

# Adopting Health Literacy Best Practices Through Systems Change to Improve Medication Directions and Adherence

by Bhumi Khambholja, PharmD, MS, Stan Hudson, MA, Michele Erikson, George E. MacKinnon III, PhD, MS, Kenneth G. Schellhase, MD, MPH

**H**ealth literacy can be defined two ways: 1) as the degree to which individuals have the ability to find, understand, and use information and services to inform health-related decisions and actions for themselves and others; and 2) as the degree to which organizations enable individuals to find, understand, and use information and services to make health-related decisions and actions for themselves and others.<sup>1</sup> Although there are certain characteristics that might put a person at higher risk for lower health literacy (such as being older in age, having limited education, having limited English proficiency, or being at a lower income level), it is important to recognize that health literacy is fluid and situational.<sup>2,3</sup> Any person can experience lower health literacy in a specific situation or when under stress or pain. Overall, gaps in health literacy have been associated with decreased secondary prevention, poor health status, and increased hospitalizations and emergency room visits.<sup>3</sup>

Many prescription medication directions require interpretation by patients, and misinterpretation can lead to undertreatment, overtreatment, or poor control of their health conditions. Research has shown that approximately 50% of prescription medication is not taken correctly, resulting in approximately 125,000 deaths, 10% of hospitalizations, and between \$100 billion and \$289 billion in costs annually.<sup>4</sup> Using patient-friendly language and precise instructions during patient education or medication reviews is an important strategy to improve patient understanding of medications. In addition, since patients are often inundated with health information, clear and explicit written medication directions are required. The prescription medication label is often the only source of information patients

have in order to remember how to take their medication correctly and prevent medication-related issues. This is particularly important for chronic disease management and prevention of further complications.

Electronic prescribing greatly improved the readability of prescriptions for pharmacists; however, more focus is needed to improve the ability of patients to correctly understand and act upon medication directions on the label. The use of medical jargon or omission of key information are issues that community pharmacists often encounter and address. The issue also goes deeper than this, as the health literacy issues patients experience are often silent and unknown to healthcare professionals. The meaning of commonly used terms and frequencies in medication directions may not be known to all patients, resulting in medication not being taken at the right time, the right way, or at all. Verbally expressing understanding also does not always correlate to patients demonstrating how to take their medication correctly.<sup>5</sup> Since it is difficult to assess a person's health literacy at a specific point in time, it is important that there are universal

## Abstract

Gaps in communication and misinterpretation of medication directions can cause medication errors by patients and caregivers that can lead to poor adherence. Health systems should adopt universal health literacy precautions to improve how medication information is communicated for patient engagement. Wisconsin Health Literacy and its academic partners at the Medical College of Wisconsin are working to improve the use of clear and explicit directions by prescribers through systems change and adoption of Universal Medication Schedule directions. Currently, there has not been widespread implementation of Universal Medication Schedule directions, and a multi-disciplinary approach is required. Implementation of Universal Medication Schedule directions as a standard should be part of the model to address poor adherence and patient safety, and improve chronic disease management.

precautions in place: practices and systems to make the clear communication of health information a standard. These systems improve patient engagement in their care.

## Medication Label Initiative

Wisconsin Health Literacy (WHL), a division of Wisconsin Literacy, Inc. is a non-profit organization based in Madison, WI that works to improve health literacy across the state and beyond its borders. It accomplishes this by working with healthcare organizations to improve clear communication of health information and by developing community programs to address public health challenges. WHL has been working in conjunction with its academic partner at the Medical College of Wisconsin to improve the adoption of patient-centered prescription labels. The first three phases focused on community pharmacies and resulted in 1 in 5 pharmacies in Wisconsin implementing U.S. Pharmacopeia prescription label standards with improved readability based on patients' preferences and needs. In phase 4, WHL is working with academic, pharmacy, medical, health administrator,





and health information technology partners across the state to improve the use of clear directions by prescribers.

