



AGENCY FOR HEALTHCARE RESEARCH AND QUALITY



# **Pharmacy Health Literacy: Making Labels Easier to Use**

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# Disclosures



- I work for the Agency for Healthcare Research and Quality
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# What AHRQ Does

## Health Systems Research

AHRQ invests in research to understand how to make health care safer and improve quality

## Practice Improvement

AHRQ creates materials to teach and train health care professionals and systems to improve care for their patients

## Data & Analytics

AHRQ generates measures and data used to track and improve performance of the U.S. health system

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# Health Literacy 101

# New health literacy definitions



## **Personal Health Literacy**

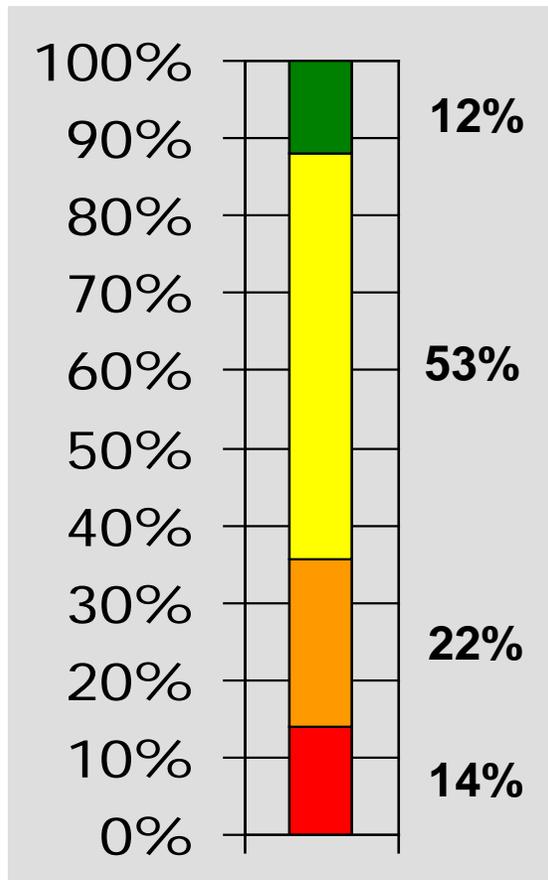
The degree to which individuals have the ability to find, understand, and use information and services to inform health-related decisions and actions for themselves and others.

## **Organizational Health Literacy**

The degree to which organizations equitably enable individuals to find, understand, and use information and services to inform health-related decisions and actions for themselves and others.

Healthy People 2030's two complementary health literacy definitions when taken together constitute health literacy

# National health literacy data



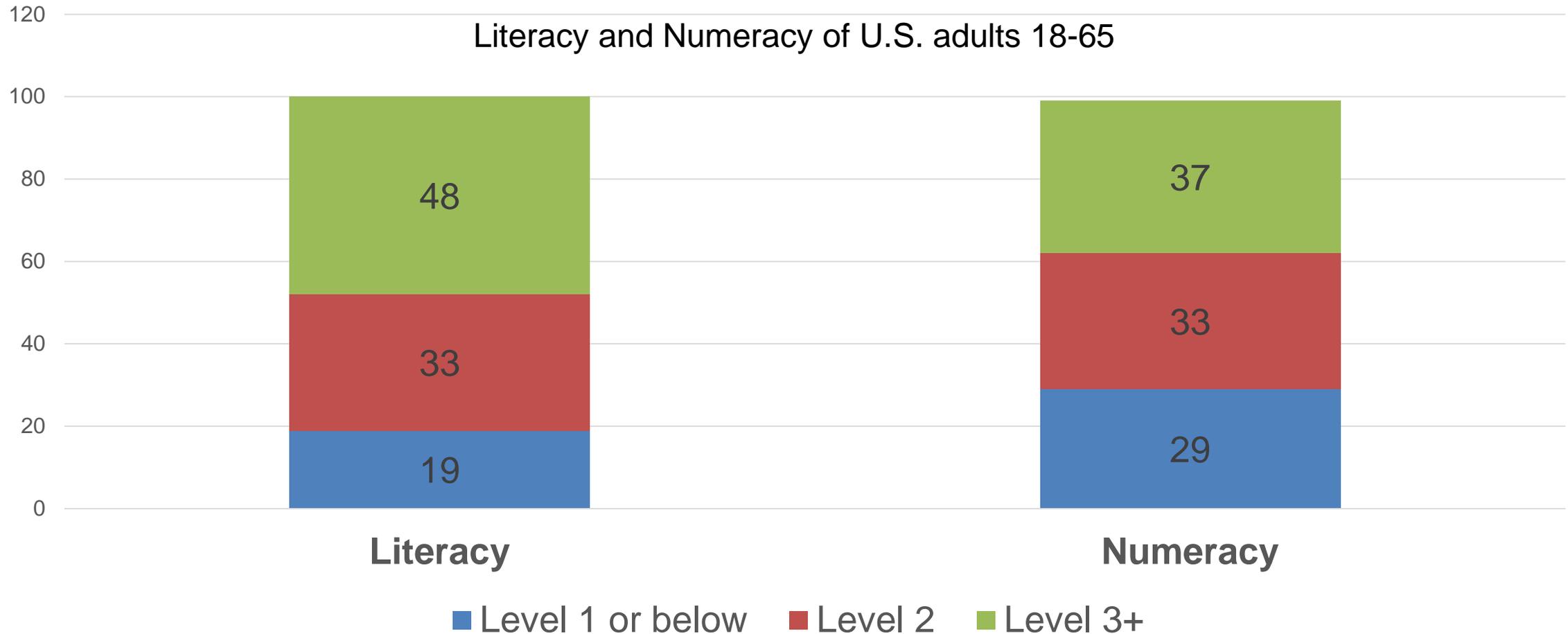
Proficient: Define medical term from complex document,  
Calculate share of employee's health insurance costs

