

Adopting a Patient-Centered Prescription Label in Wisconsin

Implementation Guide



Funding is provided by the Advancing a Healthier Wisconsin endowment of the Medical College of Wisconsin



A division of Wisconsin Literacy, Inc.

Why this Project?

The need for patient-centered labels:

In the U.S., there are 3.6 million hospital visits, 700,000 emergency room visits, and 117,000 hospitalizations annually due to injuries related to adverse drug events from medication misuse^[1, 2]. While prescription medication labels provide a potentially critical line of defense against medication errors and adverse drug events, current labels can employ complex language, provide unclear administration times, use small font sizes, and feature confusing layouts^[3, 4, 5, 6, 7]. Prescription labels are especially confusing for persons with limited health literacy, but a study suggests 46% of patients across all literacy levels misunderstood at least one medication dosage instruction^[7].

Currently, there are no mandated national uniform standards for prescription medication labels, even though existing evidence shows that patient-centered prescription medication labels improve understanding of medication instructions^[8, 9, 10]. With this in mind, Wisconsin Health Literacy undertook this project to revise and implement prescription medication labels so they are patient-centered using the United States Pharmacopeia (USP) Chapter 17 Standards.

To other pharmacists contemplating joining the project, “Why wouldn’t you? As pharmacists we all want our patients to have the best outcome they possibly can, so to me, why wouldn’t you take the time to revisit what your label looks like and to evaluate if your family members, your friends, would be able to understand what’s on there.”

*Melissa Ngo, PharmD, BCACP,
UW Health Pharmacy Services*



Brief Background - 3 Phases -

Improved Adherence:

The opportunity to assess the Medication Possession Ratio (MPR) in Phase 2 of this project presented itself with Hayat Pharmacy patients who are members of the Children's Community Health Plan (an all-Medicaid plan). The MPR was calculated before and after the label change and results revealed that the average MPR significantly improved for asthma medicines, blood pressure medicines, and birth control pills after the label redesign ($p < 0.001$)

This project began in 2014 with the first of 3 phases:

Phase 1

Funded by the Wisconsin Partnership Program at the University of Wisconsin-Madison, Wisconsin Health Literacy (WHL) explored the barriers and facilitators to implementing the USP Chapter 17 standards in Wisconsin. WHL staff interviewed pharmacists, pharmacy managers, physicians and pharmacy software vendors in Wisconsin to determine if implementing the USP standards would be feasible. The findings from these interviews were encouraging. Although many interviewees were unaware of the USP standards, most were interested in implementing them after learning about them.

The results led to the next phase of the project and were published in a White Paper, 'Adopting an Easy-to-Read Medication Label in Wisconsin'.

Phase 2

The second phase began in 2016 and involved a two-year pilot project working with a select group of pharmacies to implement new labels using the USP Chapter 17 Standards: Hayat Pharmacy, a community pharmacy in Milwaukee that serves English language learners and low income residents in its city; Hometown Pharmacy that serves patients in southern and eastern parts of Wisconsin; and UW Health Pharmacy Services, a university health system in south central Wisconsin. Due to ownership changes with some of hometown pharmacies, two additional pharmacies were formed, Forward Pharmacy and Fitchburg Family Pharmacy, and joined the project. By the end of phase two, 5 pharmacy organizations with approximately 67 pharmacies had redesigned their labels. Together they dispense 1.8 million prescriptions annually. WHL staff worked directly with pharmacists and their vendors to redesign the labels. WHL collaborated with the Medical College of Wisconsin with funding provided by the College's Advancing a Healthier Wisconsin Endowment.

Phase 3

The third phase began in January 2018 and will conclude in December 2020. This phase expands Phase 2 and will work with partner pharmacies across the state of Wisconsin to implement patient-centered labels using the USP Chapter 17 Standards. Due to the high number of anticipated pharmacies in this project, pharmacy staff will be responsible for redesigning their own labels, rather than WHL. This Implementation Guide will provide the step-by-step directions. Phase 3 is also funded by the Advancing a Healthier Wisconsin endowment from the Medical College of Wisconsin.



Now that you know the “why” behind redesigning patient-centered labels, the following steps will be helpful in redesigning your labels.

1. Schedule Initial Consultation with Wisconsin Health Literacy

Pharmacy staff who will likely be involved in the project will meet with Kari LaScala or Stan Hudson of Wisconsin Health Literacy to discuss the project details and what to expect moving forward. In preparation for this meeting, please do the following:

- Read the [Pharmacy Society of Wisconsin Journal article](#) that summarizes the earlier phases of this project and provides an overview of what to expect in this phase.
- Complete the [Pharmacy Information Sheet](#).
- Scan and email a copy of your current label to: kari@wisconsinliteracy.org

“Patients liked the new labels - having their name on top. They liked the bigger font. After starting the new labels, we had dramatically fewer callbacks from patients who got home, looked at the bottle, and had questions on what something means.”

