Health Literacy Strategies to Promote Consumer Understanding of Active Ingredient and Concomitant Use Warnings for Acetaminophen: A Randomized Trial

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The Problem Defined

- Acetaminophen overdose is the leading cause of acute liver failure (ALF) in the U.S.[1-3]

- Half to two-thirds of overdoses leading to ALF are unintentional[1-3]

- Two-fold problem:
    - Unaware of active ingredient (AI) information[4,5]
    - Confusion about concomitant use[5]

[1]Bower et al. *Am J Gastroenterol* 2007, [2]Larson et al. *Hepatology* 2005, [3]Ostapowicz et al. *Ann Internal Med* 2002, [4]King et al. *Am J Prev Med* 2011, [5]Wolf et al. *J Gen Intern Med* 2012

Objective

Evaluate the effectiveness of two strategies to increase **awareness of AI** and **risk of concomitant use** compared to usual care.

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USUAL CARE: Standard label

OTC Label

Active ingredient (in each caplet) — **Purpose**
Acetaminophen 650 mg............. Pain reliever/fever reducer
Uses ■ temporarily relieves minor aches and pains due to:
■ muscular aches ■ backache ■ headache ■ toothache
■ the common cold ■ menstrual cramps ■ minor pain of arthritis
■ temporarily reduces fever

Warnings: **Alcohol warning:** If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain reviever or fever reducers. Acetaminophen may cause liver damage. **Do not use** with any other product containing acetaminophen. **Stop use and ask a doctor if** ■ pain gets worse or lasts more than 10 days ■ fev gets worse or lasts more than 3 days ■ new symptoms occ ■ redness or swelling is present. These could be signs of a serious condition. **If pregnant or breast-feeding**, ask a heal professional before use. **Keep out of reach of children. Overdose warning:** Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose,

◄III **READ THE LABEL** III►

NDC 50580-297-24
DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

Take only as directed
TYLENOL®
8 Hour
Pain Reliever / Fever Reducer

Ac Acetaminophen Extended Release Pain Reliever
For Up to 8 Hour Relief of Minor Muscular Aches & Pain

24 CAPLETS 650 mg each

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. *Directions* ■ do not take more than directed (see overdose warning). **Adults and children 12 years and over:** ■ take 2 caplets every 8 hours with water ■ swallow whole - do not crush, chew, or dissolve ■ do not take more than 6 caplets in 24 hours ■ do not use for more than 10 days unless directed by a doctor. **Children under 12 years:** ■ do not use
Other information ■ store at 20-26 C (68-70F). Avoid excessive heat 40 C (104 F) ■ **do not use if neck wrap or foil inner seal imprinted with "Safety Seal" is broken.** *Inactive ingredients* corn starch, D&C yellow #10, FD&C red #40, FD&C yellow #6, hydroxyethyl cellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, powdered cellulose, pregelatinized starch, sodium starch glycolate, sucralose, talc, titarium dioxide. *Questions or comments?* call **1-877-895-3665 (English)** or **1-888-466-8746 (Spanish)**

Rx Label

TERRY DAVIS
444 MAIN ST., CHICAGO, IL 60611

DATE 07/01/11

HYDROCODONE/ACETAMINOPHEN 5MG/325MG TABS
MFG WATSON - For LORTAB 5 TABLETS
If you have pain:

Take: 1 or 2 pills
Wait: 6 hours before taking again
Do not take more than 8 pills in 24 hours.

Ac ...has acetaminophen (a-seat-ah-men-o-fin). ● Taking too much Can ...urt your liver. ● Check for acetaminophen in all your medicines.

USE BEFORE 07/01/12
M. WOLF, MD

RX 060-8-55527
QTY 15
NO REFILLS

PHARMACY ✚
10 E. WABASH, CHICAGO, IL 60601
(312) 555-5555

Methods

Design – 3-arm, cluster-randomized trial

Subjects – 662 primary care patients: 1) 18-80 years old; 2) English-speaking; 3) no severe cognitive, visual, hearing impairment

Sites – 1 academic and 1 community GIM clinic each in Chicago and Atlanta (N=4 clinics)

Recruitment – August 2012 – February 2013

Outcome - AI identification (accuracy + efficiency)
Knowledge of concomitant use warning

AI Identification Task

Sorting speed task:

- Accuracy of identifying acetaminophen across 8 OTC products

- Efficiency assessed via timed framing "*as quickly as you can…*"

Concomitant Use Task

- A total of 13 comparisons across 3 base products

Scenario	Primary product (A)	Comparison #1	Comparison #2 (A)	Comparison #3 (A)	Comparison #4 (A)	Comparison #5 (A)
1	Tylenol Extra Strength (icon)	Advil (no icon)	Tylenol 8hr (icon)	Generic Extra Strength Pain (no icon)	Cold medicine (icon)	Prescription (no icon)
2	Excedrin (icon)					No 5th med
3	Prescription (icon)					No 5th med

(A) = Medicines contain Acetaminophen

Sample Characteristics

- Mean Age – 47 Years

- 63% Female

- 73% African American

- 50% ≤ HS education

- 57% < $20,000

- 68% limited health literacy

AI Identification

	Study Arm			P value
	Usual Care	Written	Written+Verbal	
Total correct, Mean (SD)	6.1 (1.4)	7.0 (1.3)	7.2 (1.2)	<0.001
All correct, n (%)	19 (9.2%)	79 (47.0%)	125 (55.3%)	<0.001
Time (in seconds) among those with all correct responses, Mean (SD)	37.6 (37.2) Range 10-170	49.1 (53.6) Range 7-374	32.5 (27.9) Range 4-228	0.02

