

Prescription for Confusion:

Health Literacy & Drug Warning Labels

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Health Literacy

The capacity to obtain, process, and understand basic information and services needed to make appropriate health decisions

UNDERSTAND and USE health information

A Matter of Patient Safety

- 90 million U.S. adults have trouble understanding and acting on health information (Institute of Medicine,2004)
- Unfamiliar/complex text such as medication labels most difficult to read and understand

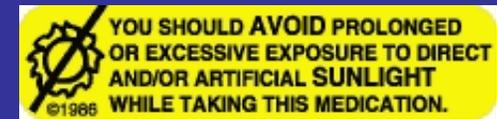
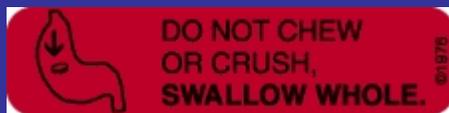
A Matter of Patient Safety

- Patient responsibility has increased for medication self-management
- More meds - average U.S. adult fills 9 prescriptions a year
- Elderly fill an average of 20 prescriptions per year

Where do patients get information on how to safely administer all of these drugs?

Consumer Medication Information: Warning Labels

- Physician and Pharmacist: Time Limited
- Patient Information Forms: Industry-generated, not standardized, not used (?)
- Warning Labels (a.k.a. Auxillary or Secondary Labels)



The Value of Warning Labels

- Display warnings or special instructions on how to administer drug
- Placed directly on drug container
- Use of icons, color
- Minimal text compared to information sheets

BUT ARE THEY USEFUL TO PATIENTS?

THE CONSUMER

And Now, A Warning About Labels

By DEBORAH FRANKLIN

Open your medicine cabinet, and take a close look at every prescription pill bottle you've got. Chances are, each vial is plastered with at least one colorful warning sticker that contains a bold but strangely ambiguous phrase or two — accompanied, perhaps, by a cryptic drawing.

You might see, for example, a red sticker depicting a gushing faucet, with a message in fine print that reads, "MEDICATION SHOULD BE TAKEN WITH PLENTY OF WATER." But, how much is plenty? Would a cup of coffee be acceptable instead?

Another common sticker urges, "DO NOT CHEW OR CRUSH, SWALLOW WHOLE," next to a

These insistent little strips of paper or plastic — hundreds of them — are designed and manufactured by a number of well-meaning companies, each according to its own format, symbology and color scheme.

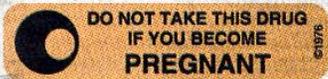
The warning stickers on prescription bottles have not traditionally been deemed important contributors to patient education. Compared with the package insert prepared by the drug's manufacturer under the hot breath of the Food and Drug Administration or the one-page consumer summaries that pharmacists add, the warning stickers are just fluffy little extras.

As such, they are not standardized, regulated or even reviewed by the F.D.A. Nor are they generally tested for effectiveness before they hit the market.

But some health literacy experts worry that many patients, overwhelmed by a proliferation of paper warnings — often written in turgid prose — are relying instead on the stickers to tell them how to take medications.

"What I'm hearing from patients is that they don't really much use these handouts that are stapled to the bag," said Dr. Ruth Parker, an internist who treats patients at the large public hospital associated with Emory University in Atlanta. "What they will sometimes do is look at the label."

Dr. Parker recently completed two studies on the topic with Dr. Terry Davis of Louisiana State University at Shreveport and Dr. Michael Wolf of Northwestern's Feinberg School of Medicine in Chicago. The scientists said that, so far, they had not heard of anyone who was harmed by erroneous



American College of Physicians Foundation

Ambiguous wording and artwork, combined with nonintuitive color selections, are among the problems that can make prescription drug confusing to take

And Now, Some Warnings About W

Continued From First Science Page

group with a broad cross section of reading skills. About a third of those enrolled in one of two studies tested below a sixth-grade reading level. Another third of the group read at a level higher than 12th grade.

The researchers showed the volunteers samples of real warning stickers, one at a time, and asked them individually to explain what action the label was urging. The high number of errors across the board was startling.

For example, when the volunteers saw the sticker with the little pill-popping bota bag, some participants in the studies inverted the meaning completely, and thought that it meant they should chew the pill and crush it before swallowing.

Others thought the stomach was a

Reading Confusion Into Drug Warnings

When researchers asked consumers to interpret prescription warning stickers, these are among the responses they gave:



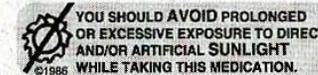
"Chew pill and crush before swallowing."

"Chew it up so it will dissolve swallow whole or you might



"Use extreme caution in how take it."

"Medicine will make you feel Take only if you need it."



"Don't take medicine if you're in the sunlight too long."

"Don't leave medicine in the

"A lot of people thought that icon meant the drug was radioactive," Dr. Wolf said.

blue sticker.

"Designers need to realize patients are imputing meaning color of these labels," Dr. D.

WARNING LABELS: A NATIONAL CONCERN

- New York Times (October 25, 2005)
- CBS Early Morning News (October 28, 2005)
- CBS/ABC Evening News (currently aired locally)
- Forbes Magazine (to be released)

Our Investigations

- LSUHCS – Northwestern – Emory Partnership
- Conducted interviews with 500+ primary care patients in 3 states
- Tested patient comprehension of
 - warning label messages
 - icon meaning
 - label color

Lessons Learned

- Patient comprehension of warning labels is poor
- Average comprehension rate for warning labels is **47%**
- The Problem...
 - Text too difficult
 - Too many steps per label
 - Icons are confusing
 - Random use of color
 - Poor message clarity

The Big Picture

- ✓ Hundreds of warning labels created by several companies, pharmacy chains
- ✓ No universal set of warning labels
- ✓ No standards or regulations to guide warning label development
- ✓ No consumer involvement in development to date
- ✓ Language concordance?
- ✓ Assurances that best evidence drives warning labels?



mouth three times a day

**MAY CAUSE DROWSINESS,
ALCOHOL MAY INTENSIFY THIS EFFECT.
USE CARE WHEN OPERATING A CAR OR DANGEROUS MACHINERY.**

 familiar with its effects.

**DO NOT CHEW
OR CRUSH,
SWALLOW WHOLE**

**IT IS VERY IMPORTANT THAT YOU
TAKE OR USE THIS EXACTLY AS**

WATER



**DO NOT CHEW
OR CRUSH,
SWALLOW WHOLE**

© Rx30

LIMIT ALCOHOL USE WHILE

Roadmap for Policy, Practice

- **Standardize, Regulate Label Development**
 - Message text should be < 6th grade level
 - Simplify steps
 - Give meaning to color
 - **Pilot test among consumers!**
- **Universal Icons**
- **Language Concordance**
- **Train health professionals on literacy and medication risk communication**

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