Implementing Universal Medication Schedule Directions For Use When E-Prescribing: A Toolkit for Health Systems

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This toolkit was developed by Wisconsin Health Literacy in collaboration with their academic partners at the Medical College of Wisconsin and health system partners. It provides practical information and strategies for health system pharmacists, administrators, and staff to implement Universal Medication Schedule (UMS) directions so that patients receive clearer medication directions on their prescription medication labels.

Wisconsin Health Literacy, a division of Wisconsin Literacy Inc., is a statewide non-profit organization based in Madison, WI. It works to improve both individual and organizational health literacy through its programs and services.

Medical College of Wisconsin is a private institution headquartered in Milwaukee, WI. It consists of a Medical School, Pharmacy School, and Graduate School and is the second largest research center in Wisconsin.

Please email <u>healthliteracy@wisconsinliteracy.org</u> with your questions and comments.

Medication Label Initiative:

The toolkit was created in Phase 4 of Wisconsin Health Literacy's Medication Label Initiative to implement patient-centered prescription medication labels. The goal of the initiative is to make it easier for patients to find, understand, and act upon the information on prescription medication labels. As prescription directions (also referred to as prescription sigs) come directly from prescribers, Phase 4 is focused on improving adoption of clearer medication directions by prescribers.

Additional information on this initiative can be found on <u>Wisconsin Health Literacy's website</u> and by reading the article <u>Adopting Health Literacy Best Practices Through Systems Change to Improve Medication Directions and</u> <u>Adherence</u> in the Journal of the Pharmacy Society of Wisconsin.

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Background

In 2008 the Institute of Medicine (now known as the National Academy of Medicine) recognized prescription medication labels as a vital tool to prevent adverse drug events, yet approximately half of patients across all literacy levels misunderstand dosage instructions (Institute of Medicine, 2008). The 2003 National Assessment of Adult Literacy found that about a third of adults in the US did not have the intermediate health literacy proficiency necessary to be able to use a prescription label to determine what time a person should take medication. Davis et al. (2006) found that 67.1-91.1% of English-speaking patients at varying literacy levels could correctly state how to take medication after being shown directions on five different prescription labels. In this study, 71% of patients with low literacy could read the instructions correctly, but only 35% could demonstrate how to take the medication correctly, showing that correctly reading directions does not correlate to understanding. Multiple other studies corroborate the finding that patients interpret 'daily', 'two times a day' and 'three times a day' in different ways (see 'Evidence from research' on page 7). Patients may also take medications at different times every day. These issues can result in toxicity or an inadequate therapeutic response. Patients with lower literacy, who are over 65 years old, and patients who take multiple medications are more likely to misinterpret prescription directions.

About Universal Medication Schedule Directions

Universal Medication Schedule (UMS) directions were created and tested by researchers to improve understanding of when to take medication by patients so that medication is taken as intended. UMS directions use health literacy best practices such as providing explicit 'morning', 'noon', 'evening', 'bedtime' times for medication administration and using numerals instead of spelled out numbers (examples can be found below). UMS directions result in decreased misinterpretations of when to take medication and simplify drug regimens, which both contribute to improved medication adherence (Wolf et al., 2011, 2016, 2020; Davis, 2008).

In a study of 359 patients from primary care clinics, only 61% of patients correctly understood 'times per day' directions compared to 89% of patients who correctly understood UMS directions (Davis et al., 2008). See 'Evidence from research' on page 7 for additional information from research studies.

They have also been tested in five additional languages (Bailey et al., 2012). The United States Pharmacopeia's (2012) Prescription Label Standards and the National Council for Prescription Drug Programs (2013) recommend the use of UMS directions to simplify directions for patients.

Regular Directions	UMS Directions	
Take one tablet by mouth daily	Take 1 tablet by mouth in the morning	
Take one tablet by mouth every day	OR Take 1 tablet by mouth at bedtime	
Take one tablet by mouth twice daily	Take 1 tablet by mouth in the morning and 1 tablet in the evening OR	
Take one tablet by mouth two times a day	Take 1 tablet by mouth in the morning and 1 tablet at bedtime	
Take one tablet by mouth three times daily	Take 1 tablet by mouth in the morning, 1 tablet at noon, and 1 tablet at bedtime	
Take one tablet by mouth three times a day	OR Take 1 tablet by mouth in the morning, 1 tablet at noon, and 1 tablet in the evening	

Examples of UMS directions:

Encoding UMS directions into electronic prescribing (e-prescribing) decreases the steps required for prescribers to use UMS directions. Epic Systems has a 'UMS sig feature' that can automatically convert traditional directions to the UMS format. Other health systems can make UMS directions available for their prescribers by manually inputting UMS directions for prescribers to select. Health systems can also reach out to their Electronic Health Record vendor to see if UMS directions can be made available for prescribers.

