

Health Literacy – Prescribing and Medication Management

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Patient Safety

Medication error: most common medical mistake

- 90 million Americans have trouble understanding & acting on health information
- Unfamiliar/complex text most difficult to read
- 3 billion Rx written a year
- Pharmacist/physician time is limited
- Elderly fill 30 Rx/year, see 8 physicians
- 2/3rds of all adults use prescription drugs



Medication Errors

- **2006 Institute of Medicine (IOM) Report, Preventing Medication Errors**
 - >1/3rd of the 1.5 million adverse drug events in the US each year occur in outpatient settings
 - Poor patient understanding and unintentional misuse of Rx drugs (specifically poor understanding of drug labeling) is a root cause of med errors, poor adherence and poor health outcomes
- **2008 IOM, Standardizing Medication Labels**
 - Greater attention on clarity of label instructions

Number of Cases & Annual Estimate of

Adverse Drug Event†	Overall		Hospitalizations*		
	Cases, No.	Annual Estimate, No. (%)	Cases, No.	Annual Estimate, No. (%)	Hospitalized, %
Allergic reactions	6890	235 202 (33.5)	375	13 232 (11.3)	5.6
Unintentional overdoses	7249	225 298 (32.1)	1919	62 607 (53.4)	27.8
Adverse effects	5846	200 887 (28.6)	1069	36 397 (31.0)	18.1
Secondary effects	669	24 371 (3.5)	102	4 333 (3.7)	15.6
Vaccine reactions	644	15 790 (2.3)	22	751 (0.6)‡	4.8

Over half of hospitalizations from unintended overdoses or supra-therapeutic drug levels

Budnitz, D. S. et al. *JAMA* 2006;296:1858-1866.



Prescription Warning Labels

Can Patients Comprehend Rx Drug Warning Labels?



NO!



Simple Familiar Wording Understood by Most Patients



84%

(1st grade)

$\leq 6^{\text{th}}$ grade reading level = 78.4%

(p=ns)



More Complex Message Limited Comprehension



59%

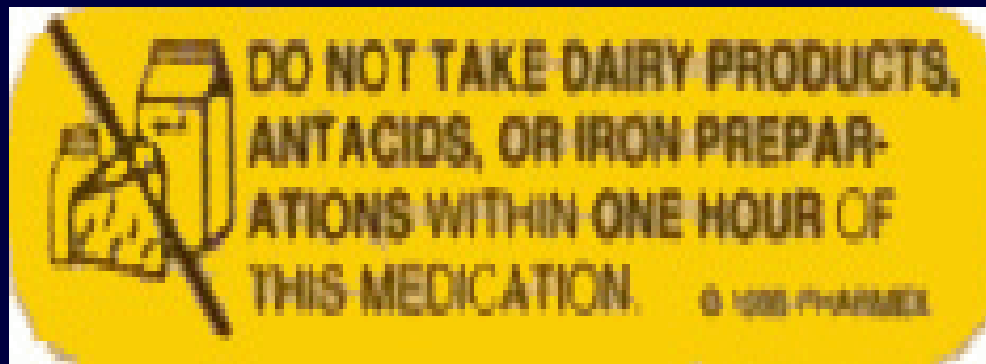
(4th grade)

≤6th grade reading level = 36.5%

($p < 0.001$)



Multi-step Instructions Rarely Understood



8%

(10th grade)

≤6th grade reading level = 0%

















($p < 0.001$)



Patient Warning Labels

- Low literate patients 3 times more likely to mis-interpret Rx warning labels
 - could result in misuse of Rx
- Patients ≥ 65 yo more likely to mis-interpret labels
- Multi-step instructions are difficult for all patients regardless of literacy level

Improving Patient Warning Labels

Existing Message	Icon	%	Revised Message	Icon
SHAKE WELL. Before using.		96	Shake well before using.	
Warning: Do not use if you are pregnant, suspect that you are pregnant, or while breast feeding. Consult your doctor or pharmacist.		96	Do not use if you are pregnant, think you are pregnant, or breast feeding.	
Take with food or milk.		94	Take with food or milk.	
Do not drink alcoholic beverages when taking this medication.		84	Do not drink alcohol.	
You should avoid prolonged or excessive exposure to direct and/or artificial sunlight while taking this medicine.		82	Limit your time in the sun.	
May cause drowsiness. Alcohol may intensify this effect. Use care when operating a car or dangerous machinery.		51	May cause drowsiness. Be careful when driving a car or using machinery.	
For external use ONLY.		49	Use only on your skin.	
Obtain medical advice before taking nonprescription drugs. Some may affect the action of this medicine.		43	Talk to your doctor before using any over-the-counter drugs.	