Intermediate: Determine healthy weight from BMI chart,  
Interpret prescription and over-the-counter drug labels

Basic: Understand simple patient education handout

Below Basic: Circle date on appointment slip,  
Understand simple pamphlet about pre-test instructions

# 52 million adults have low literacy skills 74 million adults have low numeracy skills



# Everyone wants clear information

- Health literacy isn't static
  - ▶ It declines with fatigue, stress, illness

## **Health Literacy Universal Precautions:**

Structuring the delivery of care as if everyone may have limited health literacy

# **Patient-Centered Labels**

## Lessons from prescription labeling

# USP Chapter 17: Prescription container labeling to promote patient understanding



- Organize the label in a patient-centered manner
- Emphasize information important to patients
- Simplify language
- Give explicit instructions
- Include purpose for use
- Limit auxiliary information
- Address limited English proficiency
- Improve readability
- Alternative-access methods to address visual impairment

# Wisconsin Health Literacy Focus Group Results



## Consumers like

- Color, bolding, large font
- White space
- What drug is for
- Most important info at top
- Name of medicine

## Consumers don't like

- Unclear directions
- Clutter

# Results in Wisconsin

**Hometown Pharmacy**  
429 West Cottage Grove Road  
Cottage Grove, WI 53527 608-839-3335

Rx 336830 N Dr MABIE, MATTHEW  
MICKEY MOUSE 04/20/16  
Take 1 tablet by mouth once daily for blood pressure

**ATENOLOL 100 MG TABLET** SANDOZ  
Qty: 30 NDC: 0781-1507-01 white / round  
Use By: 04/20/17 RPh: MM GG 264 / 264  
2 Refill(s) Until 04/20/17 Qty Left: 60

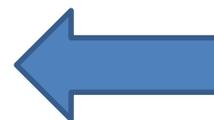
**MAY CAUSE DIZZINESS**

**IMPORTANT: USE EXACTLY AS DIRECTED. DO NOT SKIP DOSES OR DISCONTINUE UNLESS DIRECTED BY YOUR DOCTOR.**

CAUTION: Federal law prohibits transfer of this drug to any person other than the patient for whom prescribed.

THIS DRUG MAY IMPAIR YOUR ABILITY TO DRIVE OR OPERATE MACHINERY. USE CARE UNTIL YOU BECOME FAMILIAR WITH ITS EFFECTS.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.



Old

Revised



**ROBERT JOHNSON** 05/16/16

Take 1 tablet by mouth in the morning and take 1 tablet in the evening.

**ATORVASTATIN 20 MG TABLET**

Take with FOOD May cause DIZZINESS  
Do not CRUSH Do not DRIVE

**RX 1234567-12**

**Hometown Pharmacy** Refills: 3  
202 South Main Street Verona, WI 53593 Dr. Lou Fallagant  
(608) 848-8020 Use by: 05/16/17

Sandoz NDC: 12345-1234-12

# Labeling can make a difference

- A patient-centered label that:
  - ▶ Prioritized information
  - ▶ Used larger font size
  - ▶ Increased white space
  - ▶ Made instructions explicit, using the Uniform Medication Schedule
- Improved adherence among patients with
  - ▶ Limited literacy
  - ▶ Medications to be taken  $\geq 2$  times a day

