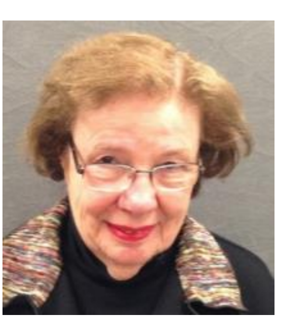
HARC X
Oct. 22, 2018

Improving Prescription Medication Labels to Help Patient Understanding and Adherence

through implementation of USP standards for patient-centered labels

Our panel



Joanne Schwartzberg, M.D.
Moderator
Scholar In Residence ACGME
Chair, USP Health Literacy Expert Panel

Steven Sparks
MS
Wisconsin Health Literacy

David Mott
PhD, FAPhA, RPh
UW School of Pharmacy

Introduction

Medication misuse has resulted in more than 1 million adverse drug events per year in the United States

Patients' best source (and often only source) of information regarding the medications they have been prescribed is on the prescription container label

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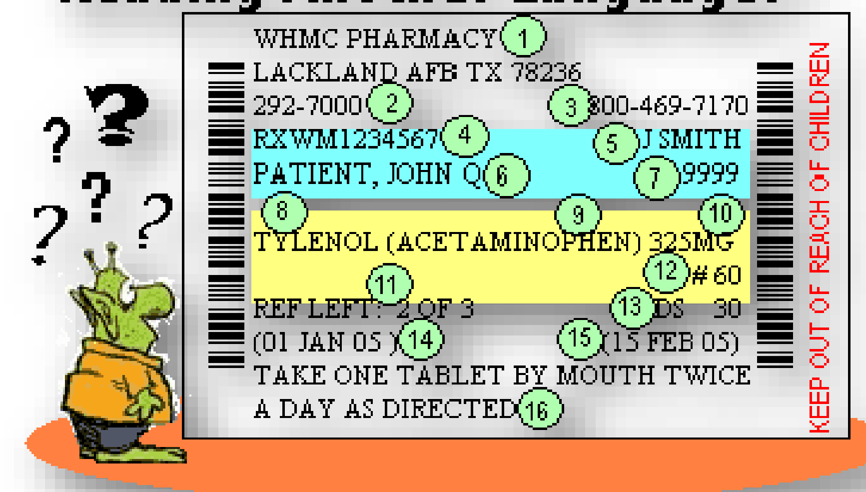
The problem: Prescription confusion



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Why does prescription container labeling matter?

- Adverse drug events (ADEs):
- 3.6 million office visits
- 700,000 emergency room visits
- 117,000 hospitalizations
- Lack of universal standards for labeling on dispensed prescription containers is a root cause for patient misunderstanding, non-adherence, and medication errors

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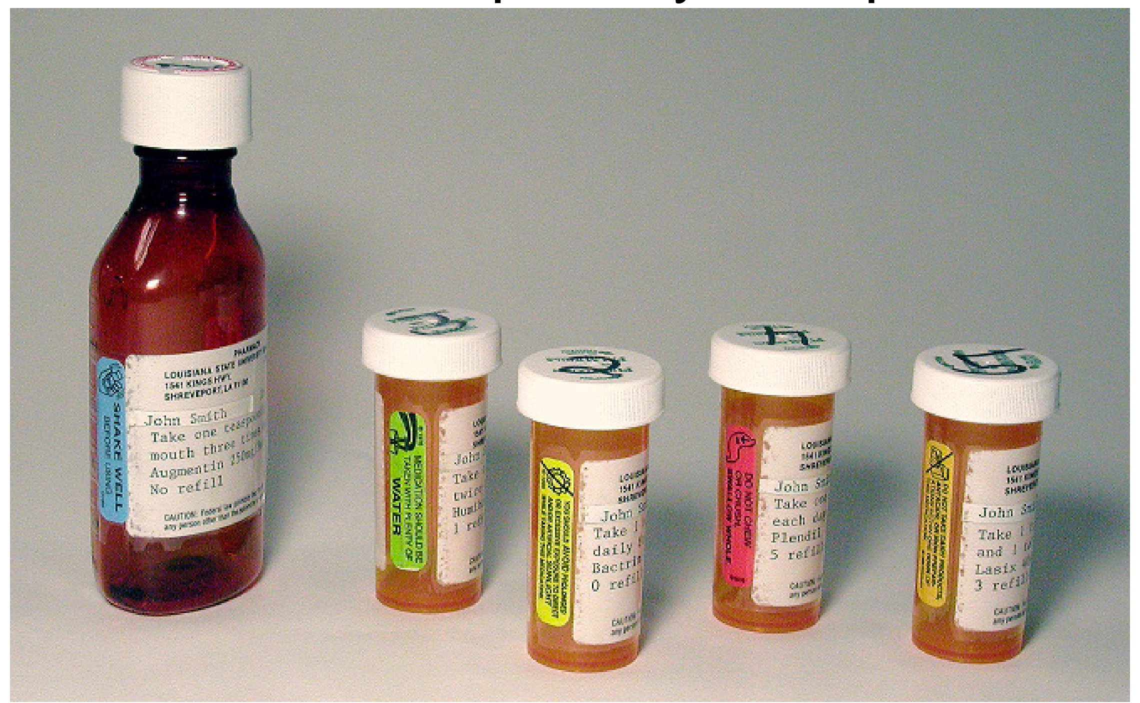
"How would you take this medicine?"