Webb J, Davis TC, et al. Pat Ed & Counsel. 2008;72: 443-449.

Prescription Drug Labels

Understanding of Prescription Labels

- 2/3rds of U.S. adults \geq 60 yo have inadequate or marginal literacy skills
- 81% of patients \geq 60 yo at a public hospital could not read or understand basic materials such as prescription labels

[Health Literacy](#); accessed Feb 27, 2009

Williams, MV. *JAMA*, December 6, 1995.

“How would you take this medicine?”

395 primary care patients in 3 states



- 46% did not understand instructions ≥ 1 labels
- 38% with adequate literacy missed at least 1 label



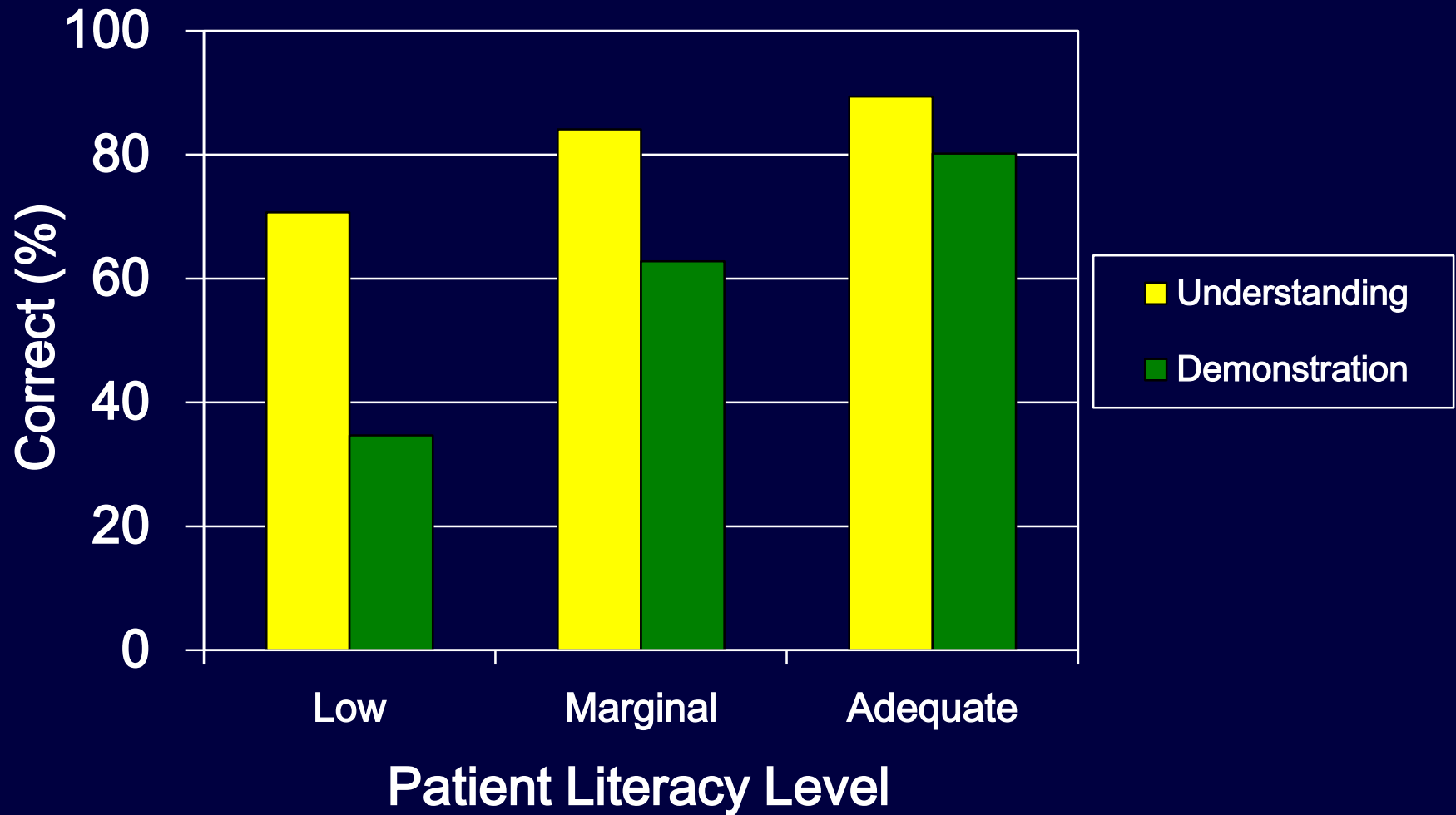
“Show Me How Many Pills You Would Take in 1 Day”



Davis TC et al. Ann Int Med. 2006;145:887-894.



