Limited Literacy and Vision as Risk Factors to Unintentional Misuse of OTC Drugs



Northwestern University



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Health Literacy & Learning Program

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Background

- Misuse of OTC drug products prevalent, often unintentional¹
- Label instructions typically only means to inform patients
- Misunderstanding of label information root cause of errors
 - Low health literacy strong risk factor
 - Primary focus of FDA improvement efforts to date



¹Wolf et al. Risk of unintentional overdose with non-prescription acetaminophen products. JGIM. 2012;27:1587-1593.



Information Access

Problematic packaging

- Limited real estate
- Minimal white space
- Small and variable font
- Poses 2 challenges
 Ability to see content
 Ability to read content



 Consumers of all literacy levels struggle to read labels





Visual Acuity as a HL Prerequisite

- Label must first be seen to be understood
- Evidence of HL associations, but none on visual acuity except impairment
- What are the relationships of both with OTC comprehension?







 To determine if visual acuity is associated with risk of OTC medication errors among a sample of functionally independent primary care adults





Methods

- Design: Cross-sectional, observational
- Subjects: 500 primary care patients, 1) 18-80 years old; 2) English speaking; 3) no severe cognitive, hearing or visual impairment
- Sites: 1 academic and 1 community GIM clinic each in Chicago and Atlanta (N = 4 clinics)
- Outcome: Functional understanding of 1) dosing instructions and 2) concomitant use





Visual Acuity

Assessed via Snellen eye chart

 \Box Severe impairment excluded ($\geq 20/200$)

Remaining dichotomized into 2 groups:
 Normal vision (20/20-20/25)
 Low vision (20/30-20/100)

 $\mathbf{O} \mathbf{Z}$ F. FPOTEC





Functional Understanding

Dosing Task

- Exceed max daily dose (4000mg/day)
- Improper Dosing
 - Too many pills/dose
 - Too many doses/day
- Improper Spacing
 - Doses too close together







Functional Understanding

Concomitant Use Task

- Taking 2 acetaminophen products at the same time when contraindicated
- Varied by brand, # of ingredients, indication



Base Product

Secondary Product





Sample Characteristics

- Mean age: 49 years
- 63% female
- 57% African American
- □ 39% HS or less
- □ 35% <\$20,000
- □ 39% limited HL
- □ 19% heavy APAP use (>2 times/week)
- \Box 54% low vision
 - Older, AA, lower income, less education, heavier APAP users, limited HL (50% vs. 25%)





Results – Dosing Task

Generic Single Ingredient





*patients may have made more than one of these errors



Results – Concomitant Use

Brand Single Ingredient (Pain)



		Model A	Model B	Model C ¹
Dosing Error				
Visual Acuity				
	Normal Vision			
	Low Vision	1.77 (1.33-2.34)**		1.67 (1.25-2.21)**
Health Literacy				
	Adequate			
	Limited		1.84 (1.34-2.52)**	1.71 (1.25-2.35)*
Concomitant Use Error				
Visual Acuity				
	Normal Vision			
	Low Vision	1.62 (1.15-2.27)*		1.42 (1.10-2.00)*
Health Literacy				
	Adequate			
	Limited		4.35 (2.94-6.43)**	4.14 (2.80-6.12)**



controlling for: race/ethnicity, age, APAP use *<0.05 **<0.001 ¹interaction of VA and HL NS



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Conclusions

Over half our sample had low vision

- Misuse of OTC products is common, independently impacted by visual acuity and health literacy skills
- Mild visual deficits capable of impacting safe use





Limitations

- Cross-sectional
- Hypothetical scenarios
- □ Limited to OTC acetaminophen products
- Did not assess for use of corrective lenses





Implications

- Increase screening by clinicians
 - Updated prescriptions, corrective lenses
- Direct federal and industry efforts towards appropriate packaging changes
 - Limit content
 - Larger font size
 - Increased white space





Thank You!

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