A Broken System

Findings of the ACPF White Paper on Drug Labeling

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Committee Charge

- Investigate current system for patient Rx communication
- Primary target: container labeling
- Describe problem(s) → identify root causes → consider steps for improvement

Seek a **Standard** and **Integrated** System of Patient Medication Information
A Central Question

Where do patients get information about their prescription drugs?
Value of Rx Labels
• Tangible
• Brief
• Repeatedly used
• Only source for many
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46%
Value of Rx Labels

- Tangible
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54%
Value of Rx Labels

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54%

< 10% read them
Rx Misunderstanding: An Old Topic

- Evidence on labels dates back decades
- Cognitive Factors Research First to Address
- Older adults, those on multiple meds at greatest risk
- Suggested Improvements also well-studied

Finding 1

• Inadequate patient understanding of prescription dosing instructions and warnings is prevalent and a significant safety concern.
Beyond the Patient…A Broken System

- Minimal federal oversight for Rx drugs
- State boards of pharmacy regulate labeling, but currently provide little guidance
- Result: variability in prescribing and dispensing of Rx drugs
A Step Back in Time

- Problem dates back 50+ years

- Durham-Humphrey Amendment (1951) Labeling for OTC drugs regulated by FDA but less attention to Rx drug labeling

- Assumes physician adequately counsels patients on prescribed meds
• Lack of universal standards and regulations for medication labeling is a root cause for medication error.
Improving the Primary Label

Provider Perspective
Evidence Base for Labeling Standards

1. Use explicit text to describe dosage/interval in instructions.
2. Use a recognizable visual aid to convey dosage/use instructions.
3. Simplify language, avoiding unfamiliar words/medical jargon.
4. When possible, include indication for use.
5. Include distinguishable front and back sides to the label.
6. Organize label in a patient-centered manner.
7. Improve typography, use larger, sans serif font.
8. When applicable, use numeric vs. alphabet characters.
9. Use typographic cues (bolding and highlighting) for patient content only.
10. Use horizontal text only.
11. Use a standard icon system for signaling and organizing auxiliary warnings and instructions.
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Finding 3

- An evidence-based set of practices should guide all label content and format.
The ‘Sig Line’ (a.k.a. Dosage Instructions)

- Most important, most problematic
- Tailored directions, only on container
- Seemingly simple, often unclear
- Require patients to interpret dosage times
- Best practices known!
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Take two tablets by mouth twice daily
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Take two tablets by mouth twice daily
Take 2 tablets in the morning, and
Take 2 tablets at bedtime.
Finding 4

- Instructions for use on the container label are especially important for patients and should be written in the most clear, concise manner. Language should be standardized to improve patient understanding for safe and effective use.
Moving Beyond the Primary Container Label

On the Bottle

Patient Information Leaflets

Package Inserts

Med Guides
Moving Beyond the Primary Container Label

On the Bottle

Standard, Integrated System of Patient Medication Information

Package Inserts

Med Guides
Finding 5

• Drug labeling should be viewed as an integrated system of patient information. Improvements are needed beyond the container label, and other sources of consumer medication information should be targeted.
Point of Prescribing, Dispensing

- Physician as learned intermediary
- Pharmacists have mandate
- Most trusted source of health information
- Labeling cannot replace provider counseling
Finding 6

- Health care providers are not adequately communicating to patients, either orally or in print, for prescribed medicines. More training is needed to promote best practices for writing prescriptions and counseling patients.
Evidence-Based Practice

- Advance science of drug labeling
- New, standard label must ultimately be tested
- Can we improve behavior, outcomes?
- Communicate best practices to both pharmacy and medicine
Finding 7

7. Research support is necessary to advance the science of drug labeling and identify best practices for patient medication information.
Summary

- Rx container label most important to patients (‘last line of information support’)
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• Rx container label most important to patients ('last line of information support')

• Variability a likely root cause of med errors
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- View labeling as a system of patient information
Summary

• Rx container label most important to patients (‘last line of information support’)

• Variability a likely root cause of med errors

• Dosage instructions primary focus for change

• View labeling as a system of patient information

• Seek improvement, set evidence–based standards
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