## Universal Medication Schedule

Universal Medication Schedule (UMS) directions use health literacy best practices, such as using numerals instead of spelled-out numbers; sentence case; and explicit "morning," "noon," "evening," and "bedtime" timings. They provide clear and simple directions for patients to improve self-management, and they were created in response to the need to standardize prescription directions to prevent adverse drug events (Figure 1).<sup>6</sup>

Patients who have lower health literacy, take complex drug regimens, and experience poor communication from their providers are more likely to be non-adherent.<sup>7,8</sup> Addressing health literacy through systems change was recommended as a method to address medication adherence and management of heart failure by the American College of Cardiology.<sup>9</sup> Solutions to non-adherence are multi-pronged, require a team-based approach, and include providing actionable, patient-friendly medication directions.<sup>8,9</sup>

**FIGURE 2. Example of a UMS Pictogram for Prescription Label**

Morning		1 tablet
Noon		
Evening		1 tablet
Bedtime		

**FIGURE 1. Example of Regular Prescription Directions and the Equivalent UMS Directions**

Regular Directions	UMS Directions
Take one tablet by mouth twice daily	Take 1 tablet by mouth in the morning and 1 tablet in the evening
Take one tablet by mouth every 12 hours	
Take one tablet by mouth at 8a and 8p	




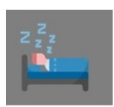
Patients are able to demonstrate how to take their medication better with UMS directions compared to directions with hourly intervals, times per day, or even specific times.<sup>10</sup> This is postulated to be due to the need for math with hourly frequencies, lack of specificity with per day frequencies, and specific times not working with patients' schedules.<sup>10</sup> Without intervention, patients are unlikely to consolidate the number of times per day they take medications, which contributes to poor adherence.<sup>11</sup> UMS directions have been associated with improved understanding of when to take medication by patients and improved adherence for patients who take medication more than one time a day or are over 65 years old.<sup>10,12-15</sup> Simplifying drug regimens and fitting them into a patient's schedule are important strategies to combatting non-adherence. Some pharmacy labels have already included a color-coded UMS pictogram to help patients take their medication at the right time of day (Figure 2). Discharge instructions often include a medication schedule for patients also (Figure 3). This type of visualization could help patients with limited English proficiency understand medication directions. Improving the use of UMS directions when prescribing reduces discrepancies between different sources of information,

decreasing the risk of misunderstandings by patients. UMS directions are considered a best practice by the National Council for Prescription Drug Programs and are supported by the Structured and Codified Sig Format, which follow a defined format so that directions are appropriately transmitted electronically.<sup>16</sup> Currently, they have also been translated and shown to improve understanding of directions and consolidation of drug regimens in patients with limited English proficiency whose primary language was Spanish, Russian, Korean, Chinese, or Vietnamese.<sup>13,17</sup> Most daily medications for adults can fit the UMS format.<sup>6</sup> An expansion of UMS directions that uses a 'Take-Wait-Stop' approach to prescribing as-needed opioid pain medication is also being studied to assess the impact on safe opioid use.

## Objective

Although the use of UMS directions has repeatedly been shown to be beneficial for patients, they have not yet been put into widespread practice. Barriers to implementation include lack of awareness of their benefits, not being incorporated into electronic prescribing systems, and costs to implement new processes. Pharmacists pay significant attention to the barriers patients face to taking their medication

**FIGURE 3. Example of a Medication Schedule Given to Patients at Discharge**

Medicine Name and Strength	Morning	Noon	Evening	Bedtime
				
Metformin 500mg	1	1	1	
Glipizide ER 10mg	1			
Gabapentin 500mg	1		1	
Metoprolol 50mg	1		1	

correctly, and already provide a number of solutions to address poor adherence, such as motivational interviewing, medication therapy management sessions, medication synchronization, refill alerts, and compliance packaging. Yet there remains a need for prescribers to use clear and explicit medication directions. The goals of this project are to improve the use of UMS directions and change prescribing habits to become more patient centered.

