

**To Err is Human:**  
*Patient Understanding of Prescription  
Drug Label Instructions*

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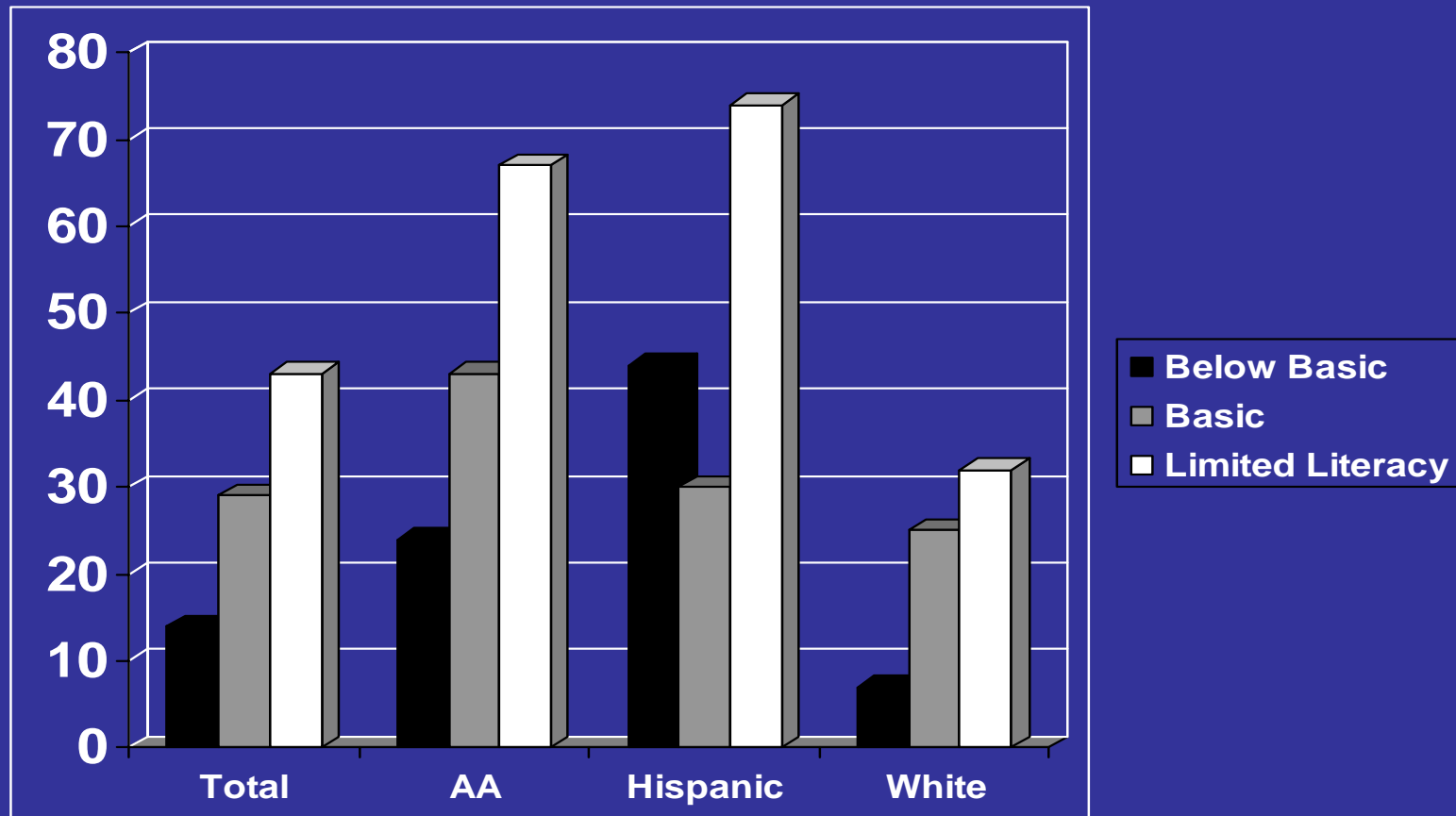
# Health Literacy

- *“Ability to obtain, process, and understand basic health information and services needed to make appropriate health decisions”*
- A reflection of both the patient and healthcare system
- Estimates of limited health literacy are linked to data on functional literacy



# Prevalence of the Problem

National Assessment of Adult Literacy (2003)