Wolf, Davis, et al. 2016

# Room for Improvement

<p><b>1 Drug Facts</b></p> <p><b>Active ingredient (in each caplet)</b> Acetaminophen 500 mg.....Pain reliever/fever reducer</p> <p><b>Purpose</b></p>	<p><b>Drug Facts (continued)</b></p> <p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>■ pain gets worse or lasts more than 10 days</li> <li>■ fever gets worse or lasts more than 3 days</li> <li>■ new symptoms occur ■ redness or swelling is present</li> </ul> <p>These could be signs of a serious condition.</p>				
<p><b>2 Uses</b></p> <ul style="list-style-type: none"> <li>■ temporarily relieves minor aches and pains due to:             <ul style="list-style-type: none"> <li>■ the common cold ■ headache</li> <li>■ minor pain of arthritis ■ backache</li> <li>■ muscular aches ■ toothache</li> <li>■ premenstrual and menstrual cramps</li> </ul> </li> <li>■ temporarily reduces fever</li> </ul>	<p><b>If pregnant or breast-feeding</b>, ask a health professional before use.</p> <p><b>Keep out of reach of children. Overdose warning:</b> In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.</p>				
<p><b>3 Warnings</b></p> <p><b>Liver warning:</b> This product contains acetaminophen. Severe liver damage may occur if you take</p> <ul style="list-style-type: none"> <li>■ more than 4,000 mg of acetaminophen in 24 hours</li> <li>■ with other drugs containing acetaminophen</li> <li>■ 3 or more alcoholic drinks every day while using this product</li> </ul> <p><b>Allergy alert:</b> Acetaminophen may cause severe skin reactions. Symptoms may include:</p> <ul style="list-style-type: none"> <li>■ skin reddening ■ blisters ■ rash</li> </ul> <p>If a skin reaction occurs, stop use and seek medical help right away.</p> <p><b>Do not use</b> ■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.</p> <ul style="list-style-type: none"> <li>■ if you have ever had an allergic reaction to this product or any of its ingredients</li> </ul> <p><b>Ask a doctor before use if you have liver disease</b></p> <p><b>Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin</b> ▶</p>	<p><b>4 Directions</b></p> <p><b>do not take more than directed (see overdose warning)</b></p> <table border="1"> <tr> <td data-bbox="1337 692 1567 963">adults and children 12 years and over</td> <td data-bbox="1567 692 1987 963"> <ul style="list-style-type: none"> <li>■ take 2 caplets every 6 hours while symptoms last</li> <li>■ do not take more than 6 caplets in 24 hours, unless directed by a doctor</li> <li>■ do not use for more than 10 days unless directed by a doctor</li> </ul> </td> </tr> <tr> <td data-bbox="1337 963 1567 1035">children under 12 years</td> <td data-bbox="1567 963 1987 1035">ask a doctor</td> </tr> </table> <p><b>5 Other information</b> ■ store at 20-25°C (68-77°F)</p> <p><b>6 Inactive ingredients</b> carnauba wax, corn starch*, croscarmellose sodium*, hypromellose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate*, stearic acid *may contain one or more of these ingredients</p> <p><b>7 Questions or comments?</b> 1-800-719-9260</p>	adults and children 12 years and over	<ul style="list-style-type: none"> <li>■ take 2 caplets every 6 hours while symptoms last</li> <li>■ do not take more than 6 caplets in 24 hours, unless directed by a doctor</li> <li>■ do not use for more than 10 days unless directed by a doctor</li> </ul>	children under 12 years	ask a doctor
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children under 12 years	ask a doctor				

# Distracting information

## Uses

- temporarily relieves minor aches and pains due to:
  - the common cold
  - headache
  - backache
  - minor pain of arthritis
  - toothache
  - muscular aches
  - premenstrual and menstrual cramps
- temporarily reduces fever

- Can I use it for foot pain? Shoulder pain?
- Simplify to: This medicine relieves minor aches and pains and reduce fever.

# It's not information if I can't understand it

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

- How many pills is 4,000 mg?
- If I only take 2 caplets in a day, I still can't take another drug with acetaminophen?
- If I'm taking acetaminophen for a week, and I only have 4 drinks a day for 4 of the days, am I OK?

# Unclear instruction

**Allergy alert:** acetaminophen may cause severe skin reactions.

Symptoms may include:

■ skin reddening    ■ blisters    ■ rash

If a skin reaction occurs, stop use and seek medical help right away.

- Other parts of the label say to ask a doctor or pharmacists?  
Should I call 911? Go to the ER?
- Active tense and simpler: If you develop a **rash** or your **skin turns red or blisters** while taking this medicine, stop taking it and call your doctor.

# Repetitious Information

**Do not use** ■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.  
■ if you have ever had an allergic reaction to this product or any of its ingredients

- Repeats information about not taking other medicines with acetaminophen.

# Wrong emphasis

**Ask a doctor before use if you have liver disease**

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**Ask a doctor or pharmacist before use if you are  
taking the blood thinning drug warfarin**

- Will this catch the eye of people with liver disease or taking warfarin?

# Wrong emphasis

**Ask a doctor before use if you have liver disease**

---

**Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin**

- Will this catch the eye of people with liver disease or taking warfarin?
- Isn't this better?

