Original Work

Adopting Patient-Centered Prescription Medication Labels in Wisconsin

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Abstract

In 2013, the United States Pharmacopeia introduced new Patient-Centered Prescription Medication Label Standards. In 2014, Wisconsin Health Literacy (WHL) undertook a research project to determine if the standards could be successfully implemented in Wisconsin. Findings showed there was little awareness of the standards, but when they were explained, pharmacists and software vendors were in support of adopting them.

In 2016-2017, WHL, in collaboration with an academic faculty partner from the Medical College of Wisconsin, completed a second phase of the project, working with 5 pilot pharmacy organizations to implement new labels based on the USP standards at 64 locations dispensing approximately 1.8 million prescriptions annually.

Project Advisory and Patient Advisory Councils were formed to provide input for the project. Participating pharmacies worked with a WHL consultant to design new labels. Each pharmacy organization followed a different redesign process based on organizational structure and pharmacy software vendor.

The new labels were well received by pharmacy managers, pharmacy staff and patients, based on surveys completed by over 500 patients and 92 pharmacists at participating organizations. Analysis of one organization's prescription fill data showed improved adherence in 3 drug classifications after implementation of the new labels.

Phase 3 began in January 2018, with a goal of expanding patient-centered labels to additional pharmacies across the state.

When Hayat Pharmacy owner Hashim Zaibak, PharmD, thinks about patient-centered prescription medication labels, one patient sticks in his mind.

"I was going over all her medications after she was released from the hospital," Zaibak said. "I asked her to show me how she used her Spiriva. The directions said, 'Inhale the contents of one capsule once a day.' She put the capsule in the inhaler. Then she inhaled but she never pierced the capsule. She was just getting plain air. Even though I thought the directions were clear, she was not taking the medicine properly."

This patient is not alone in her confusion. In one study, 3 in 5 persons with low health literacy incorrectly demonstrated use of a medication with instructions "take two tablets by mouth twice daily." Even for those with adequate health literacy, 1 in 5 made mistakes.[1]

Communicating effectively about medications has long been a top priority for Wisconsin Health Literacy (WHL), a division of statewide nonprofit Wisconsin Literacy, Inc., located in Madison, WI. WHL's mission is to improve communication between those who give and those who receive health communications. Patient misunderstanding about medication use has a high risk for adverse drug events. With existing evidence that patient-centered prescription medication labels improve understanding of medication instructions,[2] WHL conducted a project to revise and implement prescription medication labels to conform to United States Pharmacopeia (USP) patient-centered medication label standards.[3]

Background

Patient-Centered Labels Make a Difference

The project began with evidence that patient-centered labels are effective. Multiple studies have shown positive results, especially for patients with limited health literacy and more complicated medication regimens:

- A 2016 study reported redesign of patient-centered labels improved both medication adherence and when the medication was taken. The effect was stronger among patients with limited literacy and more complex drug regimens.[2]
- Another 2016 study reported label redesign improved the comprehension and functional health literacy of older adults taking more than 2 prescription medications daily.[4]
- In 2011 the V.A. National Center for Patient Safety tested an evidence-based prescription label, finding it was preferred and improved comprehension in Veteran patients.[5]

USP Standards

The path toward creating more patient-centered medication label standards nationally began in 2007, when the American College of Physicians Foundation issued a whitepaper, "Improving Prescription Drug Container Labeling in the United States."[6] The groundbreaking whitepaper reinforced the idea that the prescription label is the most tangible source of information about prescribed drugs and how to take them, and that the label is a crucial line of defense against medication errors and adverse drug events.

The following year, the USP appointed a Health Literacy and Prescription Container Labeling Advisory Panel to develop prescription labeling standards. After extensive study, the USP developed a set of standards for patient-centered medication labeling as General Chapter 17 in USP's National Formulary.[3] The standards became official in April 2013 (Figure 1).