*Matt Mabie, pharmacist, RPh,
Owner of Forward Pharmacy*

Steps to Implementing Patient- Centered Labels



2. Understand the Elements of a Patient-Centered Label

After meeting with WHL, review the following information to better understand the importance of - and the elements of - a patient-centered label.

1. Review the **USP Chapter 17 Standards**. This specifies what should be included (and excluded) on the label, where information should be positioned on the label, and the rationale behind the standards.
2. Review the **sample USP-compliant label templates created by WHL**. There is more than 1 way to redesign prescription labels, and this template contains different samples that are all USP-compliant.

Note: the patient's name, directions for use, and drug name/strength are in the same order in each of these labels. Although the USP Chapter 17 standards do not state that the directions for use be placed above the drug name/strength, WHL met with patient groups and this was their preference. It may be something to consider when you redesign your labels.

3. Review the tested, standardized **Universal Medication Schedule sig list for pills**. Embedded in the USP Chapter 17 standards is information about employing best practices for directions for use. One such method involves using the Universal Medication Schedule (UMS) for daily-use, solid dose-forms of medication. These 15 sigs used in the [study](#) have been tested and have shown better patient understanding.
 - Review this [study](#) about expanding the UMS beyond daily-use, solid dose forms of medication and for information on how best to write fractions.

USP Standards In A Nutshell

1. Emphasize instructions and other information important to patients; place less critical information away from dosing instructions.
 - a. Patient's name, drug, directions at the top
 - b. Directions in simple language
 - c. Sentence case
2. Improve readability – designed/formatted to be easy to read
 - a. Contrast
 - b. White space
 - c. Large type
 - d. Simple fonts
3. Give explicit directions
 - a. Numerals spelled out (2, not “two”)
 - b. Separate dose and timing
 - c. Do not write “take as directed” or “take twice daily”
 - d. Liquids – provide dosing device
4. Include purpose for use in plain language
 - a. If included on prescription and acceptable to patient
5. Address limited English proficiency
6. Address visual impairment

3. Engage Key Stakeholders

- 1. Establish your redesign team.** To ensure a successful redesign, it is important to determine who (and how many staff members) will be responsible for overseeing the changes to your prescription label. Assign people who are familiar with, or who are interested in becoming familiar with the USP Chapter 17 Standards. Student pharmacy interns could also be considered.

Since your organization will be designing your own labels, it may be helpful to involve someone with experience using Photoshop, Microsoft Publisher, or another type of design software.

Include a representative from your software vendor, or at a minimum, identify a vendor liaison whom you will stay in contact with during the redesign.

- 2. Educate staff on the importance of patient-centered labels.** Have your staff review the [Pharmacy Toolkit](#). This has been created to help your staff better understand the project and the “why” behind the importance of patient-centered labels.
 - Establish a process for review of the toolkit to be included in all new employee orientation.

4. Strategize the Implementation Process

- 1. Determine the timeline for implementing the standards.** Set a goal for when you would like to have the redesign completed by. This will help you keep on track.
- 2. Review your label stock.** If you need to make changes to your label stock, such as changing the location of the logo or changing accent colors, this may affect your timeline; it can take several weeks to receive the new label stock once it has been ordered.
 - If you make label stock changes, consider using up your current label stock first to avoid wasting it, or if you are a multi-pharmacy organization, consider having 1 pharmacy use the remaining label stock while getting started on the label redesign and implementing it at other pharmacy sites.
 - WHL can offer funds to help purchase label stock (subject to availability of funds in the WHL grant and depending on number of other organizations previously requesting funding support.)
 - Are you able to buy label stock that is larger in size? Many pharmacies are unable to do this because it would then become necessary to purchase larger bottles. However, this may work well for other types of prescriptions that don't use bottles, such as bubble packed wrap.



3. Collaborate with your software vendor when redesigning the labels. Involving your software vendor in the label redesign process is critical. Explain to them how you would like to redesign your labels and work with them in doing so. The process will be different for pharmacies depending on the vendor, location, relationship with the individual pharmacy, and software modification services available at the pharmacy itself.

- Some vendors will want you to send them a copy of your current label, as well as a design template of your proposed new label and can then work with you to implement those changes.
- Some pharmacies are able to make label changes on their own, while others must work with a remote vendor for all label changes.
 - Software issues can sometimes present barriers to USP-compliant prescription labels, especially as it relates to sigs. For example, the software you use may only write information in ALL CAPS, or it may spell out a numeral, instead of just using the numeral (i.e., “two” instead of “2”.) Talk with your software vendor to see if they can offer solutions to help in this regard. What may seem impossible can sometimes be possible if asked.

4. Be sure to include any necessary state and federal regulations and warnings. Here are the applicable statutes:

[WI Chapter Phar 7](#) | [WI Chapter Phar 8](#) | [WI Chapter 450](#) |
[Federal Requirements](#)

5. Communicate With Wisconsin Health Literacy Prior To Going Live With Your Label.

1. Email a copy of your new label to Wisconsin Health Literacy for review and suggestions to further enhance patient understanding.

