

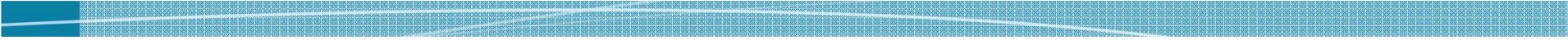
Evaluating Consumer Comprehension of Prescription Drug Information

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Background



- Safe and effective use depends upon patient behavior, which requires information
- Many efforts to educate patients — FDA, sponsors, pharmacies
- Medications dispensed with a variety of Patient Information Materials (PIMs)
 - Package Insert (PI)
 - Medication Guides (MG)
 - Consumer Medication Information (CMI)

Are These Materials Effective?

- Comprehension is necessary for effectiveness (not necessarily sufficient)
- Amenable to scientific evaluation
- “Label Comprehension” studies required for OTC labels – standard methods in use
- Study to evaluate PIMs comprehension

Study Design

- Small demonstration study (N=52)
 - Single-arm evaluation of comprehension
1. Enrollment
 2. Participants review PIMs
 3. Comprehension tested
 4. Vocabulary tested
 5. Literacy tested

Study Participants

- Inclusion/exclusion
 - Adults, age ≥ 18
 - Education: no college
 - 46% of US adults, 61% of seniors 65+ (US Census)
 - English-speaking
 - No selection based on medical condition
- Recruited by advertising, paid \$50
- Sample characteristics
 - 63% male
 - Age (mean): 52 years (± 14); 31% ≥ 60 years old
 - 69% Caucasian, 29% African-American
 - 87% High School graduates
 - 29% low-literacy (REALM ≤ 60 , 8th grade)

Patient Information Materials

Actual in-market materials; masked product and sponsor

MedGuide

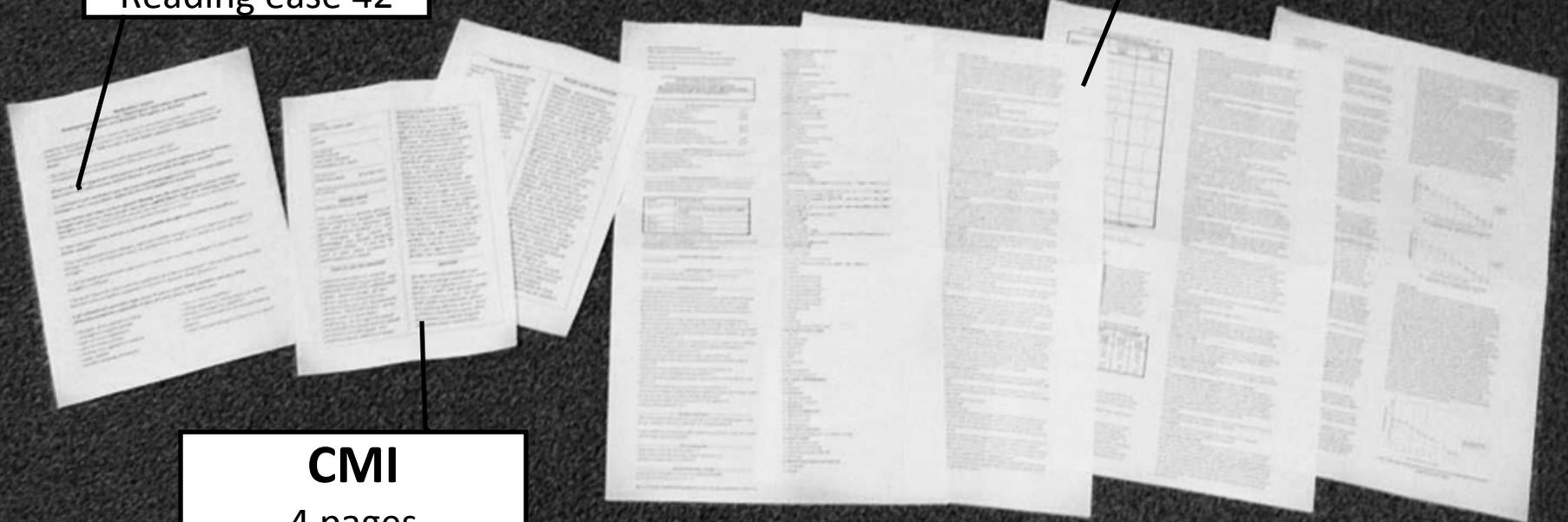
2 pages
Font 12 p
592 words
Reading ease 42