A few years prior, in 2011, California became the first state to adopt its own standards to make labels easier to read. The standards included increasing font size and dedicating 50% of the label space to information intended for the patient. In 2013, prior to announcement of the USP Standards, the State of New York adopted supportive language for patient-centered labels.[7] Late in 2013, Utah became the first and only state to formally adopt the USP standards when its Board of Pharmacy adopted rules that it was "unprofessional conduct" for a pharmacy or pharmacist to fail to comply with USP Chapter 17 standards.[8] After much confusion from pharmacists on what was mandatory and what was optional related to the label rules, the Utah Board of Pharmacy made a decision to encourage use of the USP standards as a guide to help prevent medication misuse and not to enforce the standards.[9]

The USP has since made revisions to the standards in 2016 and 2017, and is now working on another update.

Theory of Systems Change and Voluntary Approach

This project and its continued expansion is based on Rogers' Diffusion of Innovations Theory. The theory describes the adoption of an innovation as following a pattern over time, gaining momentum and spreading as different groups adopt that innovation.[10] The first phase of the project sought input from key pharmacy stakeholders regarding factors (i.e., attributes of the innovation) which could influence the adoption of patient-centered labels. Based on the interviews with pharmacy stakeholders, experiences of other states adopting patient-centered labels, and the advice of Pharmacy Society of Wisconsin and other key Wisconsin stakeholders, WHL decided to pursue a voluntary—not regulatory—approach to pharmacy redesign of labels and implementation. WHL staff believed the voluntary approach would be more successful to get the adoption process started. The pharmacies that implemented the USP standards in phase 2 of the project are serving as "innovators," the first group to adopt an innovation under the Diffusion of Innovations Theory. The pharmacies who participate in phase 3 of the project will serve as the second group—or "early adopters" – under the theory. The project team anticipates that phase 3 will propel adoption of patient-centered medication labels to the tipping point when adoption becomes the norm for good customer-focused pharmacy practice in Wisconsin. While the focus of this project is the State of Wisconsin, it is anticipated that adoption of the USP standards may well extend to other states, as evidenced by interest already expressed. Wisconsin Health Literacy will provide printed and web resources to help pharmacies outside the scope of the Wisconsin project.

FIGURE 1. USP Standards in Brief

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

Three Phase Project to Implement Patient-Centered Labels

Phase 1

The first of three phases in the project began in 2014 shortly after the USP standards were released. With grant funding from the Wisconsin Partnership Program of the University of Wisconsin-Madison, WHL staff interviewed Wisconsin pharmacists, pharmacy managers, physicians and pharmacy software vendors to examine the relative advantage, compatibility, complexity, trialability, and observability of the USP standards (patient-centered labels). These interviews provided information about facilitators and barriers that could impact the implementation of patient-centered labels in Wisconsin. Findings indicated that awareness of the standards was low. However, when interviewees learned more about the standards, they overwhelmingly supported implementing them, and felt they would fit into current pharmacy workflow. The results were published in a white paper, "Adopting an Easy-to-Read Medication Label in Wisconsin,"[11] and led directly into the second phase of the project.