93 million adults in the U.S. have limited literacy skills

# DO PATIENTS UNDERSTAND HOW TO SAFELY TAKE THEIR PRESCRIPTION DRUGS?



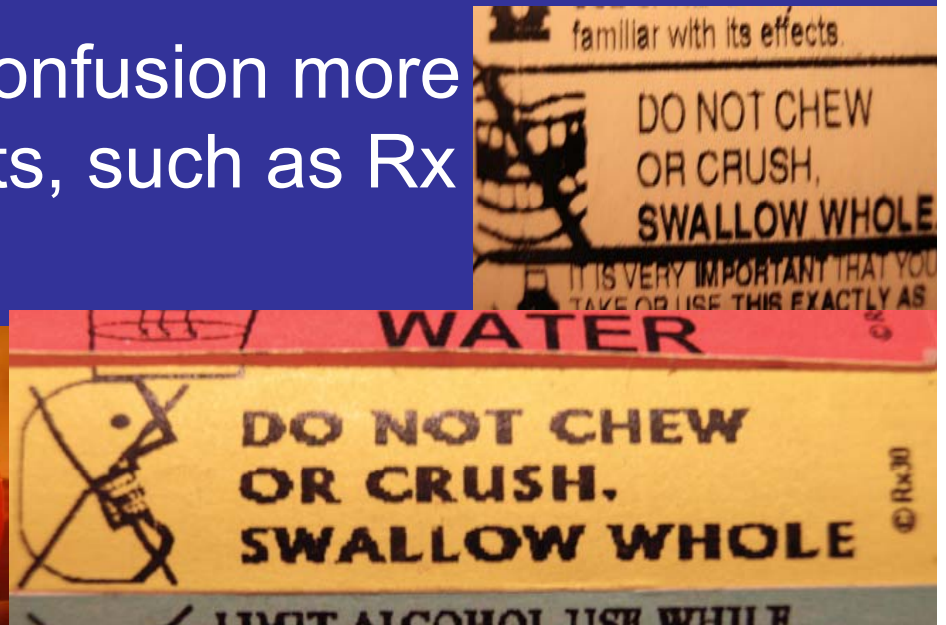
# Patient Medication Error

- In ambulatory care settings, patients – not physicians– assume responsibility
- Errors as a result of misunderstanding instructions are common (Ghandhi et al., 2003; Forster, et al., 2003; Blendon, et al., 2002)



# Patient Medication Error

- Physicians, pharmacists not counseling patients (Morris, et al., 1997; Metlay et al., 2005)
- Greater emphasis on label
- In *health literacy* terms, confusion more likely in unfamiliar contexts, such as Rx labels



# Our Investigation

1. Do patients understand existing medication instructions included on prescription drug labels?
2. Can they demonstrate understanding?

*Hypothesis: Patients with lower literacy skills will have poorer understanding*

# Patients

- 3 sites (Shreveport, LA; Jackson, MI; Chicago, IL)
- 458 patients approached, 446 consented to study. 16 excluded for impairments with hearing (n=3) or vision (n=13). 10 excluded due to non-English speaking, and 25 excluded due to incomplete information.
- **395 patients participated in the study (response rate = 91.6%).**

# Interview and Procedure

## Identifying the Rx primary labels:

- Interviews with physicians and pharmacists conducted to identify common prescriptions and instructions.

## 5 prescriptions chosen:

- Two antibiotics (amoxicillin and trimethoprim)
- Expectorant (guaifenesin)
- Anti-hypertensive, channel blocking agent (Felodipine)
- Diuretic (Furosemide)

# Interview and Procedure

- Data: sociodemographic (age, gender, race/ethnicity, education, source of payment for medications), literacy level (REALM)
- Actual pill bottles were given to patients for review. “How would you take this medicine?” (verbatim response documented)
- Responses rated by three independent reviewers ( $K_n = 0.85$ ). Expert panel (n=5) independently reviewed 147 discordant ratings. For 76% of responses, consensus was achieved. Majority rule applied to 35 remaining.

# Sample Demographics, by Literacy Level

	<u>Adequate</u>	<u>Marginal</u>	<u>Low</u>	<u>P Value</u>
Age, Mean (SD)	42.6 (13.6)	44.9 (13.5)	50.8 (12.7)	<0.001
Race, %				<0.001
Black	29.0	63.7	73.3	
White	65.2	32.7	25.3	
Other	5.8	3.6	1.4	
Education, %				<0.001
Grades 1-8	1.9	2.7	14.7	
Grades 9-11	1.6	34.5	41.3	
H.S. grad/G.E.D.	43.0	45.1	40.0	
> H.S.	43.5	17.7	4.0	
# medications taken	1.4 (1.1)	1.5 (1.1)	1.4 (0.9)	0.37