395 primary care patients in 3 states



- **46%** did not understand instructions ≥ 1 labels
- **38%** with adequate literacy missed at least 1 label

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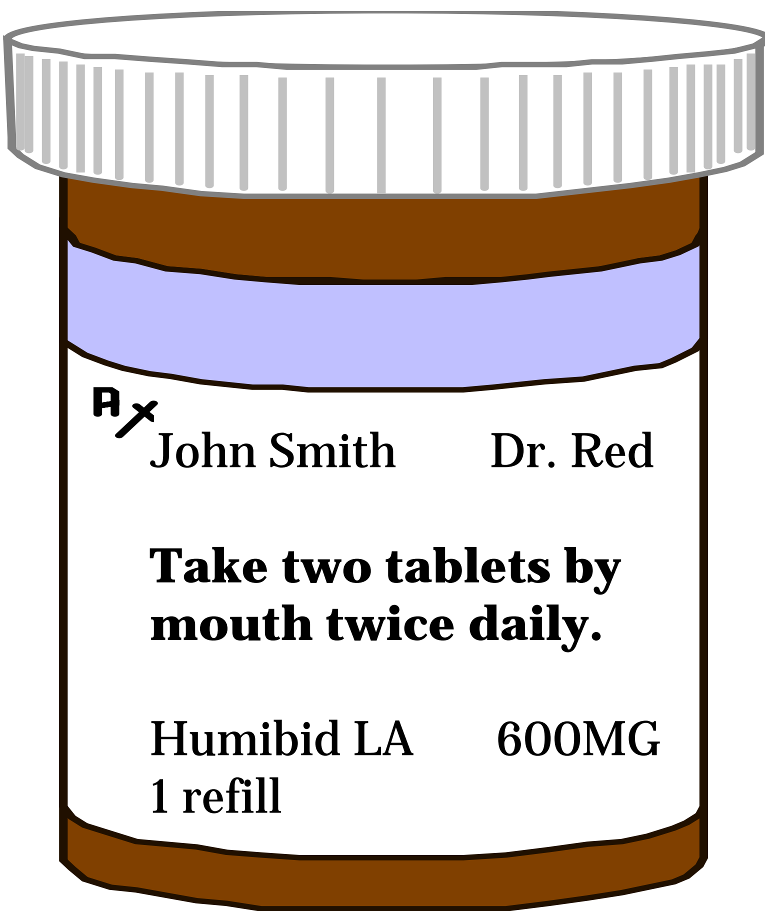
"Show me how many pills you would take in 1 day"



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Rates of Correct Understanding vs. Demonstration

“Take Two Tablets by Mouth Twice Daily”

Patient Literacy Level	Understanding	Demonstration
Low	71	35
Marginal	84	63
Adequate	89	80

Correct (%): 0, 20, 40, 60, 80, 100

Patient Literacy Level

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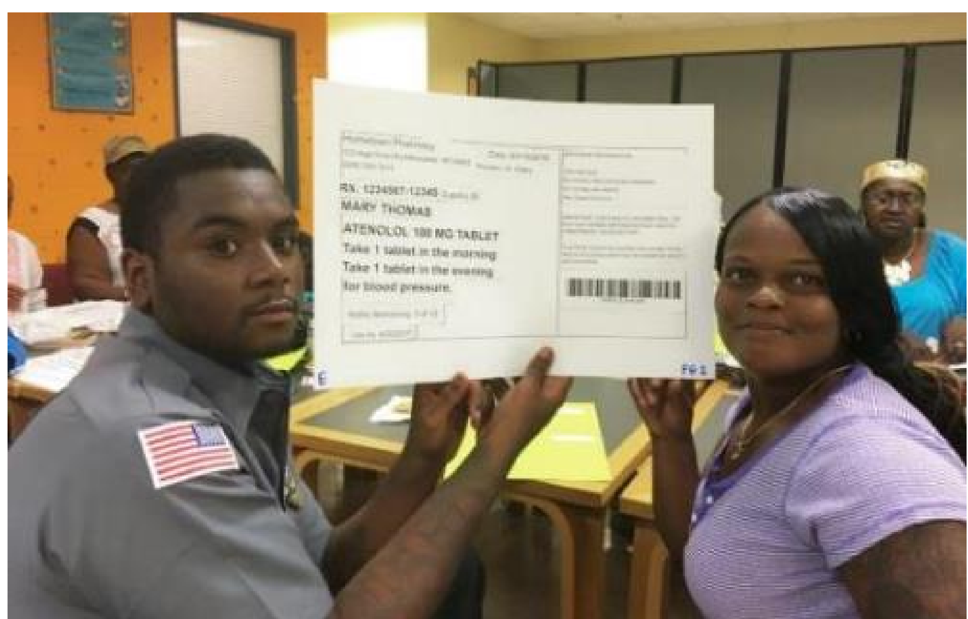
Listening to patients