PI

8 pages
Font 5.5 p
14,477 words
Reading ease 15

CMI

4 pages
Font 11 p
1,553 words
Reading ease 40



Subjects Review PIMs

- “Review the materials as you normally would when you get a new medicine.”
- Review privately
 - Videotaped to allow coding of review times
- Review time
 - Median = 30 minutes (± 15 min)
 - 3x more than usual (reported 10 minutes ± 27)

Comprehension Test

- Tested 7 communications objectives
 - “Open book” test
- Scenario-based assessment
 - In line with OTC label comprehension testing methods
 - Example:

“Debbie has been taking <drug> for two weeks and she begins to notice that she seems to be feverish and sweaty and nauseous.
What should Debbie do?”
- Correct responses required specific knowledge from PIMs, not just default “talk to doctor”

Performance

A-

- Should not stop medication abruptly (90%)
 - MG, CMI, PI

B

- Product name (85%)

Performance

D-

- Indication (62%)

F

- Watch for suicidality in teens (58%)
 - Medication Guide's *sole* focus
 - + CMI; Boxed Warning in PI

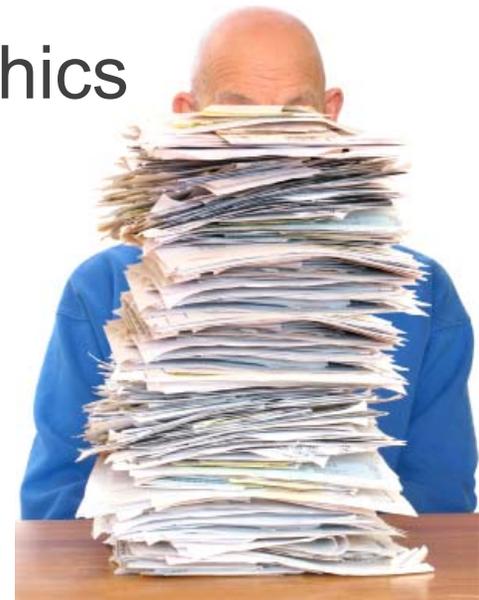
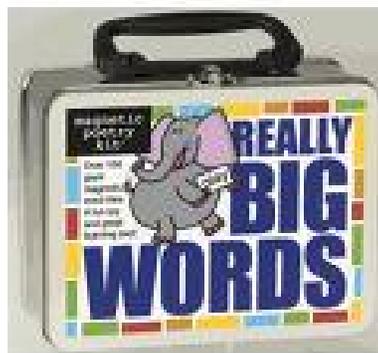
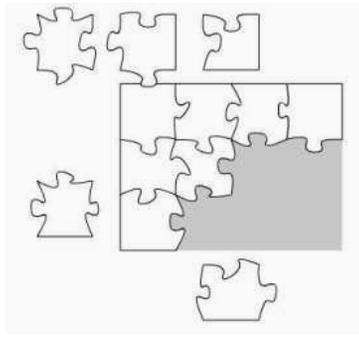
Performance

F-

- Dehydration: Inform prescriber (25%)
 - CMI
- OK to take pain medication (19%)
 - CMI, PI
- Symptoms of possibly fatal syndrome (13%)
 - CMI, PI
- **Low-literacy = lower comprehension**
 - 42% vs 54% correct across all 7 items

Impressions

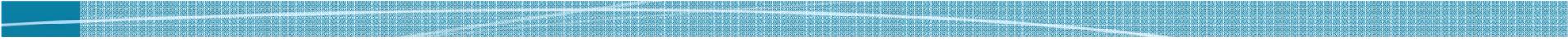
- Too much information
- Too little focus and prioritizing
- Too little use of typography & graphics
- Too many “big words”
- Too many separate pieces
- Too little integration



Limitations

- Small sample
- Lower education
- Not actual patients / users
- No physician / pharmacist counseling
- Tested only some communication objectives, only one (complicated) product
- Subjects aware of testing
- Subjects aware of videotaping of review