Stakeholder Engagement

This type of technology and systems change requires awareness and support from multiple health system groups for sustained engagement. Pharmacy staff who are involved in informatics or are in a management role are ideal to lead this initiative, as they will have the required background knowledge and connections to stakeholders. Key messages to gain buy-in from stakeholders can be found on page 6. The following groups should be engaged during the planning process for successful adoption of UMS directions (groups may overlap):

Pharmacy	Commitment by pharmacists and technicians is critical, and pharmacy involvement is needed to plan and implement e-prescribing changes.		
Examples: Director of Pharmacy, Clinical	A team of informatics, clinical, and other outpatient pharmacists can		
Informatics Pharmacist, Pharmacy Project	make key decisions and inform their respective teams of when		
Manager, Pharmacy Operations Lead,	changes are happening and why. Pharmacists can also use UMS		
Primary Care Pharmacist, Director of	directions during verbal education and as a strategy to improve		
Outpatient Pharmacy	medication adherence.		
Prescribers and Clinic Staff Examples: Physicians (including Medical Directors in Specialty and Ambulatory, Primary Care, Patient Safety), Nurse Practitioners, Physician Assistants, Nurses, Medical Assistants	Providers who prescribe medication and other clinic staff who interact with patients and the e-prescribing system need to be convinced of the clinical benefits of using UMS directions when prescribing and during verbal education. Identifying a health literacy champion in each group will improve support for adoption of UMS directions and sustained change. In addition, it is important for prescribers to be aware of patient factors (such as non-traditional work schedules) that affect the UMS time used, limit the use of free text, and review the prescription order prior to authorizing.		
Information Systems/Informatics	Analysts or informatics pharmacists are needed to make e-prescribing		
Examples: Clinical Informatics Pharmacist,	changes. They also need to test integration of UMS directions with		
Pharmacy Analyst, Ancillary Applications	information systems that process e-prescriptions and external		
Lead, Director of Information Systems	pharmacy software solutions the health system may have.		
Senior Leadership Examples: Chief Medical Information Officer (CMIO), Chief Medical Officer (CMO), Vice President of Population Health, Vice President of Quality Improvement	Additional approval through committees or by leadership may be required. Leadership support of e-prescribing changes will drive the project forward.		
Patient Education/Experience	Involving members of the patient education or experience team will		
Examples: Patient Education Lead, Director	help communicate the need for UMS implementation systemwide		
of Patient Experience, Director of Patient	and improve the use of clear and explicit medication directions		
Education, Health Literacy Council Director	overall.		

Key Decisions

Careful planning is required to implement UMS directions. Research supports the use of UMS directions for maintenance medications with standard dosing. Traditional 'per day' directions should be mapped to the appropriate UMS timing. However, certain medications may not be able to use UMS directions. Examples of instances where it may not be appropriate to use UMS directions and guidance on mapping is given below (examples are not all inclusive).

Some health systems may wish to use a phased approach to decrease implementation burden and to be able to test functionality. Health systems could start with a subset of medications or direction frequencies to change to the UMS format and expand from there. For example, using UMS directions for high blood pressure, cholesterol, and diabetes medications or instead of 'twice a day' and 'three times a day' frequencies would be most impactful.

- What directions or medications should be excluded from the UMS format?
 - Long directions such as tapered or titrated directions (directions need to fit on outpatient pharmacy labels, which can usually fit approximately 144 characters)
 - Directions with over 4 doses per day
 - 'As needed' medications
 - Medications based on professional judgement:
 - Medications where directions are individualized based on response or patient factors (short acting insulin, amphetamine salts, methylphenidate, modafinil, benztropine, buspirone, citalopram, escitalopram)
 - Medications that need to be separated from others (sucralfate, antacids)
- What UMS timing should traditional medication directions map to?
 - Medications that may need to be taken at bedtime:
 - Medications that cause drowsiness/dizziness (beta blockers, alpha blockers, antimuscarinics)
 - Medications that may work better when taken at bedtime (statins)
 - Medications where the last dose may need to be taken in the **evening** instead of at bedtime:
 - Medications taken around meals (sulfonylureas, metformin, H2 blockers)
 - Medications that may interfere with sleep (diuretics)
 - Patient specific UMS times should be used by prescribers for patients who have a non-traditional work schedule

Messaging and Educational Materials

Combining the evidence from research studies with real patient stories/issues is an effective method of communicating the rationale for adopting UMS directions. Steps should be taken to prevent medication errors by patients as health systems are increasingly being held accountable for the outcomes and cost of care. Medication adherence initiatives are important for health systems as well as outpatient pharmacies to improve outcomes. Medication adherence is key to high performing, high quality health care organizations.

Prioritizing patient engagement initiatives will enable patients to be active participants in managing their health.