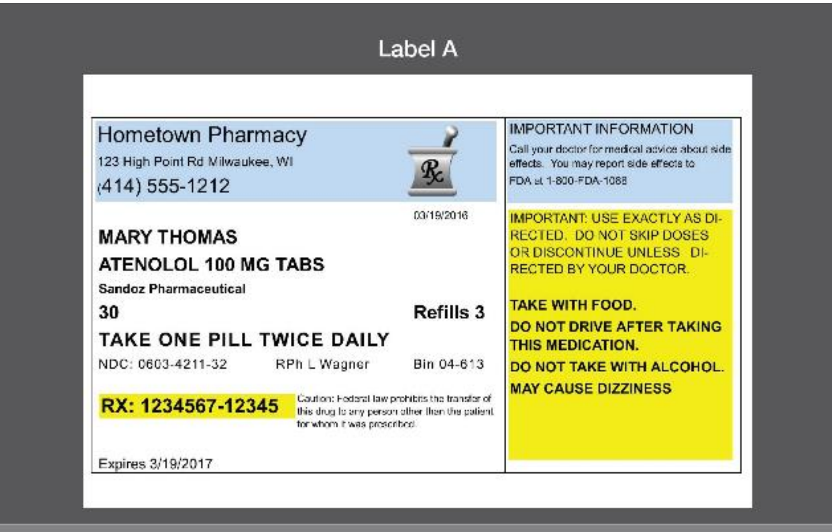


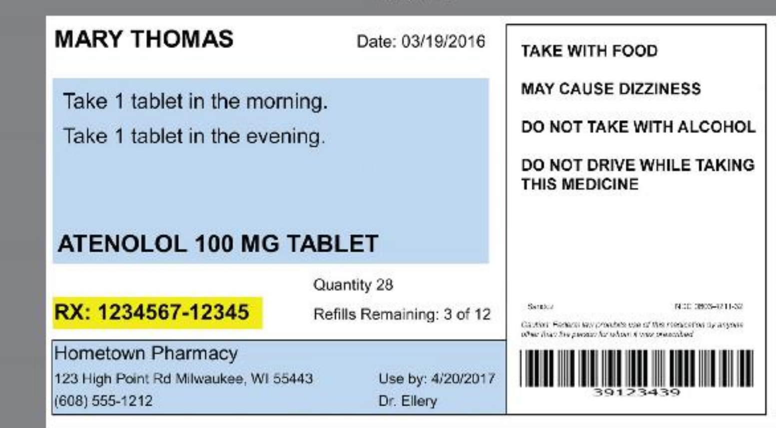
Focus groups

Patient Advisory Council

Listening to patients

"What is your favorite label" survey





What patients like, don’t like

What Patients like	What patients don’t like
Color, bolding, large font	Info for pharmacists
White space	Confusing dates
What drug is for	Addresses
Most important info at top	Clutter
Name of medicine	Unclear directions (twice daily)
Prescriber name	All capital letters
	Pharmacy info at top

Other patient concerns

- Believe generic drugs are not as powerful and for the “poor”
- Concerned those with low literacy may not be able to read any label
- Auxiliary labels: unfamiliar term

Other stakeholder input

- Project Advisory Council

- Pharmacy Survey (n=400)
  - 85% favored adoption
  - 61% want to see adoption in their place of work

USP Patient-Centered Medication Label Standards

Changing Prescription Medication Use Container Instructions to Improve Health Literacy & Medication Safety

12 October 2007 IOM Roundtable on Health Literacy Workshop

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IOM Workshop Summary

- Container label is the patient's most tangible source of information about prescribed drugs and how to take them
- Container label is a crucial line of defense against medication errors and adverse drug effects
- **46%** of patients across all levels of literacy misunderstood 1 or 2 dosing instructions*
- **54%** misunderstood one or more auxiliary warnings*
- Workshop convened to address how prescription labels affect patient safety and how to address identified problems

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USP Headquarters, Rockville, MD

Setting Drug Standards

USP, founded in 1820, is a scientific non-profit organization that sets standards for the identity, strength, and purity of medicines, food ingredients and dietary supplements manufactured, distributed and consumed worldwide

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Setting Drug Standards

- USP standards are developed and revised by more than 1000 volunteer experts on 23 committees, including international participants, who work with USP under strict conflict-of-interest rules.
- USP's drug standards are enforceable in the US by the Food and Drug Administration, and those standards are used in over 140 countries.

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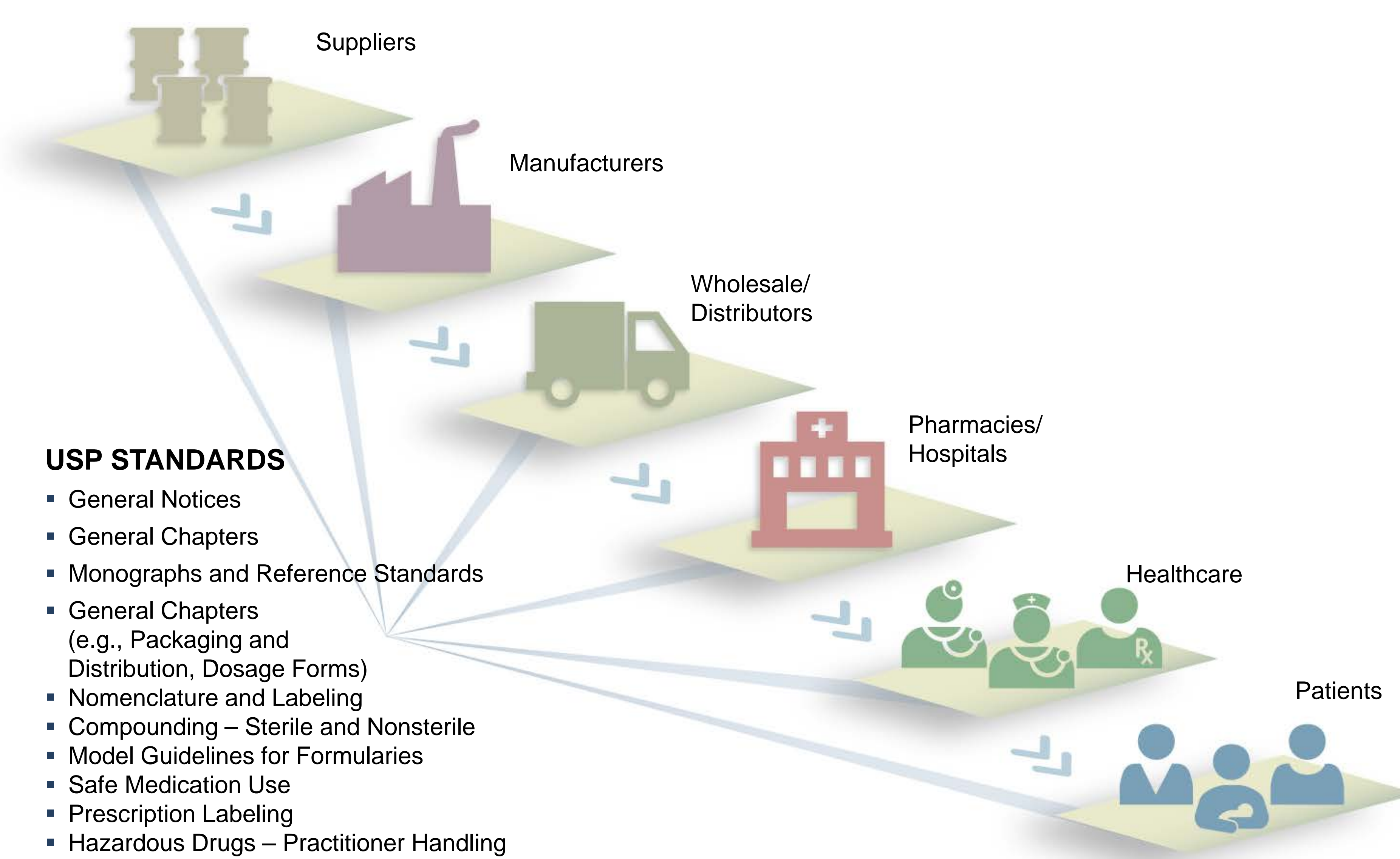
USP Standards: Ensuring Quality Medicine Reaches Every Patient