Rates of Correct Understanding vs. Demonstration “Take Two Tablets by Mouth Twice Daily”



Davis TC et al. Ann Int Med. 2006;145:887-894.



Improving Understanding of Rx Drug Label Instructions

- Purpose: evaluate whether the use of more explicit language to describe the dose and frequency of prescribed drugs could improve comprehension, especially among patients with limited health literacy
- 359 patients
- 3 commonly prescribed meds
 - Glyburide, metformin, atenolol
- 10 mock pill bottles different dose and frequency

Improving Understanding of Rx Drug Label Instructions

- 3590 responses
- 839 (23% incorrect)
- 78% of patients misunderstood ≥ 1 label
 - 71% *adequate*
 - 84% *marginal*
 - 93% *low*

Low understanding with hourly intervals or times of day

- Take 1 pill by mouth every 12 hrs with a meal (53% correct)
- Take 2 tablets by mouth twice daily (61% correct)

Highest understanding with time periods

- Take 2 pills in the morning and 2 pills in the evening (89% correct)
- Take 1 pill by mouth every day. Take in the morning (89% correct)

Results

Table 2. Correct Interpretation of Prescription Medication Instructions, By Literacy Level

Drug/Label instruction [†]	Literacy level			P value
	Adequate	Marginal	Low	
	(n=195)	(n=109)	(n = 55)	
Atenolol, 50 mg				
[Times per day] Take one tablet by mouth once daily.	84	78	74	0.18
[Time periods] Take 1 pill by mouth every day. Take in the morning.	91	92	72	<0.001
[Specific times] Take 1 pill by mouth every day. Take at 8 a.m.	86	83	76	0.20
Metformin, 1000 mg				
[Hourly intervals] Take 1 pill by mouth every 12 hours.	61	51	30	<0.001
[Times per day] Take one tablet by mouth twice daily.	90	78	70	0.001
[Time periods] Take 2 pills by mouth every day. Take 1 with Breakfast and 1 with supper.	88	84	78	0.14
[Specific times] Take 2 pills by mouth every day. Take 1 at 8 A.M. and 1 at 5 P.M.	85	69	74	0.003
Glyburide, 5 mg				
[Times per day] Take two tablets by mouth twice daily.	71	57	33	<0.001
[Time periods] Take 2 pills in the morning and 2 pills in the evening.	92	88	76	0.004
[Specific times] Take 2 pills by mouth at 8 a.m. and 2 pills at 6 P.M.	90	86	76	0.03

[†]Bracketed text indicates the classification of language used to state frequency of drug use



Universal Medication Schedule

Roundtable on Health Literacy

5th Workshop

October 12, 2007; Washington, DC.

"Improving Prescription Drug Use Container
Instructions: An Issue of Health Literacy and Medication
Safety,"

<http://www.iom.edu/CMS/3793/31487/43961.aspx>

Transcription of Rx to label Imperfect and Variable

Prescription	Examples of Pharmacy 'Sig' Interpretations
Lipitor 10 mg tabs Take one tab QD Dispense #30 Indication: for high cholesterol No refills	<ul style="list-style-type: none"> - "Take one tablet daily." - "Take 1 tablet by mouth for high cholesterol." - "Take one (1) tablet(s) by mouth once a day." - "Take one tablet by mouth every day for high cholesterol."
Fosamax 5 mg tabs Take one tab QD Dispense #30 Indication: osteoporosis prevention Do not lie down for at least 30 minutes	<ul style="list-style-type: none"> - "Take 1 tablet by mouth daily." - "Take one tablet by mouth every day for osteoporosis prevention. Do not lie down for at least 30 minutes after taking." - "Take 1 tablet every day, 30 minutes before breakfast with a glass of water. Do not lie down." - "Take one tablet every day."
Bactrim DS tabs Take one tab BID Dispense #6 Indication: UTI No refills	<ul style="list-style-type: none"> - "Take one tablet by mouth twice daily for UTI" - "Take one tablet by mouth twice daily for urinary tract infection." - "Take 1 tablet by mouth 2 times a day." - "Take 1 tablet twice daily for 3 days."
Ibuprofen 200 mg tabs Take 1-2 tabs TID PRN pain Dispense #30 No refills	<ul style="list-style-type: none"> - "Take 1 to 2 tablets by mouth as needed for pain." - "Take 1 to 2 tablets by mouth three times daily as needed for pain." - "Take 1 to 2 tablets by mouth as needed for pain ** Not to exceed 4 times a day" - "Take 1 to 2 tablets 3 times a day as needed for pain."

