Creating a Standard for Medication Prescription Labels

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Assistant Vice President Drug Information

IOM Roundtable on Health Literacy
Health Literacy Past, Present, and Future: Workshop
Washington, DC 2014 Nov 6
Developing a Standard for Prescription Container Labels in the US

HISTORY
The problem: Prescription confusion

When Reading Your Prescription Label, Do you Feel Like You're Reading Another Language?

- WHMC PHARMACY
- LACKLAND AFB TX 78236
- 292-7000
- RXWM1234567
- PATIENT, JOHN Q
- TYLENOL (ACETAMINOPHEN) 325MG
- REF LEFT: 2 OF 3
- (01 JAN 05) TAKE ONE TABLET BY MOUTH TWICE A DAY AS DIRECTED
Journey to a patient centered label
Improving Prescription Container Labeling in the US

10-12-2007 American College of Physicians Foundation White Paper key findings

- Inadequate understanding of Rx instructions & warnings is prevalent and important safety concern
- Lack of universal standards for labeling is root cause of medication error
- Evidence-based practices should guide label content & format
- Prescription instructions are important for patients and should be clear and concise
- Patient medication information should be an integrated system that extends beyond the container
- Healthcare providers are not communicating adequately to patients
- Research is needed to identify best practices
Changing Prescription Medication Use
Container Instructions to Improve
Health Literacy & Medication Safety

10-12-2007 IOM Roundtable on Health Literacy Workshop

- 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 warning*
- Workshop convened to address how prescription labels affect patient safety and how to address identified problems

*Michael Wolf
Standardizing Medication Labels: Confusing Patients Less

2008 IOM report on 10-2007 Workshop

- ACP White Paper, research, expert opinions, and thought leader reactions at the Workshop set the foundation for the report
- Health literacy, public health, regulatory, pharmacy and medical practice, patient advocacy, and standards developers represented
- Focus was on developing patient-centered prescription labels that were clear, simple, unambiguous, comprehensible across literacy levels, and standardized
- Concept of universal medication schedule (UMS) was proposed*

- **USP offered to serve as neutral multidisciplinary convening organization for developing prescription container labeling standards**
- Participants endorsed USP’s offer

*Alastair J. J. Wood
May 18, 2008:

The USP Safe Medication Use Expert Committee authorized creation of 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
USP Expert Panel formed Dec 2008

- Co-chair Gerald McEvoy, Pharm.D.
- 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)
Lack of universal standards for labeling

- **December 2008** - Formation of original USP Health Literacy and Prescription Container Labeling Ad-hoc Advisory Panel
- **January 2011** – proposed General Chapter <17> *Prescription Container Labeling* appeared in *Pharmacopeial Forum* 37(1) [Jan-Feb 2011]
- **February 2011** - Formation of USP Prescription Container Labeling Expert Panel (Formerly: Health Literacy and Prescription Container Labeling Advisory Panel)
- **October 2011-February 2012** – Review of public comments and draft revisions by the Expert Panel
- **February 2012** - Revision of GC<17> presented to NSL EC for approval
- **May 2012 through May 1, 2013**: Communication, Education Programs
- **June 2012**: NSL EC ballots on General Chapter <17> *Prescription Container Labeling*
- **November 2012**: General Chapter <17> was published in *USP 36-NF 31*
- **May 2013**: General Chapter <17> becomes official
- **2014**: Revisions proposed for visual impairment and patient-centered dosing
Lack of universal standards for labeling

- Organize the prescription in a patient-centered manner
- Emphasize instructions and other information important to patients
- Improve readability
- Optimize typography
- Optimize white space
- Simplify language
- Use explicit text to distinguish dose/interval instructions
- Address limited English proficiency
- Include purpose for use
- Limit auxiliary information to what is essential and evidence-based
- Address visual impairment
### Which interpretation is right?