## Adoption of Explicit Directions by Prescribers

A pilot study to implement UMS directions was conducted at an outpatient clinic. The process of electronically prescribing medication was kept the same and physician champions improved awareness of the need for this change. Without the need for added steps or further cognitive burden, and by understanding the benefits to their patients, prescribers started utilizing UMS directions.

WHL will continue working with health systems across the state to make the use of UMS directions as easy as possible for prescribers. To assure that any changes to electronic prescribing meets the needs of the end user, one electronic health record software vendor has created a UMS sig feature, where traditional directions are automatically converted to the UMS format prior to being electronically signed and submitted to an outpatient pharmacy. Implementation of this feature is one piece of shifting prescribing habits to becoming more intentional and changing how medication directions are communicated for better patient engagement.

It will also be important for prescribers to adopt other electronic prescribing best practices, such as using discrete directions where possible; avoiding splitting directions between the 'sig' and 'notes' fields; and reviewing every prescription before transmission. Leadership support across the healthcare ecosystem and advocacy will be necessary for adoption of clearer medication directions for patients. Listening to the voice of the patient is also key to patient-centered care, and their needs and concerns will be used as a driver for change in this initiative. Both a widespread awareness campaign and champions to advocate for change will be utilized. WHL

## Commentary by Dr. Schellhase and Dr. Mackinnon

Addressing the overlap of health literacy and medication adherence is a priority whose time has come. Cardiovascular disease is only one of many domains where the importance of adherence has come into stark relief. Recent clinical guidance from the American College of Cardiology regarding the management of congestive heart failure (CHF)—one of the most common and costly conditions in the U.S.—cites medication adherence as a “top 10” pivotal issue in heart failure treatment.<sup>9</sup> This is due to the profound influence of medication use and subsequent adherence on the effectiveness of medical therapy for CHF,<sup>9</sup> yet estimates of medication non-adherence range from 20% to 50%. Similarly, the U.S. Surgeon General's 2020 Call to Action to Control Hypertension highlighted the importance of adherence.<sup>21</sup> In a conceptual model that diagrams the influences on disparities in hypertension control, medication adherence is a key patient-level factor that influences hypertension control.<sup>21</sup> The report goes on to invoke the need for a specific strategy for medication adherence as part of protocols for hypertension management.<sup>21</sup>

However, neither of these authoritative publications has explicitly drawn out the connection between health literacy and adherence. While health literacy may be a patient-level factor, addressing gaps in health literacy cannot be solved primarily at the individual patient level. We need to meet patients where they are with the literacy level they have, now. Consequently, it takes a systems approach, such as the one described in this article, to make prescription bottle labels more readable and understandable to patients with limited health literacy. We need to embrace new and emerging technologies and leverage existing platforms (e.g., electronic health records and prescribing) to address such disparities in health literacy which directly impact medication adherence and tangential health outcomes. This work should be understood in a broader context of systematic ways to improve health outcomes, and reduce disparities in those outcomes, that do not rely on new advances in medical care. Through a coordinated and inclusive multidisciplinary approach, health systems, providers and pharmacies must work in tandem to address health disparities inclusive of health literacy that lead to suboptimal patient outcomes. It relies on us working to better deliver the outcomes that can and should be attained by current science—simply by helping patients take their medications as intended.

is also working on integrating the concept of UMS and utilizing clear directions for patients into pharmacy and medical student education and training.

## Systems Change

The movement of new knowledge from research studies to real-world practices requires a multidisciplinary approach. Health administrators, prescribers, pharmacists, and health information technology professionals are important stakeholders in adopting clear and explicit medication directions. The use of

champions has been shown to be vital for innovation and change, as they are able to effectively build and communicate a vision for change; navigate the power dynamics and social environment within a health system; address and understand concerns; and naturally advocate for change among peers to build confidence.<sup>18</sup> Patient-centered care principles are now often integrated into the training of health professionals, leading to the generation of champions for change on a larger scale.