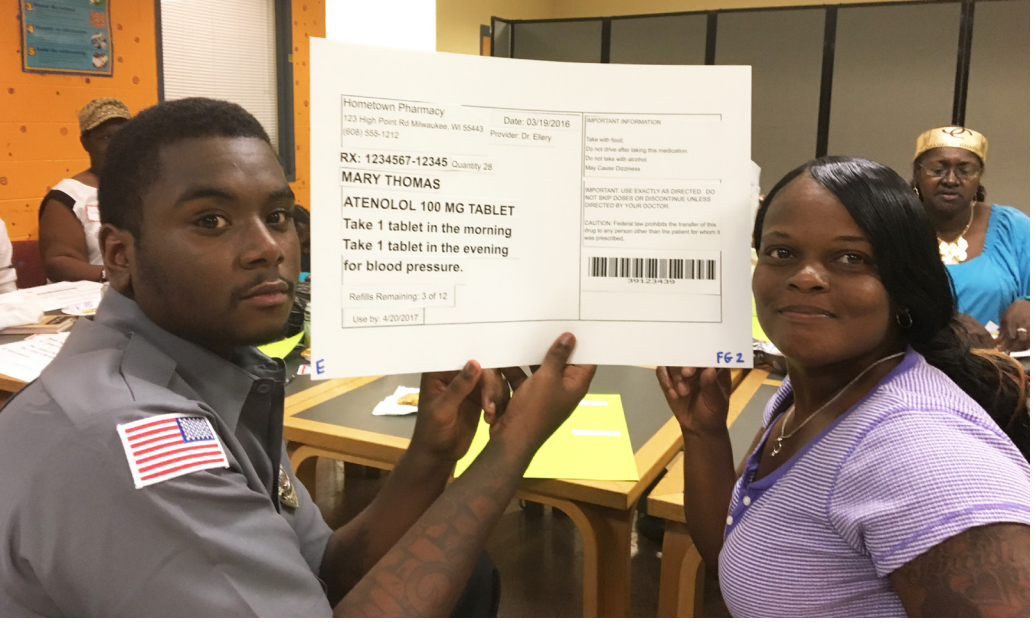


FIGURE 2. Focus Group Participants Show Their Preferred Label Design (above)

Phase 2

The second phase began in 2016 in collaboration with academic partner Kenneth Schellhase, MD, at the Medical College of Wisconsin Department of Family and Community Medicine. Phase 2 was a two-year project to implement the standards in pilot pharmacies. The Institutional Review Board of the Medical College of Wisconsin approved the project. The Advancing a Healthier Wisconsin endowment of the Medical College of Wisconsin provided grant funding.

Phase 2 had five main components: 1) solicit stakeholder input; 2) recruit and engage pharmacy organizations; 3) revise medication labels; 4) implement revised labels and 5) evaluate stakeholder response.

Stakeholder Input

Wisconsin Health Literacy staff recruited a 17-member Project Advisory Council and 11-member Patient Advisory Council, conducted an email/internet survey of members of the Pharmacy Society of Wisconsin (PSW), coordinated patient semi-structured interviews and focus groups, and implemented a general public internet survey to obtain input about various aspects of the project.

The Project Advisory Council included representatives from PSW, Medical College of Wisconsin, Epic Systems, USP, University of Wisconsin-Madison School of Pharmacy, a purposeful sample of pharmacists and Dr. Michael Wolf, nationally recognized medication label researcher. The group met quarterly to receive updates and to provide advice and recommendations to advance the project.

The Patient Advisory Council was recruited with advice from the Wisconsin Network for Research Support, whose staff has expertise in forming and operating advisory groups.[12] A purposeful sample of participants was recruited with a diversity of age, race, geographic location, health status and literacy levels. The group met quarterly to review materials and project activities to ensure they were clear and understandable by patients of all literacy levels.

The email/internet survey of PSW members included topics such as awareness of USP Patient-Centered Medication Label Standards, attitudes toward adoption of the standards, and barriers to adoption.

Wisconsin Health Literacy staff conducted two individual semi-structured interviews and two focus groups of adults representing "patients." A convenience sample of participants for the focus groups was recruited through a community center in Milwaukee, Wisconsin, which serves low literacy adults. The purpose was to discover what patients like and don't like about labels. In a group exercise, WHL staff cut apart the different elements on a typical medication label and asked the participants to design their own labels (Figure 2). The project's Patient Advisory Council was asked to go through the same exercise. The experience proved to be very enlightening and formed the basis for many of the format changes made by the pilot pharmacies. Feedback was consistent from the focus groups, individual interviews, and the Patient Advisory Council.

Wisconsin Health Literacy also developed an internet survey called "Vote for Your Favorite Label" to gain insight into patient label preferences. Through social media, the public was invited to select which of two labels they preferred and what they liked or didn't like about each (Figure 3). They also answered a few label questions and had the opportunity to write about a medication label experience.