Lack of Universal Standards

May 18, 2007:

The USP Safe Medication Use Expert Committee established an Advisory Panel to:

- Determine optimal prescription label content and format to promote safe medication use by critically reviewing factors that promote or distract from patient understanding of prescription medication instructions
- Create universal prescription label standards for format/appearance and content/language

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USP Expert Panel Members

- Co-chair Gerald McEvoy, Pharm D. Co-chair
- Co-chair Joanne G. Schwartzberg, MD

- Cynthia Brach (AHRQ Health Policy Researcher)
- Sandra Leal, Pharm.D., CDE (Community Pharmacy Practitioner/IOM Bilingual Advisor)
- Linda Lloyd M.Ed. (HRSA Health Literacy Expert)
- Melissa Madigan, Pharm.D., J.D. (Policy - NABP)
- Dan Morrow, Ph.D. (Academia/Researcher)
- Ruth Parker, M.D. (Health Literacy Expert/Practitioner)
- Cynthia Raehl, Pharm.D., FASHP, FCCP (Academia/Practitioner)
- William Shrank, M.D., MSHS (Academia/Practitioner)
- Patricia Sokol, RN, J.D., (AMA - Medication Safety Expert)
- Darren Townzen, R.Ph., MBA (Community Pharmacy/NCPDP)
- Jeanne Tuttle, R.Ph. (Health System Practitioner/Researcher)
- Joan E. Kapusnik-Uner, Pharm.D., FCSHP (Data Industry)
- Michelle Weist, Pharm.D., BCPS (Health System Practitioner/CPOE Expert)
- Michael Wolf, Ph.D., MPH (Health Literacy Researcher)

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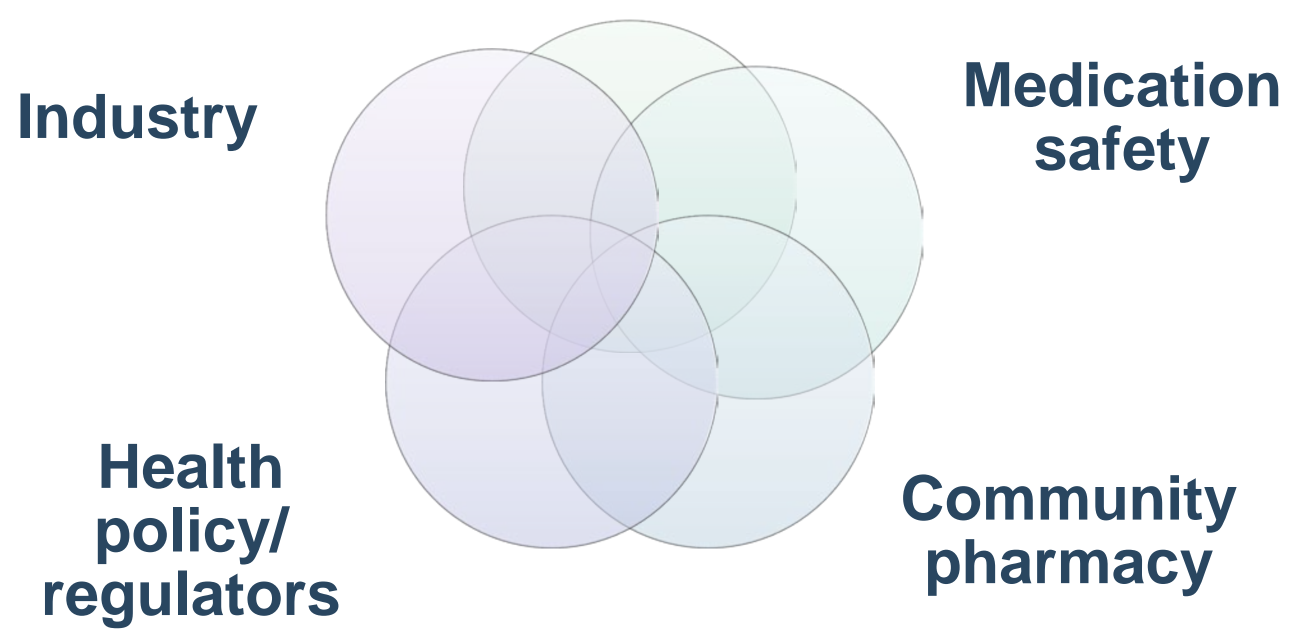
Expert Panel Composition



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Health Literacy: <17> *Prescription Container Labeling*

- Published in USP-NF November 2012
- Official May 2013
- Revision published February 2016
  - Access for visually impaired
  - Endorsement of the Universal Medication Schedule
  - Endorsement of metric units and associated dosing components for oral liquids
- 2018 revision underway
  - Strengthen metric standard
  - Syringe –only use for oral liquid doses under 10mL
  - Label specifications for implementation
- California, New York, Utah, Texas* and Wisconsin have evaluated / use of patient centered label