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Wolf, et al., submitted 2007



Transcription of Rxs

- 85 Rx labels evaluated
- Dose frequency omitted on 6% of instructions
- Timing explicitly only stated on 2% of instructions
- Indications only transcribed onto 38% of labels
- Alendronate states not to lie down for at least 30 min after taking – only transcribed 50% of instructions
- Reading difficulty was above recommended levels for 46% of instructions
 - 14% greater than HS level



Patient's day

BID Med & TID Med & QID Med

8 episodes/day!!!

u	7am	X	4pm	
u	8am	X	5pm	
u	9am	X	6pm	
u	10am		7pm	X
u	11am		8pm	
u	Noon		9pm	X
u	1pm	X	10pm	
u	2pm		11pm	X X
u	3pm	X		



Proposal for Universal Medication Schedule (UMS)

- Breakfast
- Lunch
- Supper
- Bedtime



Patient's Day

TID Med

■ Breakfast time T

■ Lunch time T

■ Supper time

■ Bed time T

Patient's day

TID Med & QID Med

- Breakfast time T Q
- Lunch time T Q
- Supper time Q
- Bed time T Q

Patient's day

TID Med & QID Med & BID Med

- Breakfast time T Q B
- Lunch time T Q
- Supper time Q B
- Bed time T Q

Patient's day

TID Med & QID Med & BID Med

8 episodes/day reduced to 4/day

■ Breakfast time	T	Q	B
■			
■ Lunch time	T	Q	
■			
■ Supper time		Q	B
■			
■ Bed time	T	Q	

Patient Understanding of UMS

Randomized Trial (Comprehension Testing)

- 500 patients, 2 sites (Chicago, Shreveport)
- BID, TID, QD prescriptions tested
 - Enhanced text only
 - Standard label
 - UMS label
- UMS 5x better comprehension compared to standard label ($p < 0.001$)



Standard Dosing Times on Prescriptions

Alastair Wood, MD

1234 Springfield Drive
Nashville, TN 54321
(302) 432-1234

<p>1. _____</p> <p>Dose: _____</p> <p>Take for: _____</p>	<p>2. _____</p> <p>Dose: _____</p> <p>Take for: _____</p>	<p>3. _____</p> <p>Dose: _____</p> <p>Take for: _____</p>																								
<p>Schedule</p> <table border="1"> <thead> <tr> <th>Breakfast</th> <th>Lunch</th> <th>Dinner</th> <th>Bedtime</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table> <p>_____</p> <p>_____</p>	Breakfast	Lunch	Dinner	Bedtime					<p>Schedule</p> <table border="1"> <thead> <tr> <th>Breakfast</th> <th>Lunch</th> <th>Dinner</th> <th>Bedtime</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table> <p>_____</p> <p>_____</p>	Breakfast	Lunch	Dinner	Bedtime					<p>Schedule</p> <table border="1"> <thead> <tr> <th>Breakfast</th> <th>Lunch</th> <th>Dinner</th> <th>Bedtime</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table> <p>_____</p> <p>_____</p>	Breakfast	Lunch	Dinner	Bedtime				
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Standard Dosing Times on Containers

Glyburide 50mg 09/26/2007

This medicine is for **Michael Wolf**

To treat **Diabetes**

Prescribed by **Ruth Parker, MD**

Filled by **Target Pharmacy**
123 State Street
St. Paul, MN 12345
(312) 123-4567

You have **11** refills

Refer to Rx# **789-3452-1-0**

**Take 2 tablets in the morning,
and 2 tablets at bedtime**

Breakfast	Lunch	Dinner	Bedtime
2			2

- Take with a meal
- Swallow tablet whole
- Do not drink alcohol

Benefits of Standard Dosing Times on Prescriptions

- **Patients, physicians, pharmacists use the same schedule**
- **Variability in Rx reduced**
- **Variability in transcription of Rx reduced**
- **Patients understanding improved**
- **Patient adherence improved**
- **Therapeutic outcome improved**