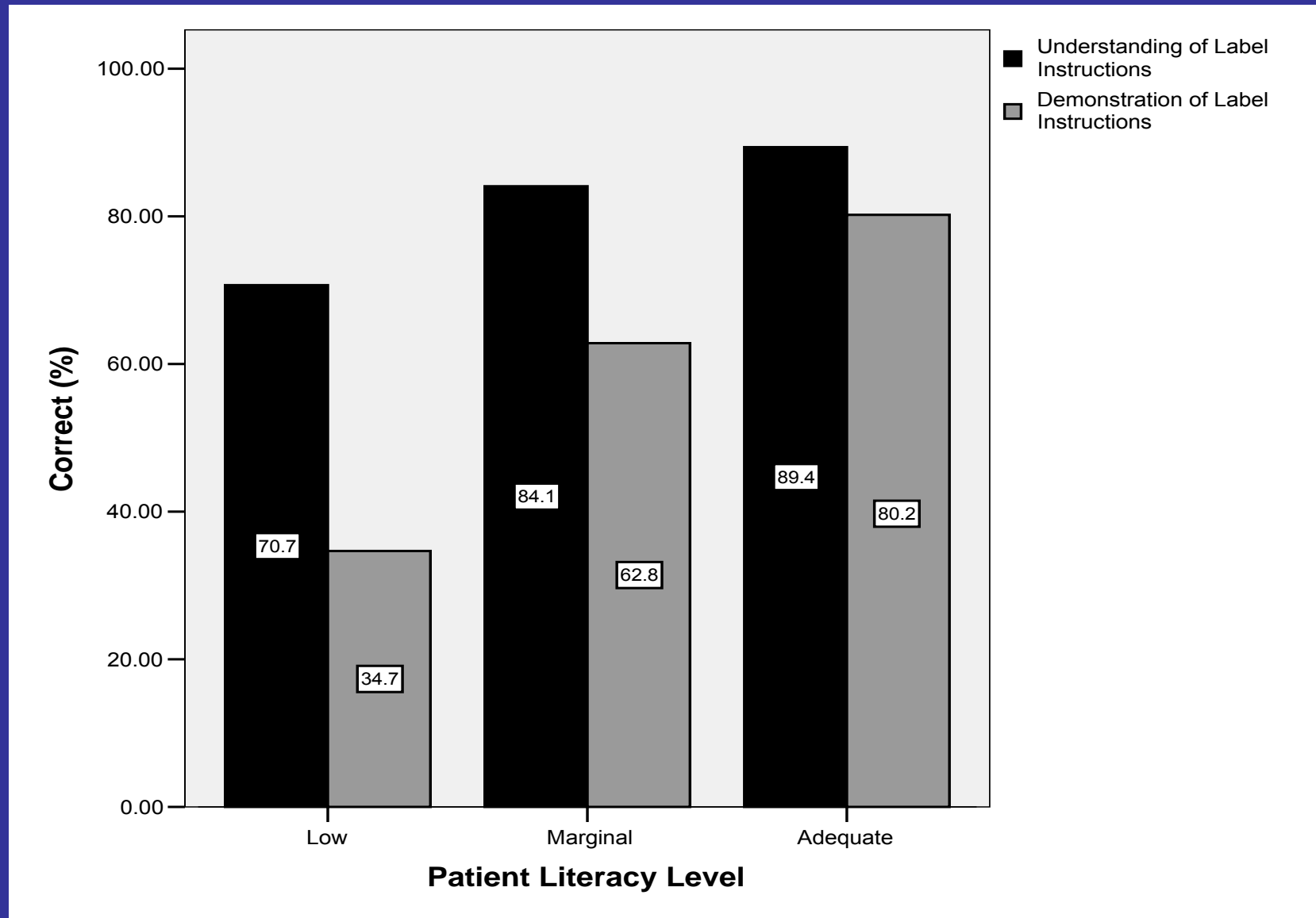
# Percent of Patients Understanding Primary Labels, by Literacy Level

Drug	Label	Adequate	Marginal	Low	P value
Amoxicillin	Take one teaspoonful by mouth 3 times daily.	82.6	65.5	58.7	<0.001
Trimethoprim	Take one tablet by mouth twice daily day for 7 days.	73.0	66.4	52.0	<0.001
Guaifenesin	Take two tablets by mouth twice daily.	89.4	84.1	70.7	<0.001
Felodipine	Take one tablet by mouth once each day.	94.7	87.6	86.7	0.03
Furosemide	Take one tablet in the morning and one at 5pm	91.3	91.2	82.7	0.09

# What Predicts Misunderstanding?

	<u>AOR</u>	<u>95% CI</u>
Literacy Level		
Marginal (7 <sup>th</sup> -8 <sup>th</sup> grade)	2.1	1.2-3.9
Low ( $\leq$ 6 <sup>th</sup> grade)	2.8	1.3-5.7
# of Medications taken		
1-2 meds	2.7	1.2-5.9
3-4 meds	3.6	1.5-7.8
$\geq$ 5 or more	4.0	1.7-8.0

**Figure 1. Rates of Correct Understanding vs. Demonstration for the Primary Label Instruction, “Take Two Tablets by Mouth Twice Daily”**



# Results Summary

- 46% of patients misunderstood 1 or more label instructions
- Problems:
  - clarity
  - numeracy
  - language/syntax (i.e. tablespoon)
  - steps (i.e. dose, interval, duration)
- Patients on more medications had greater difficulty

# Limitations

- Understanding vs. adherence/error
- FQHC recruitment
- Language concordance
- Representation by age

# Conclusion

- Consumer-directed medication information needs improvement (container label, attached label?)

## **FDA Recent Actions**

*Prescribing Information for Drug and Biological Products*  
(effective June 30, 2006)

- Targets the health professional (PPI as 'label')
- Focuses, re-distributes (without minimizing) information
- "Patient counseling" section
- Recommendations for patient-directed information and instructions?