Rogers' Diffusion of Innovation Theory was used in the previous three



phases of the Medication Label Initiative to guide adoption of patient-centered labels in pharmacies, and it continues to explain how widespread implementation of UMS directions can occur.<sup>19</sup> Every organization will adopt change at a different rate based on its ability to tolerate a degree of uncertainty associated with change. Implementation of the UMS sig feature by early adopters will provide insights on successful implementation and daily functioning, trigger interest and discussion, and help motivate change at other organizations. Early adopters serve as a catalyst for more widespread adoption and commonly include health systems who have strong thought leaders, access to resources, and an established practice of inter-professional collaboration.<sup>20</sup> Health system-specific processes, culture, and social norms will influence the successful adoption of the UMS feature. For this particular initiative, health systems with the organizational structure to address health literacy issues within their organization will be able to better advocate for change and communicate why it is needed.

The role of community pharmacies and staff also cannot be overlooked. Certain characteristics of UMS, such as sentence case, using numerals instead of spelled out numbers, and a pictogram, can only be adopted at the pharmacy level. In the first phase of the Medication Label Initiative, pharmacists demonstrated a willingness and keen interest in making prescription labels easier to understand, and community pharmacies in Wisconsin were able to make some changes to standardize and format directions for clarity during Phases 2 and 3.<sup>19</sup> UMS also has the potential to aid the other adherence interventions pharmacists employ, such as motivational interviewing and medication organization during comprehensive medication reviews or adherence packaging. Overall, community pharmacy staff continue to play a key role in clear directions for patients.

## Conclusion

Universal Medication Schedule directions improve understanding of when to take medication, simplify drug regimens, and can improve adherence. Implementation requires multiple members of the healthcare team and for all stakeholders to understand the needs of patients to effectively manage their medication regimens. Using unambiguous

medication directions for patients to act upon is a move towards patient-centered care to engage patients in their care and improve chronic disease management.

Bhumi Khambholja is the Project Manager, Stan Hudson is the Health Literacy Director, and Michele Erikson is the Executive Director for Wisconsin Health Literacy, a division of Wisconsin Literacy, in Madison, WI. George E. Mackinnon is the Dean of the School of Pharmacy at the Medical College of Wisconsin School of Pharmacy in Milwaukee, WI. Kenneth G. Schellhase is a Professor in the Department of Family and Community Medicine at the Medical College of Wisconsin in Milwaukee, WI.

*Acknowledgements : Funding is provided by the Advancing a Healthier Wisconsin Endowment of the Medical College of Wisconsin. A special thank you to the members of the Project Advisory Council who provide invaluable support and expertise.*

*Disclosures: George Mackinnon is on the Pharmacy Society of Wisconsin's Board of Directors. The authors declare no other real or potential conflicts or financial interest in any product or service mentioned in the manuscript, including grants, equipment, medications, employment, gifts, and honoraria.*

*IRB: The Institutional Review Board at the Medical College of Wisconsin determined that Phase 4 of the Medication Label Initiative does not constitute as human subjects research on July 30, 2021.*

## References

- Office of Disease Prevention and Health Promotion. Health Literacy in Healthy People 2030. Health.gov. 2021. Accessed February 17, 2022. <https://health.gov/our-work/national-health-initiatives/healthy-people/healthy-people-2030/health-literacy-healthy-people-2030>
- Agency for Healthcare Research and Quality. AHRQ Health Literacy Universal Precautions Toolkit. 2nd Edition. AHRQ.gov. 2020. Accessed February 10, 2022. [www.ahrq.gov/health-literacy/improve/precautions/index.html](http://www.ahrq.gov/health-literacy/improve/precautions/index.html)
- Office of Disease Prevention and Health Promotion (2020). Health Literacy. Healthypeople.gov. 2018. Accessed February 11, 2022. <https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-health/interventions-resources/health-literacy>
- Viswanathan M, Golin CE, Jones CD, et al. Interventions to improve adherence to self-administered medications for chronic diseases in the United States: a systematic review. *Ann Intern Med.* 2012;157(11):785-795. doi: 10.7326/0003-4819-157-11-201212040-00538
- Davis TC, Wolf MS, Bass PF, et al. Literacy and misunderstanding prescription drug labels. *Ann Intern Med.* 2006;145(12):887. doi:10.7326/0003-4819-145-12-200612190-00144
- Institute of Medicine 2008. Standardizing medication labels: confusing patients less: workshop summary. Washington, DC: The