The advice, recommendations, surveys and focus group information had substantial impact on the conduct of the project.

Participating Pharmacies

Three pharmacy organizations were recruited through personal contacts by project team members.

1. Hayat Pharmacy had 10 sites located mostly in low income areas in Milwaukee, WI.
2. UW Health Pharmacy Services had 14 locations in and around Madison.
3. Hometown Pharmacy had 44 sites in southern and eastern Wisconsin.

The three pharmacy organizations were very different. Each used different pharmacy software vendors (Rx30, EnterpriseRx-McKesson, and PioneerRx), resulting in different processes for label change. Some pharmacies wanted to implement new labels at all sites at one time, while others chose to do one site at a time. Some pharmacies wanted to use up old label stock while others were willing to design something new. This diversity enriched the project by providing different routes to the same goal of redesigning labels.

The only out-of-pocket cost for changing labels was purchasing new label stock for pharmacies opting to do this. Funds through the grant from the Advancing a Healthier Wisconsin endowment provided financial assistance for those who made this choice. The pharmacy staff time commitment varied greatly, depending on the pharmacy organization.

The number of pharmacy sites involved in the project changed during the project. Hayat added two new locations. The ownership of several of the Hometown pharmacies changed as two new additional organizations were formed, Forward Pharmacy and Fitchburg Family Pharmacy. By the end of the project the number of participating organizations increased from

three to five, with 64 sites implementing new labels. Nine sites have not yet changed labels: seven in one organization where printers would not accommodate the newly designed larger labels, and two in another organization where it plans to use up old label stock before starting the new labels.

Leaders from all participating pharmacies said that they agreed to participate in the project because it was the right thing to do.

Melissa Ngo, PharmD, BCACP, Manager of Community Pharmacy Services, UW Health Pharmacy Services, said, "We knew this was something really important. We hadn't looked at our prescription labels in the last decade to address whether patients could understand them. This was a good way to get the label updated, make sure people understand how to take their medication and hopefully have better outcomes as a result."

Hashim Zaibak, PharmD, owner of Hayat Pharmacy agreed. "The number one reason patients don't take their medicines properly is that they're not understanding the label. If we can improve that, we can improve adherence, people taking their medications properly and, in the end, help make them healthier people."

Matt Mabie, RPh, previous co-owner of Hometown Pharmacy and current owner of Forward Pharmacy had similar thoughts. "Our motto at Hometown was 'Our family caring for your family.' We didn't want barriers to patients understanding their label. Any time there are improvements, we're going to jump on that to make the experience better for patients."

Communication and Engagement

From the outset, WHL staff identified individuals and groups that should be informed of project updates. A quarterly e-newsletter was developed and distributed to pharmacy opinion leaders in the state and nationwide. Representatives from the Project Advisory Council gave an informational presentation to the Wisconsin Pharmacy Examining Board, which expressed interest in ongoing communication. Wisconsin Health Literacy staff also contacted key leaders at Walgreens, Roundy's, CVS and Walmart to make sure they were aware of the project.

Regular communication with the participating pharmacies and other key pharmacy stakeholders also was important. The Phase 2 pharmacies were "innovators," and able to be nimble, flexible and make quick decisions. Wisconsin Health Literacy recognized that it would be more effective to approach larger chains after having gone through the implementation experience with pharmacies that had a greater degree of flexibility to make prompt label and implementation decisions. The results and testimonials from Phase 2 innovators will be key as WHL communicates with potential Phase 3 pharmacy partners.

Results

PSW Survey

Email invitations were sent to 3,879 PSW members, including mostly pharmacists, along with some pharmacy technicians and students. Responses totaled 400 (10.3%). Key results were:

- 59% were not familiar with the USP standards.
- Given an explanation of the standards, 85% favored general adoption.
- 61% said they would like to see the standards adopted in their pharmacy.
- The biggest barrier to adoption of the standards was the perceived lack of space on the label.

