

Promoting Safe Use of OTC Products

Lessons from Health Literacy Research

Michael Wolf, PhD MPH
Professor, Associate Division Chief
General Internal Medicine & Geriatrics
Northwestern University
Chicago, IL

Disclosures

Federal

- NIH
 - NCI
 - NIA
 - NIDDK
 - NINR
 - NHLBI
 - OBSSR
- AHRQ
- FDA

Private

- ACOG
- California Endowment
- California Healthcare Foundation
- Missouri Foundation for Health
- PCORI

Industry

- Abbvie
- Amgen
- Deborah Adler Design
- Eli Lilly
- Emmi Solutions
- Luto UK
- Merck
- UnitedHealthcare
- Vivus

1. OTC Products offer public health benefit if patients properly self-select & safely use them.

- Monograph products receive GRASE determination with assumption that OTC labeling ensures a consumer's appropriate use of a product when self-treating.

2. People vary – by education, literacy level, self-care experience, culture & beliefs, symptom tolerance.

- How consumers actually use (or misuse) OTC monograph-covered products may not be as expected when receiving GRASE determination.

Some Unique OTC Challenges

- **No 'learned intermediary'**
 - Consumer self-selection
- **# of Product Choices**
 - Brand + Generic Options
 - Single & Multi-Ingredient Products
- **Problematic Labeling**
 - Clarity, understandability
 - Front-of-package, Drug Facts, container vs. package
 - Size of font, information sequence

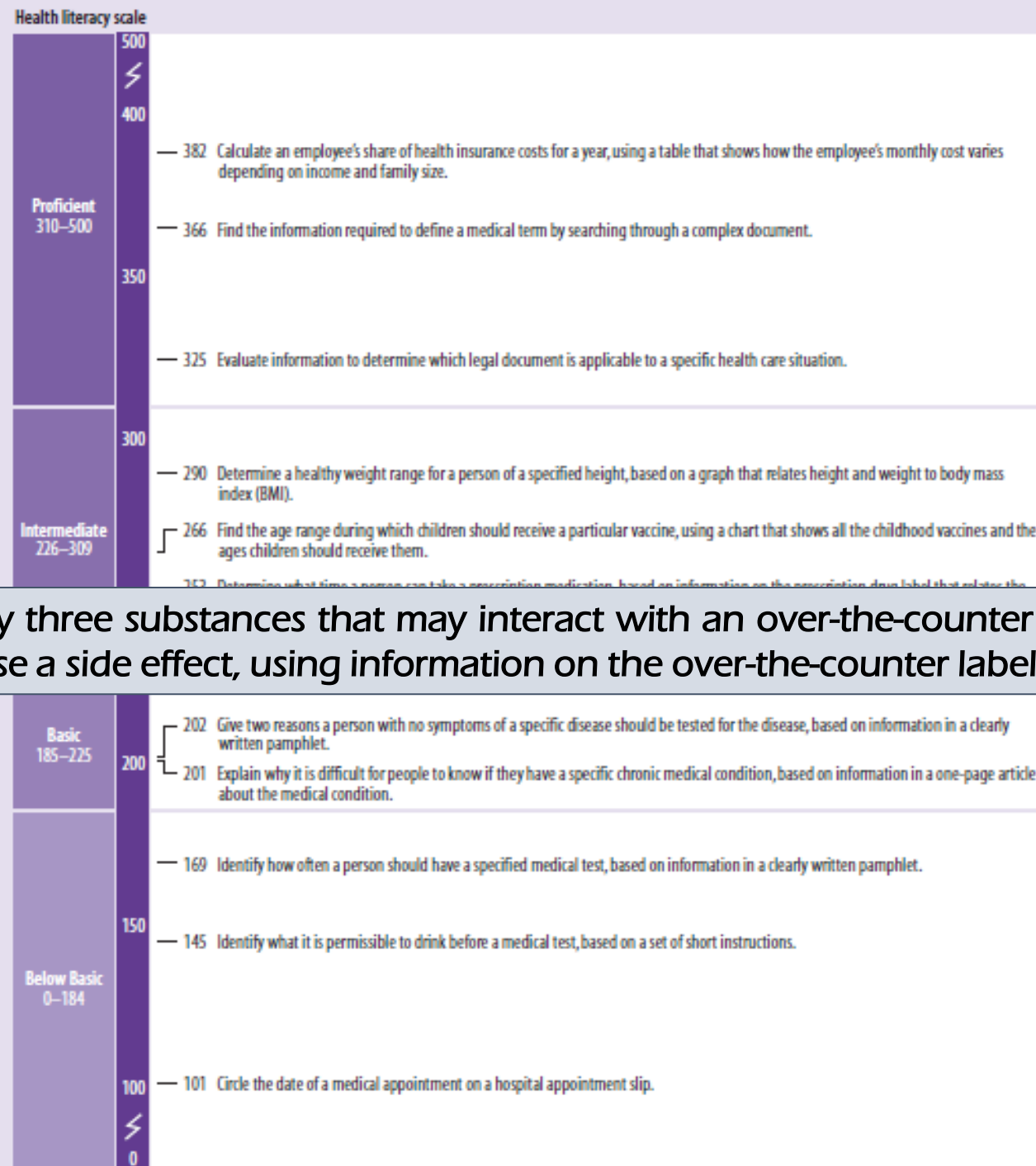
National Assessment of Adult Health Literacy, 2003

