “Process”

- Not enough to say that other parties “can” participate
- Must be VERY clear who delivers the info, where it comes from, etc.
- Eliminate duplication

# Role of the Doctor

- Doctors likely are not going to be the answer here – lack of time and incentive
- Can deliver PMI if it is totally automated with E-Rx systems
- Pilots – feasibility testing
  - Do doctors want to deliver this info?
  - Will they do so?
  - Will this enhance their communication about meds?

# Solutions? Pilots?

- Keep it simple
  - 1) Single document,
  - 2) Standards for formatting,
  - 3) Consistency of content,
  - 4) Clear process for dispensing
- Actual use testing needed
- Stress standards over “innovation”
- Focus must be patient-centeredness
- Challenge – tailor any of the content and warnings to patient characteristics?
- Mail order – the role of the pharmacist