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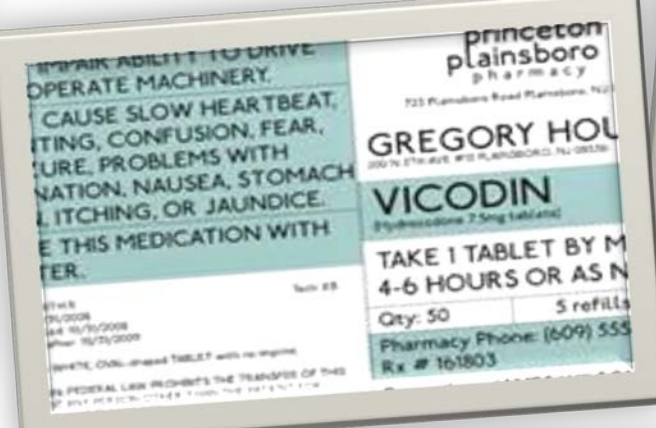
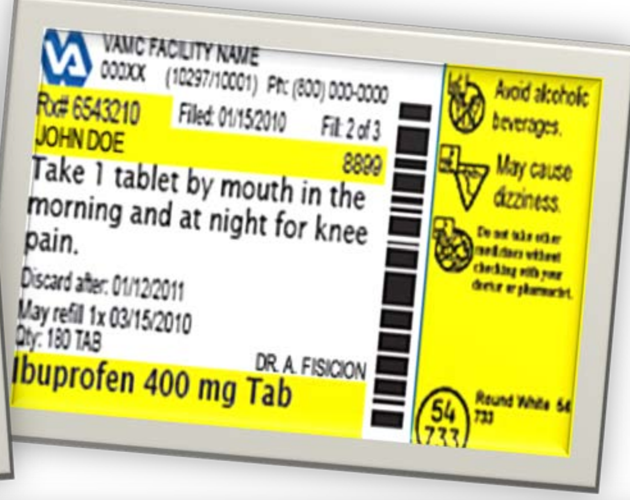
Journey to a patient-centered label





Do not drink alcoholic beverages while taking this medicine

Carry or wear medical identification stating you are taking this medicine

You should avoid prolonged or excessive exposure to direct and/or artificial sunlight while taking this medicine

Michael Wolf
04/29/71

Glyburide 5mg

Take for Diabetes

Take:
2 pills in the morning
2 pills in the evening

Morning 7-9 AM	Noon 11-1 PM	Evening 4-6 PM	Bedtime 9-11 PM
2		2	

Rx# 1234567 9/8/2009

You have 11 refills
180 pills
Discard after 9/8/2010

Provider: RUTH PARKER.MD
Emory Medical Center
(414) 123-4587

Pharmacy: NOVA Scripts Central
11445 Sunset Blvd.
Reston. VA
(713) 123-4567

NDC # 1234567

4.625"

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Prescription Label Organization (Patient-centered Manner)

- Patient-directed information must be organized in a way that best reflects how most patients seek out and understand medication instructions

- Prescription container labeling should feature only the most important patient information needed for safe and effective understanding and use

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Simplify language

- Language on the label should be:
  - Clear
  - Simplified
  - Concise
  - Familiar

  to promote correct understanding of instructions by patients

- No medical jargon
- Use the language in a standardized manner
- Sentence case (Take 1 tablet by mouth every day)
- Do NOT use all capital letters:
  - Such as TAKE 1 TABLET BY MOUTH EVERY DAY

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Give explicit instructions

- Instructions for use (i.e., the SIG or signature) should clearly:
  - separate the dose itself from the timing of each dose
  - to convey the number of dosage units to be taken and the timing
- Use standardized, explicit instructions with specific time periods each day such as
  - Morning
  - Noon
  - Evening
  - Bedtime

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Explicit Instructions (cont'd)

- Use numerals not alphabetic characters for numbers
  - Example: "Take 1 tablet in the morning and 1 tablet in the evening."
- Dosing by precise hours of the day makes it harder for a patient to follow
- For oral liquids, provide measuring device that has volume markings corresponding with dosing instructions, preferably metric (mL)

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Optimize Typography

- High-contrast print (e.g., black print on white background)
- Sentence case (i.e., punctuated like a sentence in English: initial capital letter followed by lower-case words except proper nouns with capital first letter)
- Large font size (e.g., minimum 12-point Times New Roman or 11-point Arial) for critical information

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Optimize Typography (cont'd)

- Adequate white space between lines of text (25%–30% of the point size)
- White space to distinguish sections on the label such as directions for use vs. pharmacy information
- Horizontal text only

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Address Limited English Proficiency

High-quality translation process:

- Translation by a trained translator who is a native speaker of the target language
- Review of the translation by a second trained translator and reconciliation of any differences
- Review of the translation by a pharmacist who is a native speaker of the target language and reconciliation of any differences
- Testing of comprehension with target audience
- Standardized translated instructions:
- To ensure the accuracy and safety of prescription container labeling for patients with limited English proficiency

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Purpose for Use

- If the purpose of the medication is indicated on the prescription, it should be included on the prescription container label
- Confidentiality and patient preference may limit inclusion of the purpose on labels
  - Practitioners should always ask patients their preference
- Use language that is clear and simple
- Use purpose-for-use language in clear, simple terms:
  - e.g., “for high blood pressure” rather than “for hypertension”
- http://healthliteracy.com/dictionary.asp

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Limit Auxiliary Information

- Auxiliary information on the prescription container label should be:

- Evidence-based:
  - Evidence-based auxiliary information, both text and icons, should be standardized
  - Should be applied consistently such that it does not depend on individual practitioner choice

- In simple explicit language:
  - Be minimized to avoid distracting patients with nonessential information
  - Most patients (especially the ones with limited literacy), pay little attention to auxiliary information

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2016 Revisions to USP General Chapter <17>