Health literacy scale		
Proficient 310–500	500	
	400	
	382	Calculate an employee's share of health insurance costs for a year, using a table that shows how the employee's monthly cost varies depending on income and family size.
Intermediate 226–309	366	Find the information required to define a medical term by searching through a complex document.
	350	
	325	Evaluate information to determine which legal document is applicable to a specific health care situation.
Basic 185–225	300	
	290	Determine a healthy weight range for a person of a specified height, based on a graph that relates height and weight to body mass index (BMI).
	266	Find the age range during which children should receive a particular vaccine, using a chart that shows all the childhood vaccines and the ages children should receive them.
	253	Determine what time a person can take a prescription medication, based on information on the prescription drug label that relates the timing of medication to eating.
Below Basic 0–184	250	
	228	Identify three substances that may interact with an over-the-counter drug to cause a side effect, using information on the over-the-counter drug label.
	202	Give two reasons a person with no symptoms of a specific disease should be tested for the disease, based on information in a clearly written pamphlet.
	201	Explain why it is difficult for people to know if they have a specific chronic medical condition, based on information in a one-page article about the medical condition.
	169	Identify how often a person should have a specified medical test, based on information in a clearly written pamphlet.
	150	
	145	Identify what it is permissible to drink before a medical test, based on a set of short instructions.
	100	
	101	Circle the date of a medical appointment on a hospital appointment slip.
	0	

National Assessment of Adult Health Literacy, 2003

228

Identify three substances that may interact with an over-the-counter drug to cause a side effect, using information on the over-the-counter label



Limited Health Literacy (43% of adults)

3. Marketing practices for OTC products focus consumers on symptom targets, not active ingredients.

- Consumers may properly self-select an OTC product to treat symptom, but lack awareness of what they are taking.

4. “Therapeutic Misadventures” happen with OTC products.

- Consumers (intentionally and unintentionally) misuse OTCs
 - exceed maximum daily dose
 - double-dip
 - incorrectly self-titrate dose intervals
 - over-medicate with multi-ingredient OTC products
- OTC labeling a root cause

Unintentional Misuse

- Half (52.9%) of adults lack awareness of OTC risks (Miller 2014)
- 1 in 4 (24%) adults take more than recommended max dose for one OTC product (Wolf et al 2012)
- Nearly half (46%) of adults misuse OTC products by concomitant use (Wolf et al 2012)

5. Better OTC surveillance, safety review, and responses are necessary.

- Increasing FDA resources might improve currently recognized issues:
 - recognition of OTC product concerns
 - timeliness of policy decision-making on updates to monographs
 - Ability to fast-track safety innovations

Undetected Problems

86% of patients believe their doctor is aware of all OTC medicines they are taking regularly. But...



Undetected Problems

86% of patients believe their doctor is aware of all OTC medicines they are taking regularly. But...

Only 46% reported that they routinely tell their doctor about these OTC drugs...

Improving Review Benefits All

- Justification for OTC vs. prescriptions based on labeling, ability of consumers to self-care
- Consumers presently have inadequate support for OTC decision making and safe use, disparities exist
- Reasons for an FDA expanded review program are well defined (see Federal Register)
- Performance goals should include consumer-centered outcomes (i.e. awareness, self-reported use, etc.)

NORTHWESTERN UNIVERSITY

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Health Literacy & Learning Program



Michael Wolf, MA MPH PhD
Professor, Medicine & Learning Sciences
Vice Chair – Research, Dept. of Medicine
Associate Division Chief – Research
General Internal Medicine & Geriatrics
mwolf@northwestern.edu