Promoting Safe Use of OTC Products

Lessons from Health Literacy Research

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# 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
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.
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....

Serper et al. *Pat Ed Counsel* 2013
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...

Serper et al. Pat Ed Counsel 2013
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.)
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