<table>
<thead>
<tr>
<th>Prescription</th>
<th>Examples of Pharmacy “Sig” Interpretations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lipitor 10 mg tablets</strong></td>
<td>“Take one tablet daily.”</td>
</tr>
<tr>
<td>Take one tab QD</td>
<td>“Take 1 tablet by mouth for high cholesterol.”</td>
</tr>
<tr>
<td>Dispense #30</td>
<td>“Take one (1) tablet(s) by mouth once a day.”</td>
</tr>
<tr>
<td>No refills</td>
<td>“Take one tablet orally every day for high cholesterol.”</td>
</tr>
<tr>
<td><strong>Fosamax 5 mg tabs</strong></td>
<td>“Take 1 tablet orally daily.”</td>
</tr>
<tr>
<td>Take one tablet QD</td>
<td>“Take one tablet by mouth every day for osteoporosis prevention. Do not lie down for at least 30 minutes after taking.”</td>
</tr>
<tr>
<td>Dispense #30</td>
<td>“Take 1 tablet every day, 30 minutes before breakfast with a glass of water. Do not lie down.”</td>
</tr>
<tr>
<td>Do not lie down for at</td>
<td>“Take one tablet every day.”</td>
</tr>
<tr>
<td>least 30 min</td>
<td></td>
</tr>
<tr>
<td><strong>Indication:</strong></td>
<td></td>
</tr>
<tr>
<td>for high cholesterol</td>
<td></td>
</tr>
<tr>
<td><strong>Indication:</strong></td>
<td></td>
</tr>
<tr>
<td>Osteoporosis prevention</td>
<td></td>
</tr>
</tbody>
</table>
Joanne I have removed the last example and added an "oral" example for each one.

Donna Bohannon, 9/22/2014
Standardization of Prescription Container Information

PRESENT
General Chapter <17> Prescription Container Labeling

published November 2012

official May 2013

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

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
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 specific time periods each day such as
- Morning
- Noon
- Evening
- Bedtime

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
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.

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
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 (specially the ones with low literacy), pay little attention to auxiliary information.
Labels should be designed and formatted so they are easy to read.

Minimize the need to turn the container in order to read lines of text.

Never truncate or abbreviate critical information.

Reserve highlighting, bolding, and other typographical cues to preserve readability.

Limit the number of colors used for highlighting (e.g., no more than one or two).

Use separate lines to distinguish when each dose should be taken.
Optimize Typography

- High-contrast print (e.g., black print on white background)
- Simple, uncondensed familiar fonts with sufficient space within letters and between letters (e.g., Times Roman or Arial)
- Sentence case (i.e., punctuated like a sentence in English: initial capital followed by lower-case words except proper nouns with capital first letter)
- Large font size (e.g., minimum 12-point Times Roman or 11-point Arial) for critical information
- 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
Standards Adoption

• Prescription label standards are regulated by states
  – States would need to enforce USP standard
  – Standards of practice also can apply when state regulations do not specifically endorse or preclude
• California was first state to require patient-centered labels in 2011
• National Association of Boards of Pharmacy (NABP) adopted USP prescription container standard in 2012 resolution encouraging individual states to adopt
• Utah and New York have adopted some supportive language
• Some national chains have pre-empted state adoption to the extent permitted
• Institute for Safe Medication Practice (ISMP), NCPDP, and other groups have supported
Standardization of Prescription Container Information

FUTURE
Address June 2014 US Access Board best practices for making prescription container label information accessible to visually impaired patients

Address standardized patient-centered instructions such as the universal medication schedule (UMS)
Visual Impairment

• Follow patient-centered prescription container label standards

• Provide alternative access to label information such as tactile (braille), audible, and 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
Schedule medication-taking into 4 standardized time periods (e.g., morning, noon, evening, bedtime)

- Particularly useful for simplifying daily medication regimens that include multiple oral therapies
An Enhanced Label with “UMS”
RCT in 11 FQHCs.
429 pts w DM and/or HTN.
Average 5 meds
Mean age 52, 28% W,
39% low literacy

<table>
<thead>
<tr>
<th></th>
<th>Standard Label</th>
<th>PC Label</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Understanding</strong></td>
<td>59%</td>
<td>74%</td>
</tr>
<tr>
<td><strong>Adherence</strong> (3 months)</td>
<td>30%</td>
<td>49%</td>
</tr>
</tbody>
</table>

State Board of Pharmacy in CA passed legislation for this label
NCPDP Acetaminophen Label Best Practices

- Complete spelling of active ingredients in acetaminophen-containing prescription medicines in addition to brand name
- Adopt one standard concomitant use and liver warning that aligns with OTC acetaminophen warnings on Drug Facts labels
- Prioritize standard warning label to print in top 3 warning labels to increase probability of routine inclusion on container
- Support introduction of evidence-based icons that improve consumer and patient understanding beyond explicit text alone
- Employ general health literacy and plain language principles on warning labels that are patient-centered and promote readability and understanding
NCPDP Acetaminophen Label Best Practices

Adopt one standard warning label for all acetaminophen-containing prescription medicines.
Standardize prioritization of print sequence to print among the top three pharmacy warning labels.