**If pregnant or breast-feeding, ask a health professional before use.**

# Conflicting directions

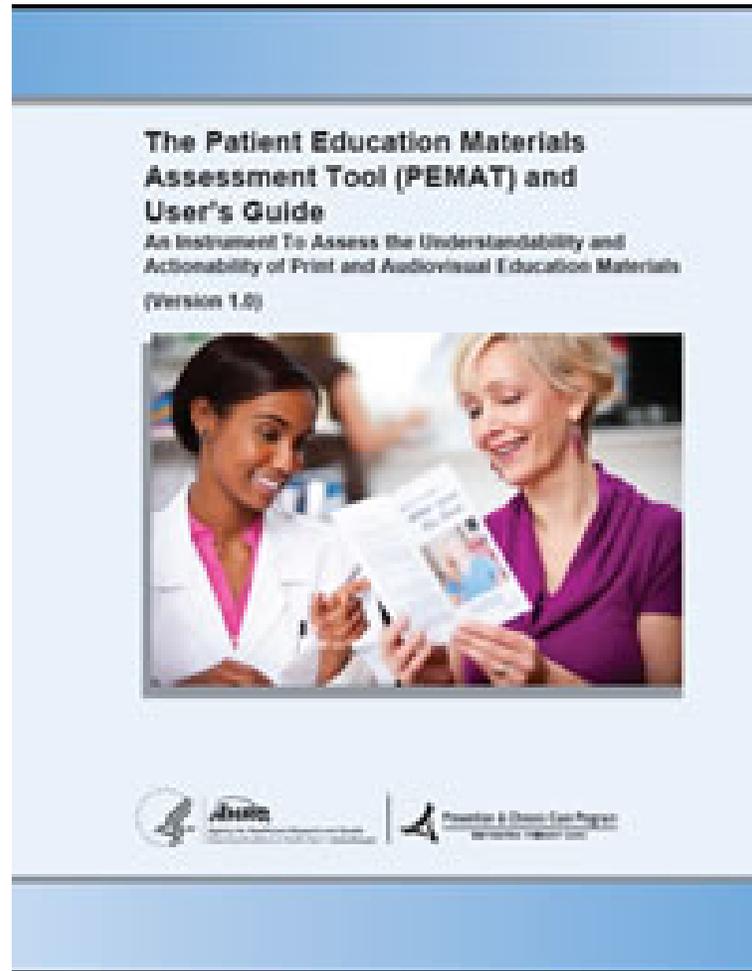
## *Directions*

■ do not take more than directed (see overdose warning)

adults and children 12 years and over	■ take 2 caplets every 6 hours while symptoms last ■ do not take more than 6 caplets in 24 hours, unless directed by a doctor ■ do not use for more than 10 days unless directed by a doctor
children under 12 years	ask a doctor

- Shouldn't I be able to take 8 caplets a day?

# The Patient Education Materials Assessment Tool (PEMAT)



- Assessment of print and audiovisual materials
- Validated measure of how easy it is to:
  - ▶ Understand
  - ▶ Act on the information
- Provides guidance on language, use of numbers, layout & design, and visual aids

<http://www.ahrq.gov/pemat>

# The gold standard: Consumer testing

Ensure that the population you're testing labels with is as diverse as America

- Age
- Race/ethnicity/English proficiency
- Literacy/health literacy

## Newest Vital Sign

<b>Nutrition Facts</b>			
Serving Size		½ cup	
Servings per container		4	
Amount per serving			
Calories	250	Fat Cal	120
		%DV	
<b>Total Fat</b>	13g		20%
Sat Fat	9g		40%
<b>Cholesterol</b>	28mg		12%
<b>Sodium</b>	55mg		2%
<b>Total Carbohydrate</b>	30g		12%
Dietary Fiber	2g		
Sugars	23g		
<b>Protein</b>	4g		8%

\*Percentage Daily Values (DV) are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

**Ingredients:** Cream, Skim Milk, Liquid Sugar, Water, Egg Yolks, Brown Sugar, Milkfat, Peanut Oil, Sugar, Butter, Salt, Carrageenan, Vanilla Extract.

## Health Literacy



**Health Literacy Improvement Tools**  
Tools to help healthcare organizations, leaders, and professionals improve health literacy.

**Health Literacy Professional Education and Training**  
Programs to increase health literacy skills.

**Health Literacy Publications**  
Guiding frameworks, articles and reports on health literacy

## Areas of Interest



### About Health Literacy

Health literacy occurs when health information and services created for the public match with people's capacity to find, understand, and use them.



### Patient Engagement and Education

Tools to improve patient engagement and education, and resources for healthcare professionals to share with



### Research Tools, Data and Funding

Tools and data to conduct, and opportunities, to fund health literacy research.