- *This is an imperative step to validating that your labels are USP-compliant.*
- We understand that there are some software limitations as it relates to the sig. The newly redesigned label may therefore be a work in progress. If so, be open to making further modifications to your label as software technology evolves.

2. Congrats! You should be proud of your redesigned labels. Share this information with your patients. Announce the new labels to patients through newsletters, bag stuffers, etc.



6. Plan for Project Evaluation/Surveys

- **Patient Surveys:** Approximately 6 months after your new labels have been implemented, WHL will ask your assistance in distributing surveys to a small number of your patients to seek feedback on the label redesign. WHL will work with you to help make this as easy and seamless as possible for you and your staff, including providing a printed survey and outlining the number of responses requested.
- **Pharmacy and staff surveys:** WHL will also seek the feedback from pharmacists and other staff members with short survey questions approximately a year after implementation.

“It’s important to make labels easier to understand. The number one reason patients don’t take their medicines properly is because they are not understanding the label. If we can improve that, we can improve adherence.”

*Hashim Zaibak, pharmacist,
owner of Hayat Pharmacy*



Final Thoughts

Communication

The best partnerships are those with open communication. Kari LaScala will stay in touch with you regularly throughout the project, but feel free to reach her or Stan Hudson with any questions or concerns at any point. Their contact information is below.

Speak With a Colleague

If you would like to speak with a pharmacist that has already gone through the label redesign process, please contact us. We would be happy to get you in touch with a prior pharmacy partner. We understand how helpful it can be to discuss any concerns or questions you may have with other pharmacists.

Sustainability

The USP periodically updates the USP Chapter 17 Standards. Be sure to consult the standards prior to any future changes you may make to your label.

Publicly Recognizing Your Pharmacy

Congrats - your pharmacy is now on the leading edge of best pharmacy practices! We want to recognize all project pharmacies that have redesigned labels that are USP-compliant. A list of participating pharmacies and their logos will be on the WHL website, and will be shared in electronic and print newsletters, at conferences, and other appropriate channels throughout the project and beyond. The Pharmacy Society of Wisconsin (PSW) will also help recognize such pharmacies through its weekly Fast-Facts e-newsletter and other promotions.

Please Contact Us With Any Questions

Kari LaScala

Associate Director
Wisconsin Health Literacy
kari@wisconsinliteracy.org
608-257-1655, ext. 5

Caitlyn Mowatt

Health Communication Specialist
Wisconsin Health Literacy
caitlyn@wisconsinliteracy.org
608-257-1655, ext 6

Stan Hudson

Health Literacy Director
Wisconsin Health Literacy
stan@wisconsinliteracy.org
608-257-1655, ext. 2

Michele Erikson

Executive Director
Wisconsin Literacy, Inc.
michele@wisconsinliteracy.org
608-257-1655, ext. 1

*Thank you
for partnering with
us on this important
project to redesign
prescription
labels!*



References

- [1] Wolf, Michael. A Better Prescription...Improving Health Literacy for All Patients. Plenary Presentation, 2015 Wisconsin Health Literacy Summit, Madison, WI, April 14-15, 2015.
- [2] Zhan C, Arispe I, Kelley E, Ding T, Burt C, Shinogle J, Stryer D. 2005. Ambulatory care visits for treating adverse drug effects in the United States, 1995-2001. *Jt Comm J Qual Patient Saf* 31: 372-378.
- [3] Berkman N, Sheridan S, Donahue K, Halpern D, Crotty K. July 2011. *Ann Intern Med* 155(2): 97-107.
- [4] ACPF (American College of Physicians Foundation). 2007. Improving prescription drug container labeling in the United States: A health literacy and medication safety initiative. Washington, D.C.: ACPF.
- [5] Institute of Medicine of the National Academies. 2008. Standardizing Medication Labels: Confusing Patients Less. The National Academies Press, Washington, D.C.
- [6] Budnitz D, Pollack D, Weidenback K, Mendelsohn A, Schroeder T, and Annet J. 2006. National surveillance of emergency department visits for outpatient adverse drug events. *JAMA* 296: 1858-1866.
- [7] Wolf M, Davis T, Bass P, Tilson H, Parker R. 2006 b. Misunderstanding prescription drug warning labels among patients with low literacy. *AM J Health System Pharm* 63: 1048-1055.
- [8] Wolf M, Davis T, Curtis L, et. al. A patient-centered prescription drug label to promote appropriate medication use and adherence. *J Gen Intern Med*. 2016:31(12):1482-1489.
- [9] Tai B, Baci Y, LaRue C, Law A. Putting words into action: a simple focused education improves prescription label comprehension and functional health literacy. *J Am Pharm Assoc*. 2016: 56(2): 145-152.
- [10] Trettin K. Implementation of VA patient-centered prescription label and patient medication information. *Procedia Manufacturing*. 2015:3:1-5.



Notes





wisconsin
**health
literacy**

A Division of Wisconsin Literacy, Inc.
211 S. Paterson St. | Suite 170 | Madison, WI 53703
www.WisconsinHealthLiteracy.org
email: HealthLiteracy@WisconsinLiteracy.org