Patient Interviews and Focus Groups

The two patient focus groups were comprised of 13 and 11 adults respectively. The first group included 9 women and 4 men, and the second included 9 women and 2 men. Participants were of mixed ages

FIGURE 3. Favorite Label Comparison



TABLE 1. What Patients Like and Don't Like about Prescription Labels

Patients Like	*Patients Don't Like*
Color, bolding, large font	Information only used by pharmacists
White space	Lots of confusing dates
Indication for drug use	Addresses
Most important info at top	Clutter
Name of medicine	Unclear directions (twice daily)
Prescriber name	All capital letters
	Pharmacy info at top

and all African-Americans. An additional two persons (1 man and 1 woman, both African Americans) were interviewed to determine if responses were different. Responses were consistent.

The participants overwhelmingly said the top of the label should include patient name, medication name, and instructions for use, in that order. Less important to them were the prescription number and number of refills. They found multiple dates confusing and were adamant that the label should only include information important to the patient, not information used only by the pharmacist.

Two observations from the focus groups were unexpected and eye-opening. Some of the focus group members with extremely low literacy struggled even to complete the exercise. That led to the realization that making an easier-to-read label was only part of the solution for them. Another interesting finding was a strong and widespread perception that generic drugs were less effective and that pharmacies give them to "poor" customers.

General Public Internet Survey

Nearly 1000 persons voted for which label they preferred, with 12% preferring label A and 88% label B (Figure 3). Of those responding to the survey questions, 88% said they found medication labels confusing and 23% said they had taken a medication wrong because the label was confusing.

One of the most enjoyable—and at the same time frightening—aspects of this project was the collection of stories from people who had found labels confusing. These stories also came through the Favorite Label website survey. Stories such as the following inspired WHL and pharmacy staff alike and reaffirmed the importance of this label initiative.

> *"A woman I knew was rushed to the ER due to an overdose of diabetes medication. She later realized she was taking almost 3 times the recommended dosage because the instructions read, "take up to 3 tablets every 24 hours" and she understood it to be "3 tablets, 3 times a day every 24 hours."*
>
> *"My grandma accidentally took 3 times the daily dose of a medication for about 4 days due to a label that stated, "Take 1 1/2 pill twice daily." She was actually just supposed to take a ½ pill two times a day, but with the "1" on the label before the 1/2, it made it look like she was supposed to take 1.5 pills twice a day."*

The focus groups, the Patient Advisory Group, and the favorite label survey provided a wealth of guidance to create the redesigned labels (Table 1).

Patients and Participating Pharmacy Staff Surveys

The success of the project was measured in part by surveys of patients and pharmacy staff.

Over 500 patient surveys were completed at multiple sites within the three original pharmacy partner organizations. Those surveys found:

- 93% said it was important for medication labels to be easier to understand.
- 83% like the new labels better or the same as the old label (only 13% said they liked the old label better).
- Patients felt the greatest benefits were that the letters were larger, the labels were easy to understand, and important information was easy to find.

A survey of pharmacy staff at the implementing organizations found that among 92 respondents:

- 84% were aware of the change.
- The greatest anticipated impact on patients was better adherence, fewer medication errors, and that patients were more likely to benefit from the medication.

Pilot Pharmacies' Experience

An estimated 1.8 million prescriptions dispensed from 64 sites annually will have easier-to-understand labels because of the collaboration between WHL and Phase 2 pharmacies. Wisconsin Health Literacy worked with each of the pharmacy partners to redesign labels based on the USP standards, feedback from the patient focus groups, analysis of other labels based on the USP standards, and extensive conversations with the pharmacies' software vendors. Wisconsin Health Literacy created an online toolkit to educate pharmacy staff on the standards and to help them explain the label change to patients. Then the pharmacies introduced the new labels at various sites over a 14-month period (Figure 4).

All participating pharmacies agreed that the experience was very positive.