- June 2014 US Access Board best practices for making prescription container label information accessible to visually impaired patients are addressed in 2016 revision
- Standardized patient-centered instructions such as the universal medication schedule (UMS) is addressed in 2016 revision
- Provision of standardized measuring devices for oral liquids corresponding with dosing instructions, preferably in metric (mL)

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Visual Impairment

- Follow patient-centered prescription container label standards
- Provide alternative access to label information such as tactile (braille), audible, or enhanced visual systems
- Enhance communications on available options
- Provide service or direct patient to alternative access
- Follow best practices for alternative access format
- Best practices recommended by the United States Access Board

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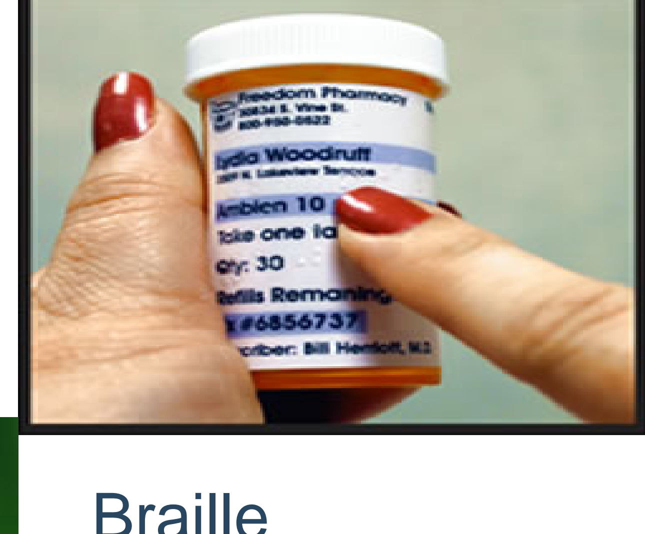
Examples of Alternative Access

Enlarged Print



Braille

"Smart Label"

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Applying health literacy practices to prescription medication labeling using principles of UMS

Standard Instruction

Take one inhalation twice daily

Key Health Literacy Principles

- Numbers in numeric form
- Sentence format
- Specific time periods
- Explicit dosing information
- Easy-to-understand terms
- Chunking/grouping information

Improved Instruction

Take 1 puff in the morning and 1 puff in the evening every day

Stacy Cooper Bailey et al. BMJ Open 2014;4:e003699

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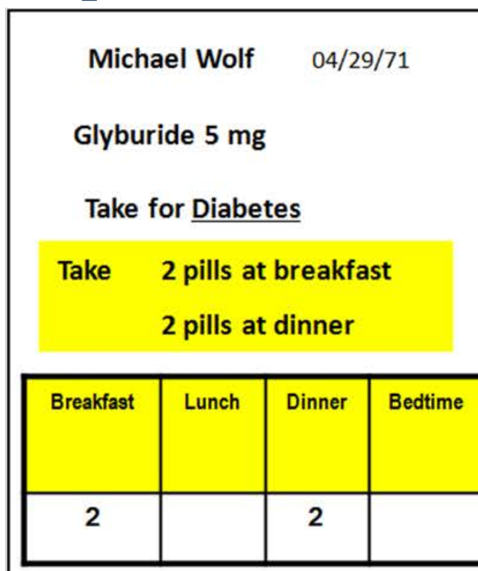
USP U.S. Pharmacopeial Convention

Patient-Centered Label Can Improve Understanding/Adherence



Rx#: 1234567 10/30/2008

You have **11** refills

180 pills

Discard after 10/30/2009

Provider: Ruth Parker, MD
Emory Medical Center
(414) 123-4567

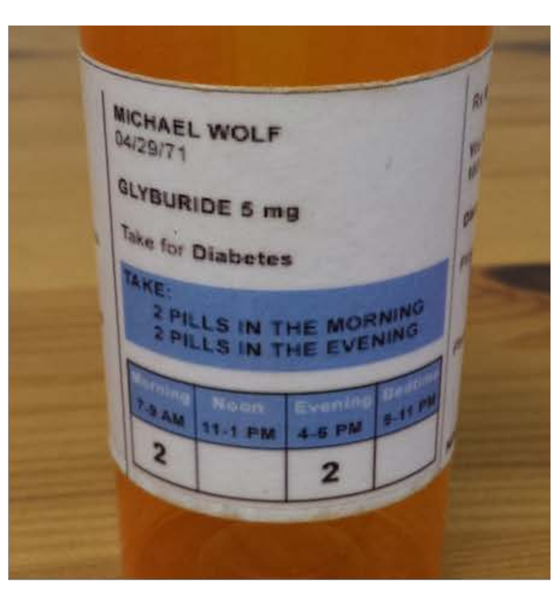
Pharmacy: NoVA ScriptsCentral
11445 Sunset Blvd.
Reston, VA
(713) 123-4567

NDC # 1234567

Important

Do not drink alcohol.

Limit your time in the sun.



RCT in 11 FQHCs.
429 pts w DM and/or HTN.
Average 5 meds
Mean age 52, 28% W,
39% low literacy