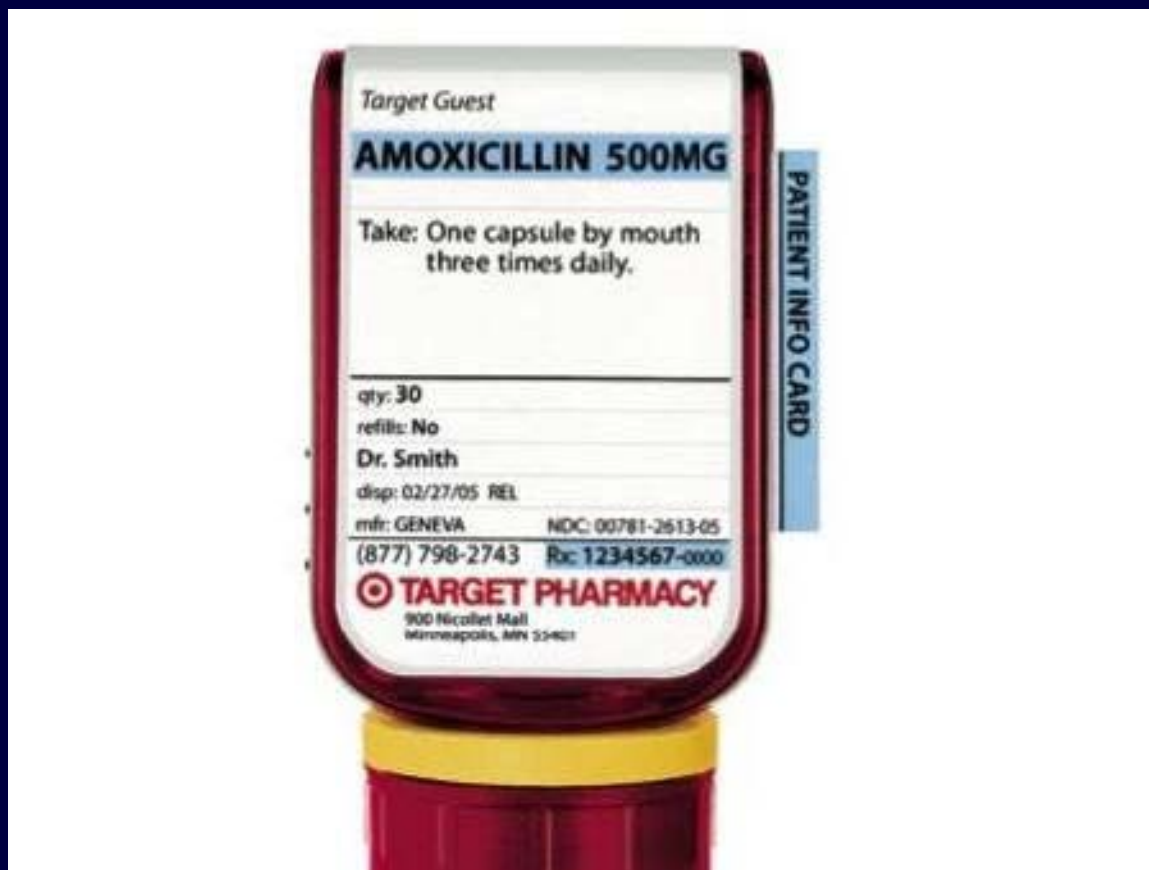


Suggestions for Improving Drug Labeling

- Simplify dosage instructions
- Bold, highlight and enlarge font of content most important to the patient
 - *De-emphasize pharmacy logo & Rx number*
- Container label & accompanying materials should be a complimentary set of info
- Written materials should have simple language, avoid medical jargon, highlight actionable actions
- Patients should be involved in the design of materials



Target's Clear Rx



Slide from Mary Ann F. Kirkpatrick RPh, PhD;
<http://www.iom.edu/CMS/3793/31487/43961.aspx>



Conclusions

- Warning labels & Prescription labels are frequently misunderstood
- New mechanisms for drug labeling are needed
 - UMS may be an option
 - Standardized prescription pads or electronic prescribing
 - Consistency in writing prescriptions
- Prescribing medications with specific directions including time of day improves understanding and may improve adherence



The End

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