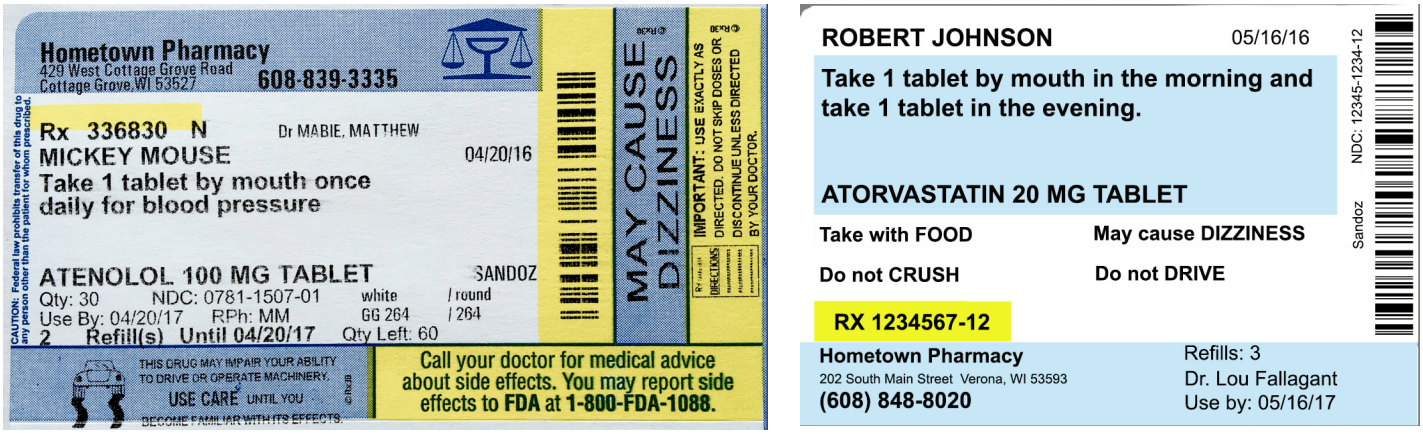
"Patients liked the new labels—having their name on top," said Matt Mabie. "They liked the bigger font. After starting the new labels, we had dramatically fewer callbacks from patients who get home, looked at the bottle and had questions on what something means."

Melissa Ngo said, "Patients like the directions on the top, improved white space, and that the prescription number is close to the pharmacy number. Their one comment was that the medication name didn't stand out, and we've worked on that."

Although all moving toward the same goal, each of the participating pharmacy organizations had a different experience based on organizational structure, previous labels, printers, prescription containers and software vendors. For example, all pharmacy locations at Hayat Pharmacy are located in relatively close proximity with a more uniform organizational structure. Hometown pharmacies, however, are located over a much wider geography and many come from a history of independent ownership with more individual site variations. UW Health pharmacies have a more complex decision-making process, given their position within a large health care system.

Each pharmacy's relationship with their pharmacy software vendor also varied. Some pharmacies could make label changes

FIGURE 4. "Before" (left) and "After" (right) Labels at Hometown Pharmacy



themselves, while others had to work with a remote vendor to make every label change. Some vendors were not able to make the requested changes to comply with all the USP standards. For example, UW Health's vendor was not able to change numbers into numerals within the directions for use, resulting in Melissa Ngo and her team having to change each manually. The varied vendor experience was a great benefit to the project, in that it has better prepared WHL to anticipate potential challenges and solutions with future pharmacy partners and their vendors.

At the end of the project, all pharmacies implementing new labels committed to continue using them.

Medication Adherence

The goal of Phase 2 of the project was implementation of the label and not to prove that patient-centered labels are effective, as this is already well-documented. However, an opportunity presented itself to study adherence by patients before and after receiving new labels. Analysis was done of prescription refill information by Hayat Pharmacy patients who are members of Children's Community Health Plan (an all-Medicaid plan). The average medication possession ratio (MPR) of these de-identified patients was calculated before and after the label change. The average MPR significantly improved after the label change for asthma medicines, anti-hypertensives, and oral contraceptives. Also, there was some evidence that MPRs improved the most for patients with very low MPRs before the label change.