Consider:

- What chronic diseases are prevalent in your community or what key health events can be prevented with effective medication therapy?
- What are the demographics of your community? Are there factors that could increase the risk of misinterpretation of medication directions (low literacy, over 65 years old, multiple chronic conditions)?
- What is the medication adherence of your patients and what adherence issues do you see? What medication errors by patients could be prevented?
- Evidence from research:

Patients across all literacy levels can misunderstand directions on prescription labels (Davis et al., 2006).

In a study of 359 patients from primary care clinics, patients were significantly more likely to understand UMS directions compared to 'per day' directions, where only **61% of patients correctly understood 'times per day' directions compared to 89% of patients who correctly understood UMS directions** (Davis et al., 2008).

Study of 500 patients from primary care clinics showed 44% of patients correctly interpreted 'three times per day' directions compared to 91% of patients who correctly interpreted UMS directions and 77% correctly interpreted 'two times per day' directions compared to 84% of patients who correctly interpreted UMS directions. Overall UMS directions were significantly more likely to be correctly interpreted (Wolf et al., 2011).

Patients were significantly better able to demonstrate when to take medication with UMS directions in their preferred language compared to 'times per day' directions in their preferred language, with 66% correctly interpreting 'times per day' directions and 83% correctly interpreting UMS directions (Bailey et al., 2012).

Improved adherence seen in patients who are over 65 years old, have limited literacy, and take medication more than one time a day (Wolf et al., 2016; Wolf et al., 2020).

• Examples of medication issues that patients experience shared with Wisconsin Health Literacy by pharmacists:

"We have had people tell us that when a prescription said to take the medication 'two times a day' they took one tablet then two hours later took the other tablet."

"Patients often think they need to wake up in the middle of the night to take their medication."

"There is confusion when using the term 'dinner'. In a farming community, the noon meal is often referred to as dinner and the evening meal as supper. I can see where using UMS directions would clarify dosing times."

"The majority of compliance packaging that our pharmacy does is due to patients taking their medications at the wrong time."

"A patient didn't realize that their insulin was dosed for morning and evening so the patient had only been receiving one dose for a month until the pharmacist contacted the patient to determine why they weren't filling their long-acting insulin enough. The directions were written to inject 12 units twice daily but the patient wasn't fully aware of the recent change as they had previously been on just once daily. Since the incident, more of our prescriptions are written using the UMS system."

"We often have to give patients ideas on how to remind themselves when to take medication."

• Resources to improve awareness:

About UMS Directions Video

UMS Information Sheet

Medication Label Initiative Video

Clearer Medication Directions for Patients Information Sheet

Timeline and Staff Hours

Planning requires approximately 40 – 80 hours of staff time depending on which medications/frequencies will be changed to the UMS format. Timeline showing suggested activities in the months prior to UMS implementation:

6-5 months	5-3 months	3 months - Implementation Implement
 Determine decision makers and form team to lead initiative Obtain leadership support 	 Make decisions about exclusions and mapping Take to relevant committees for approval 	 Test UMS directions with all information systems that process e-prescriptions Communicate target implementation date and gain stakeholder buy-in. Options include: Presentations and discussions at meetings Inclusion in mandatory trainings Updates in newsletters and emails Monitor reliability system and medication directions If needed perform corrective maintenation

Lessons Learned

Adopting UMS directions in health systems takes careful planning and is not as simple as 'flipping a switch'. Attention needs to be given to specific system capability and functionality with thorough review of what will change. Some health systems in Wisconsin have postponed adoption to address issues that were not considered during the planning period.

Education of prescribers and staff is key to success. Prescribers are in a position to ensure the correct UMS times are used for each patient. Prescriber awareness and understanding of patient medication issues and their support for the use of UMS directions are of critical importance for sustained use. Please check back for additional lessons learned that will be added as more health systems adopt UMS directions.

Additional

- Other applications of UMS
 - Some pharmacies are able to include a UMS pictogram on their pharmacy label or use UMS times to package medication for patients.
 - Some health systems have adopted external software solutions that address adherence issues and can provide medication calendars to patients. These solutions do not directly impact the clarity of medication directions on prescription labels, which is integral to patients taking their medication correctly. Example of a medication calendar:

Medicine Name and Strength	Morning	Noon	Evening	Bedtime
	<u> </u>			
Simvastatin 20mg				1
Hydrochlorothiazide 25mg	1			
Metoprolol 50mg	1			1

• Measuring impact

Although research has been done to support the use of UMS directions, health systems may wish to measure the impact at their organization. Methods to do this include evaluating:

- o Patient experience before and after UMS adoption
 - Staff explained medications well
 - Patients understood their care when they left
- o Self-reported adherence issues through survey before and after UMS adoption
 - I have forgotten to take medicine in the past 3 months
 - I know when to take all my medicine
 - I take my medicine at around the same time every day
 - My medicine fits well into my schedule
- Measuring adherence before and after UMS adoption
 - This may be accomplished with pharmacy fill data or by using payer data on changes in HEDIS or Medicare STARS performance metrics that focus on adherence

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