Pairwise comparisons for total correct: UC v W, p<0.001; UC v WV, p<0.001; W v WV p=0.14

Pairwise comparisons for % with all correct: UC v W, p<0.001; UC v WV, p<0.001; W v WV p=0.10

Pairwise comparisons for time (sec) - ttests: UC v W, NS; UC v WV, NS; W v WV p=0.004

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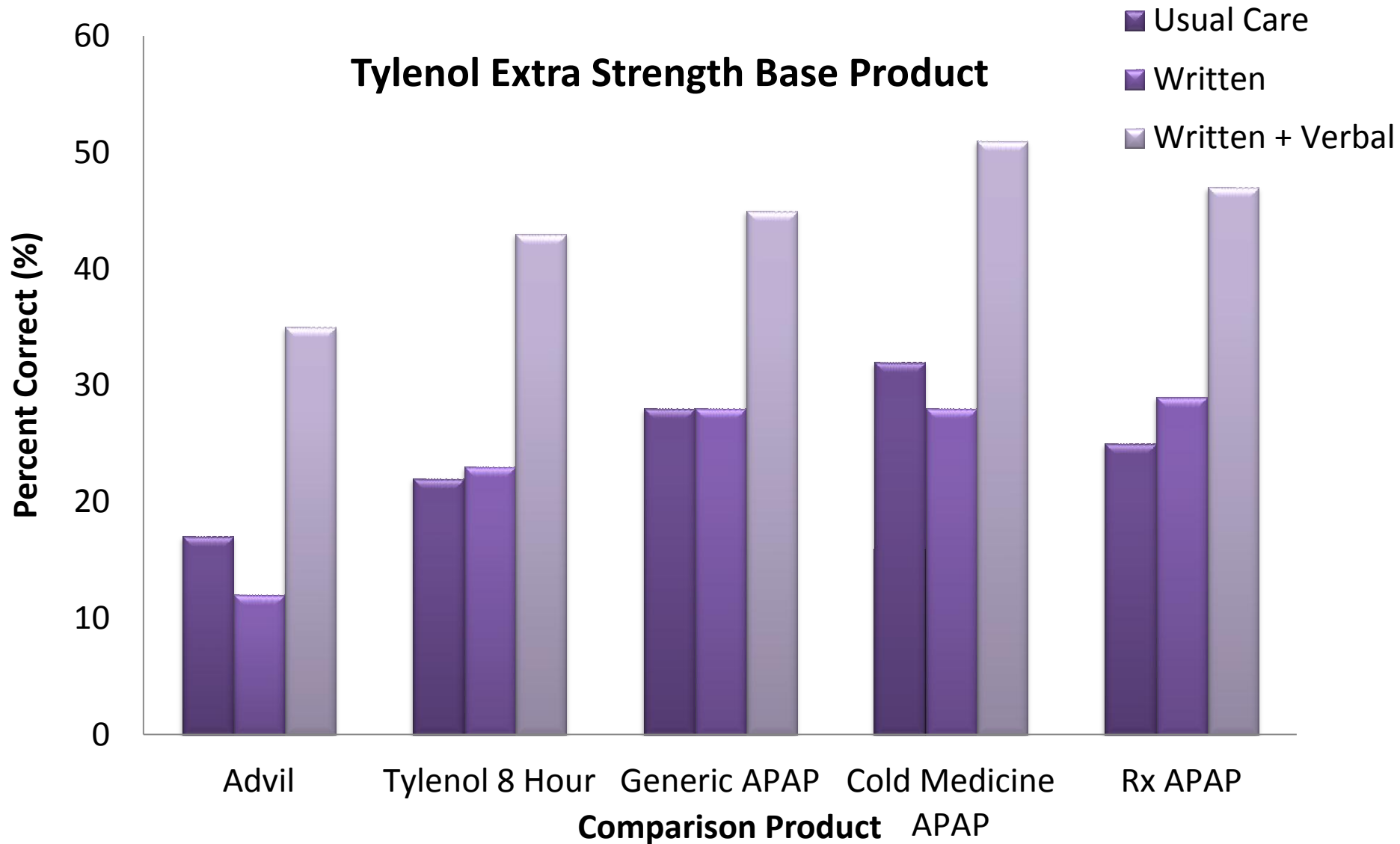Pairwise comparisons for time (sec) - ttests: UC v W, NS; UC v WV, NS; W v WV p=0.004

Concomitant Use

Multivariable Analyses

Variable	Total Correct Identification of Concomitant Use Warning			Total Correct Awareness of Active Ingredient		
	β	95% CI	P value	β	95% CI	P value
Arm						
Usual Care	---	---	---	---	---	---
Written	0.51	-0.18 – 1.21	0.15	0.81	0.55 – 1.06	<0.001
Written + Verbal	3.06	2.40 – 3.72	<0.001	1.05	0.81 – 1.29	<0.001
Age	-0.02	-0.04 – 0.01	0.13	-0.003	-0.01 – 0.00	0.37
Literacy Level						
Low	-4.16	-4.87 – -3.45	<0.001	-1.18	-1.43 - -0.92	<0.001
Marginal	-1.93	-2.64 – -1.22	<0.001	-0.40	-0.66 - -0.15	0.002
Adequate	---	---	---	---	---	---

*Controlling for OTC use in the last month

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Summary

- Written & Written + Verbal strategies improved AI identification

  - Written strategy lagged in efficiency

- Only Written + Verbal strategy improved understanding of concomitant use warning

- Neither strategy improved understanding to acceptable levels (~50%)

- Unable to reduce literacy disparities

Limitations

- Not an actual use study

     - task not reflective of need

     - increased attentiveness?

- Generalizability of sample

     - Disproportionately lower SES, lower literate

Thank You

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