	Standard Label	PC Label
Understanding	59%	74%
Adherence (3 months)	30%	49%

State Board of Pharmacy in CA passed legislation for this label

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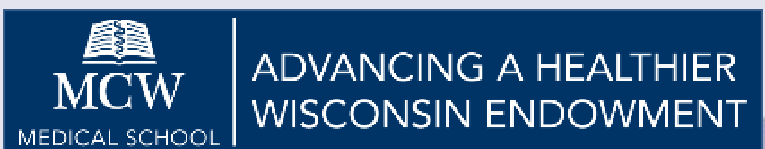
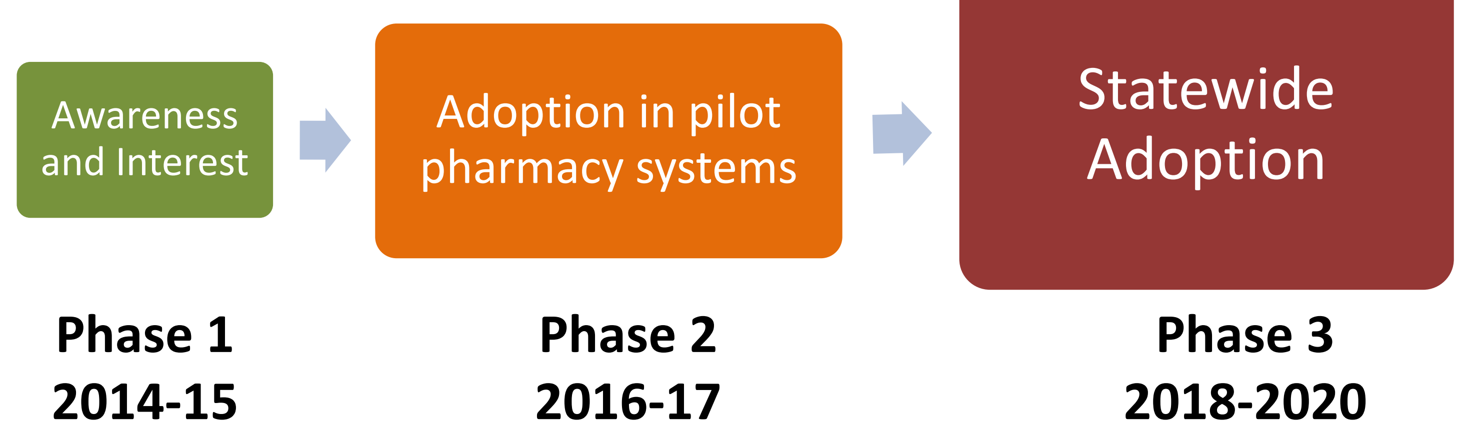
Putting USP standards into practice

Adopting Patient-Centered Prescription Medication Labels

Program funded by



3-Phase Project



Phase 1
2014-15

Phase 2
2016-17

Phase 3
2018-2020

Phase 1: Barriers and Facilitators

January 2014 – December 2015

bit.ly/MedLabel

Table 1: Key Stakeholders Interviewed	
Category	**Number of Respondents**
Chain Pharmacists	2
Pharmacists at Independent Pharmacies	3
Chain Pharmacy Managers	4
Independent Pharmacy Managers	3
Physicians	3
Software Vendors	2

Phase 2: Implementing new labels in pilot pharmacies

January 2016 – December 2017

The proof: patient-centered labels are effective

- Improved comprehension and functional health literacy in older adults (Tai et al 2016)
- Better preference and comprehension among veterans (Trettin, V.A. 2011)
- Improved regimens and adherence mostly among those with limited literacy and more complex regimens (Wolf et al 2016)

Participating Pharmacies

65 pharmacy sites

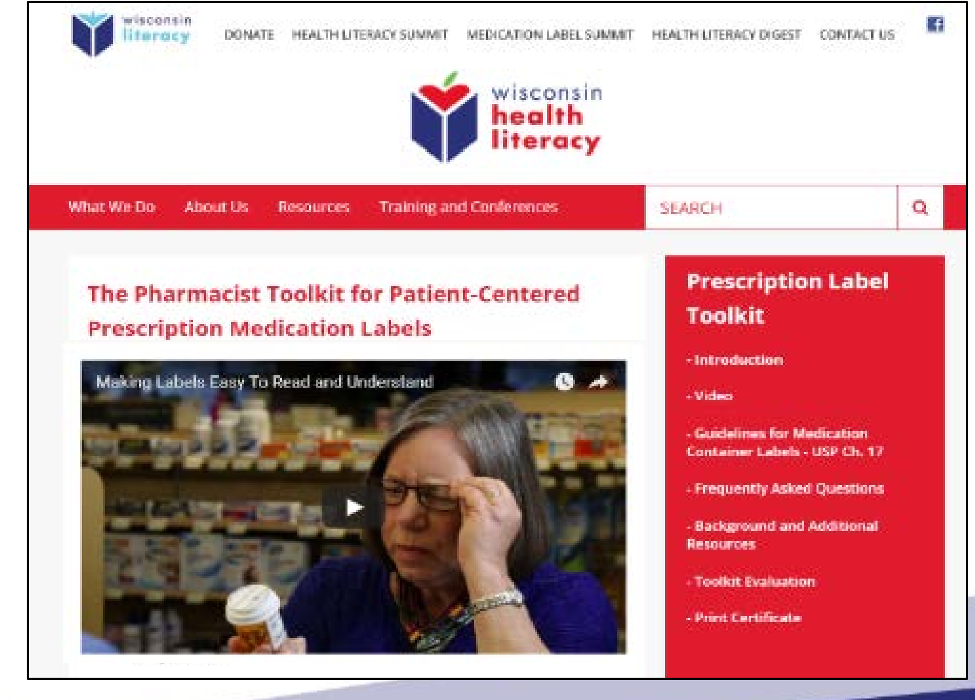
- Hometown
- Hayat
- UW Health

Pharmacies:

- Hometown
- Hayat
- UW Health
- Forward
- Fitchburg Family

The process of implementing new labels

1. Voluntary participation
2. New label design with vendor
3. Pharmacist training



bit.ly/PharmacistToolkit

Supporting activities

- Medication Label Summit

82% of attendees said they would advocate for improving labels

bit.ly/LabelSummitVideos

Supporting activities

- Stakeholder communications
  - Pharmacy Examining Board
  - Chain pharmacies
  - Health organizations