Always completely spell “acetaminophen” and all other active ingredients on the prescription label.
No abbreviation, acronym or truncated version of any active ingredient should be permitted on a prescription label.

Eliminate use of “APAP”
Adoption of NCPDP Acetaminophen Best Practices

Almost 90% of US pharmacies have adopted NCPDP recommendations and provide full spell-out for 2-ingredient combos

- Major national pharmacies have implemented (e.g., RiteAid, Walgreens, CVS, WalMart, Target, Costco, K-Mart, Safeway, Publix, Giant Eagle)
- Pharmacy software vendors (e.g., McKesson, QS1, PDX, Rx30) serving independents have implemented

APAP abbreviation eliminated from databases of all major publishers (FDB, Wolters Kluwer, Gold Standard)

Standardized acetaminophen warning label is printed in top 3 labels for 98% of prescriptions
NCPDP Standardized Oral Liquid Dosing

- Use mL as standard unit of measure
  - Discontinue usage of household units of measure (e.g., tsp)
  - Convert dosing instructions to mL when non-standard units are prescribed (e.g., mg, tsp)
- Always use leading zeros before decimal point and never use trailing zeros
- Provide dosing device with numeric graduations that correspond to labeled dose
- Educate patients and caregivers
- Educate pharmacy staff about importance of using mL as unit of measure for all oral liquids
NCPDP Standardized Oral Liquid Dosing

- Widespread support by professional practice groups, CDC, FDA, USP, and others
- Widespread national press coverage
- Pharmacy database producers are facilitating easy adoption (e.g., conversion of household units to mL)
- Several chain pharmacies already have endorsed (e.g., Walgreens, WalMart, Kroger, Publix)
- Communication with other pharmacy CEOs under way
- Schools of Pharmacy are being asked to advocate the recommendations

### NCPDP Universal Medication Schedule

#### Figure 1. Examples of Patients Dosing a 7-drug regimen.

<table>
<thead>
<tr>
<th>Hour</th>
<th>UMS* Regimen</th>
<th>Patient #1</th>
<th>Patient #2</th>
<th>Patient #3</th>
<th>Patient #4</th>
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<td><img src="image" alt="Drug C" /></td>
<td><img src="image" alt="Drug D" /></td>
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<td>6:00 AM</td>
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<td><img src="image" alt="Drug F" /></td>
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<td><img src="image" alt="Drug I" /></td>
<td><img src="image" alt="Drug J" /></td>
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<td><img src="image" alt="Drug O" /></td>
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<td><img src="image" alt="Drug Q" /></td>
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<td>10:00 AM</td>
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<td><img src="image" alt="Drug S" /></td>
<td><img src="image" alt="Drug T" /></td>
<td><img src="image" alt="Drug U" /></td>
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<tr>
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<td><img src="image" alt="Drug Y" /></td>
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<td>5:00 PM</td>
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<td><img src="image" alt="Drug N" /></td>
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<tr>
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<td>Doses</td>
<td>4</td>
<td>8</td>
<td>10</td>
<td>12</td>
</tr>
</tbody>
</table>

*Legend:*
- Drug A
- Drug B
- Drug C
- Drug D
- Drug E
- Drug F
- Drug G
NCPDP Universal Medication Schedule

April 2013 White Paper advocates industry adoption of UMS
NCPDP recommends UMS as a best practice for simplifying medication instructions for patients and their caregivers and thus potentially improving care and outcomes
Prescribers and dispensers are highly encouraged to begin incorporating UMS into their practices
Industry transition to NCPDP’s SCRIPT version 10.6 standard for e-prescribing will facilitate implementation

UMS potential benefits include:
- Increased consistent patient understanding of & adherence to medication regimens
- Simplification of dosing regimens when multiple medications are taken
- Standardization of dosing regimens likely will enhance pharmacist and prescriber productivity, accuracy, and workflow efficiencies
- Simply translation to other regimens because of English standardization