- National Academies Press. doi: 10.17226/12077
- Osterberg L, Blaschke T. Adherence to medication. *N Engl J Med.* 2005;353(5):487-497. doi:10.1056/nejmra050100
  - Bosworth HB, Granger BB, Mendys P, et al. Medication adherence: a call for action. *Am Heart J.* 2011;162(3):412-424. doi:10.1016/j.ahj.2011.06.007
  - Maddox TM, Januzzi JL, Allen LA, et al. 2021 update to the 2017 ACC expert consensus decision pathway for optimization of heart failure treatment: answers to 10 pivotal issues about heart failure with reduced ejection fraction. *J Am Coll Cardiol.* 2021;77(6):772-810. doi:10.1016/j.jacc.2020.11.022
  - Davis TC, Federman AD, Bass PF, et al. Improving patient understanding of prescription drug label instructions. *J Gen Intern Med.* 2008;24(1):57-62. doi:10.1007/s11606-008-0833-4
  - Wolf MS, Curtis LM, Waite K, et al. Helping patients simplify and safely use complex prescription regimens. *Arch Intern Med.* 2011;171(4). doi:10.1001/archinternmed.2011.39
  - Wolf MS, Davis TC, Curtis LM, et al. Effect of standardized, patient-centered label instructions to improve comprehension of prescription drug use. *Med Care.* 2011;49(1):96-100. doi:10.1097/mlr.0b013e3181f38174
  - Bailey SC, Sarkar U, Chen AH, Schillinger D, Wolf MS. Evaluation of language concordant, patient-centered drug label instructions. *J Gen Intern Med.* 2012;27(12):1707-1713. doi:10.1007/s11606-012-2035-3
  - Wolf MS, Davis TC, Curtis LM, et al. A patient-centered prescription drug label to promote appropriate medication use and adherence. *J Gen Intern Med.* 2016;31(12):1482-1489. doi:10.1007/s11606-016-3816-x
  - Wolf MS, Taitel MS, Jiang JZ, et al. Prevalence of universal medication schedule prescribing and links to adherence. *Am J Health Syst Pharm.* 2020;77(3):196-205. doi:10.1093/ajhp/zxz305
  - National Council for Prescription Drug Programs. SCRIPT implementation recommendations. NCPDP.org. 2021. Accessed January 20, 2022. <https://www.ncdp.org/NCPDP/media/pdf/SCRIPT-Implementation-Recommendations.pdf>
  - Agency for Healthcare Research and Quality. Explicit and standardized prescription medicine instructions. AHRQ.gov. 2020. Accessed February 10, 2022. [www.ahrq.gov/health-literacy/improve/pharmacy/instructions.html](http://www.ahrq.gov/health-literacy/improve/pharmacy/instructions.html)
  - Shaw EK, Howard J, West DR, et al. The role of the champion in primary care change efforts: From the State Networks of Colorado Ambulatory Practices and Partners (Snocap). *J Am Board Fam Med.* 2012;25(5):676-685. doi:10.3122/jabfm.2012.05.110281
  - Sparks SW, Schellhase KG, Werner LB, et al. Adopting patient-centered prescription medication labels in Wisconsin. *J Pharm Soc Wis.* 2018;21(4):30-36. Accessed February 10, 2022. <https://www.jpswi.org/jpswja18.html>
  - Dearing JW, Cox JG. Diffusion of innovations theory, principles, and practice. *Health Aff (Millwood).* 2018;37(2):183-190. doi:10.1377/hlthaff.2017.1104
  - U.S. Department of Health and Human Services. The Surgeon General's call to action to control hypertension. CDC.gov. 2020. Accessed March 25, 2022. <https://www.cdc.gov/bloodpressure/docs/SG-CTA-HTN-Control-Report-508.pdf>