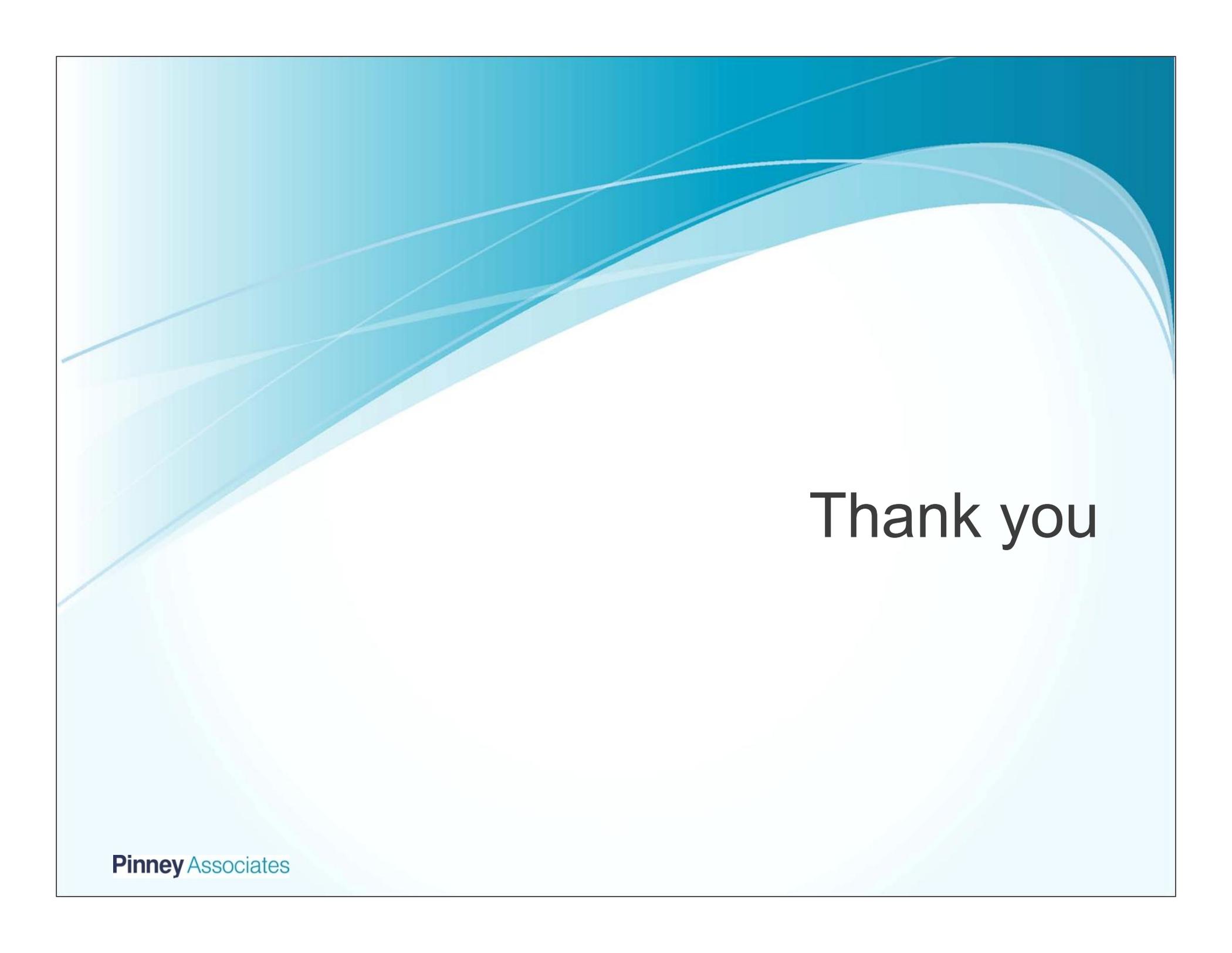
Summary and Conclusions



- Patient Information Materials are not adequately understood
- Critical life-or-death communication objectives are not being achieved
- Patient Information Materials need to be improved

A Single, Evidence-Based Standard

- Products are tested empirically pre-market, followed in-market
- Educational materials should be tested empirically pre-market, followed in-market

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Thank you