Dissemination

The project included a unique Medication Label Summit, held April 3, 2017. One purpose was to share some of the recent research into patient-centered medication labeling. Another was to provide an opportunity for pharmacists from the pilot organizations to share experiences with other pharmacies who may want to participate in the future. Of 82 attendees emailed a survey after the event, 31 (38%) responded, with these key findings:

- 82% would advocate for improving labels.
- 54% plan to get involved in label redesign where they work.

Conclusions and Next Steps: Phase 3

Phases 1 and 2 resulted in a wealth of information being used to compile an Implementation Guide for new pharmacies implementing patient-centered labels in the future. Some of the most impactful learnings are:

- Pharmacists have an intense desire to help their patients, which is a very strong driver to make the change to patient-centered labels.
- Patient involvement during the project was critical to assure that label changes with the most potential impact were emphasized.
- Every pharmacy is different, requiring flexibility during label redesign and implementation.
- Software vendors need to be involved all along the way. Some "impossible" changes ended up being possible with perseverance.
- Pharmacies should be recognized for their commitment to making labels easier to read.
- Education about the research behind the standards, e.g., the benefit of not using all capital letters, is important to help pharmacists understand and accept the changes.
- Stories are vital to motivating staff. Citing statistics about medication errors is much more effective when also telling stories about patients misunderstanding label instructions and taking medications incorrectly.[13]

Phase 3

Phase 3 began in January 2018 and is focused on leveraging experiences of the pilot pharmacies with the primary goal of expanding patient-centered labels to additional pharmacies across the state of Wisconsin. This phase also is supported by grant funds from the Advancing a Heathier Wisconsin endowment of the Medical College of Wisconsin. Readers interested in learning more about Phase 3 should contact the authors.

As of this writing, three health systems, one small pharmacy network, and one independent pharmacy have committed to working with WHL in phase 3 to improve their labels.

Representatives of the Phase 2 pharmacies have agreed to share their experience with new pharmacies beginning the patient-centered label journey.

In addition to implementing new labels at more pharmacies, WHL is also addressing modifying the "sigs," or directions for use. In Phase 2, there

Interested in working with Wisconsin Health Literacy to implement patient-centered labels in your Wisconsin pharmacy?

- Benefit from free consultation throughout the guided process
- Receive financial assistance available to purchase (optional) new label stock
- Join and connect with an ever-growing number of nationally recognized Wisconsin pharmacies making this change.

To find out more, contact Kari LaScala, Wisconsin Health Literacy, (608) 257-1655, ext. 5, or email kari@wisconsliteracy.org.

was a clear desire among pharmacies to improve the sig, but it is an incredibly complex matter and was beyond the scope of that project. In Phase 3, WHL will bring many stakeholders, including Epic Systems representatives, together in a "Sig Improvement Task Force." The task force's goal will be development of recommendations to help organizations improve their directions for use to meet the USP standards.

In the final year of Phase 3, systems and resources will be put in place so future pharmacies have step-by-step directions for implementing patient-centered labels on their own.

What would those pharmacists who already have adopted the patient-centered labels say to new pharmacies considering redesign?

Hashim Zaibak says it's good for patients and for business. "Helping patients better understand their labels will make them more adherent to their medications, love their pharmacy more and hopefully stay with that pharmacy as customers for a long time."

For Melissa Ngo, the answer is "Why wouldn't you?" She added, "Why wouldn't you take the time to think about what your label looks like and if your family or friends would be able to understand what's on that label."

Relatively small changes on a prescription label can significantly improve patients' effective use of medications. With the introduction of patient-centered labels into more pharmacies, millions more patients can experience safer medication use and better health outcomes. For more information on the project or how you can be part of this expanded effort in Wisconsin at no cost, contact Kari LaScala, Wisconsin Health Literacy, (608) 257-1655, ext. 5, or email kari@wisconsinliteracy.org.

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