November 2017

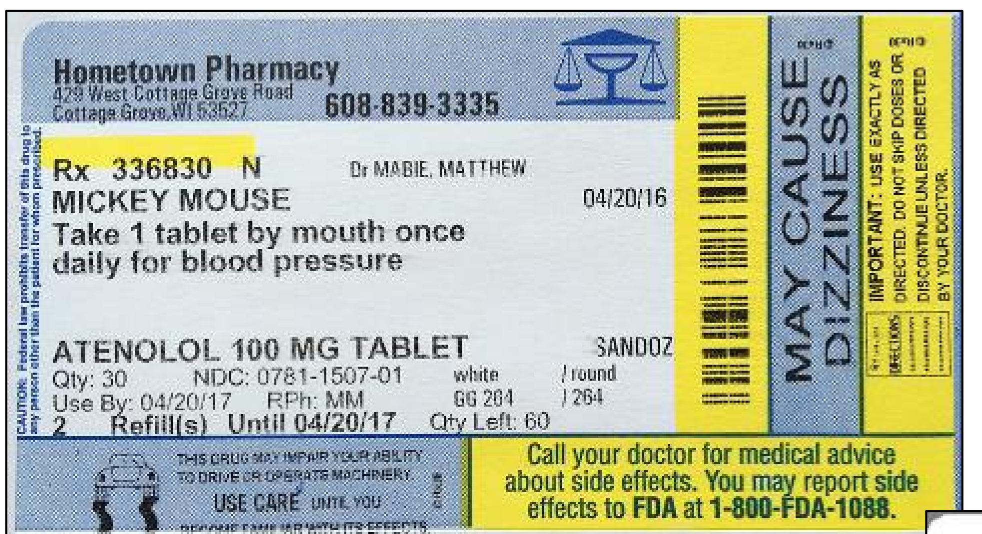
wisconsin health literacy

Making Prescription Medication Labels Easier to Understand

Medication Label project set to expand number of participating pharmacies

Wisconsin Health Literacy's (WHL) initiative to help make prescription labels easier to read will soon benefit hundreds of thousands more Wisconsin residents. The three-year project

Old & new labels



ROBERT JOHNSON 05/16/16

Take 1 tablet by mouth in the morning and take 1 tablet in the evening.

ATORVASTATIN 20 MG TABLET

Take with FOOD | May cause DIZZINESS

Do not CRUSH | Do not DRIVE

RX 1234567-12

NDC: 12345-1234-12

Sandoz

Hometown Pharmacy
202 South Main Street Verona, WI 53593
(608) 848-8020

Refills: 3
Dr. Lou Fallagant
Use by: 05/16/17

Evaluating Results

- **Patient surveys** (N=505)
  - 93%: important labels be easier to understand
  - 83% like new label better or same
  - Most like:
    - Easy to understand
    - Size of letters
    - Important information easy to find

Evaluating Results

- **Pharmacist surveys** (N=94)
  - 84% aware of change
  - Impact for patients:
    - Better adherence
    - Fewer medication errors
    - More likely to benefit from meds

HEALTH | EASING MEDICATION CONFUSION — TUESDAY, DECEMBER 12, 2017 — WISCONSIN STATE JOURNAL

AMBER ARNOLD PHOTOS, STATE JOURNAL

Ryan Bender, a pharmacist at Hometown Pharmacy in Rio, said new prescription drug labels the pharmacy started using in June are simpler for patients to understand. The labels could help patients reduce medication errors, Bender said.

Labels fight prescription errors

DAVID WAHLBERG
dwahlberg@madison.com

After a doctor prescribed a pain patch for a woman with arthritis, the patient started slurring her words. She put patches on her skin everywhere she hurt, her family discovered, not just in one place.

For a patient with epilepsy, a doctor changed a prescription from one, 1,000-milligram tablet twice a day to two 500-milligram tablets twice a day.

The patient kept taking one tablet twice a day, and subsequently had a seizure.

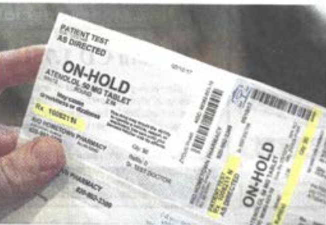
Drug labels can be confusing, especially for people who are elderly or not fully literate. Wisconsin Health Literacy is working with pharmacies to introduce new labels based on national guidelines that emphasize key information, clear instructions and readability.

"Our goal is to improve the labels so they're easier to understand and people are able to more effectively use their medications," said Steve Sparks, director of Wisconsin Health Literacy, part of Madison-based Wisconsin Literacy.

In a survey by the nonprofit this year of more than 700 patients, 88 percent said they have found drug labels difficult to understand. Nearly 23 percent said they have taken prescriptions incorrectly because of confusing labels.

Some of the patients joined

Please see LABELS, Page A10



Rio Hometown Pharmacy's new prescription drug label, at left, stresses the patient's name, drug name and instructions on taking the drug. The old label, at right, put the pharmacy name and address on top, with the prescription number and doctor name farther down.

Learnings for future success

- Pharmacists - focus on patients
- Customization is key
- Software vendors are critical partners
- Stories help motivate change
- Change needs tie to adherence

What’s Next

Phase 3: 2018-2020

Phase 3: Statewide Adoption

1. Label change expansion statewide

2. Sig improvement

3. Resources for continued adoption

4. Further label evaluation

Phase 3: Statewide Adoption

1. Label Change Expansion Statewide:

- Non-phase 2 pharmacies and systems
  - 15-21% of pharmacies in WI
- Emphasize counties with greatest health needs
- Consultation for label changes

Phase 3: Statewide Adoption

2. Sig Improvement:

- Taskforce of stakeholders
  EHR vendor, health systems, pharmacy staff
- Listening sessions – reduce variability in phrasing of sigs
- Pilot test in health system

Phase 3: Statewide Adoption

3. Resources for Continued Adoption:

- Implementation Guide
- Web Resources for Pharmacists and Health Systems
- Access to Label Change "Champions"

Phase 3: Statewide Adoption

4. Further Label Evaluation:

- Partner with WI QIO – Medicare utilization data (Hosp, ER, Clinic, RX)
- All Phase 2 pharmacies
- Phase 3 pharmacies