

# Improving Prescription Drug Labeling

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According to a 2006 report by the Institute of Medicine of the National Academies, *Preventing Medication Error*, approximately 1.5 million preventable adverse drug events occur each year.<sup>1</sup> Attention to the root causes of medication errors leading to adverse events has most often been attributed to the provider's or health care system's contributing role in errors during the prescribing, ordering, dispensing or administering of a medicine.<sup>2,3</sup> The reason attention was focused on those causes may be that most studies investigating medication error have been conducted in inpatient hospitals or nursing homes.<sup>4</sup> However, more than one-third of adverse drug events take place in outpatient settings at a cost approaching \$1 billion annually.<sup>1</sup> It has been estimated that a large proportion of outpatient medication errors occur as a result of patients themselves not administering a medicine as intended.<sup>3</sup> For ambulatory care, the patient, rather than the provider, is ultimately responsible for correctly administering a medicine as prescribed. Therefore, the processes of quality control and monitoring of medication error shift from provider to patient.

The current body of evidence detailing the incidence and causes of outpatient medication error is limited. Yet problems are likely to intensify as patients increasingly self-manage greater numbers of prescription and over-the-counter medications. Chronically ill patients and the elderly are at greatest risk for experiencing medication errors as they take more prescription

drugs annually than younger and healthier patients, and visual/cognitive impairments by age may limit reading ease and comprehension.<sup>5-9</sup> The risk for miscommunication and error may be further compounded since the average older adult sees several different health care providers annually.<sup>10</sup>

## Health Literacy as a Medication Safety Concern

Limited health literacy is another significant risk factor that could account for outpatient medication errors that are the result of improper dosing administration. Numerous studies have found low health literacy to be significantly associated with a poorer understanding of medication names, indications, and instructions.<sup>11-14</sup> More recently, health literacy skills have been linked to requisite knowledge for adherence to treatment regimens.<sup>15</sup> This current and well-publicized body of research has focused on the ability of patients to read, understand, and demonstrate instructions on drug container labels. The line of inquiry has been supported by parallel work in human factors research.<sup>5,6</sup> Davis and colleagues conducted a multisite study among adults receiving primary care at community health centers and found a high prevalence of patients, especially those with limited literacy, misunderstanding seemingly simple dose instructions provided on the primary label of medication containers.<sup>11</sup> In this study, 46% of adults misunderstood at least one prescription container label they encountered. The problem extends to the auxiliary sticker labels that provide accompanying warnings and instructions for use of the medicine. Another study demonstrated over half (53%) of patients, especially those with limited literacy, had difficulty interpreting text and icons commonly used on these auxiliary warning instructions.<sup>12</sup>

Beyond the container, drug labeling also includes accompanying medication information materials that provide indications for use and

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further detailed precautions that can not fit on the container due to space constraints. Studies have found that these materials, as with the container label, are not useful for a majority of patients, particularly those with limited health literacy.<sup>16</sup> This includes consumer Medication Guides (aka Med Guides) that are required by the Food and Drug Administration to be dispensed along with certain prescribed medicines that have been identified as having serious public health concerns. Patients with limited health literacy were significantly less likely to attend to these materials. These findings are supported by earlier research studies that suggest consumer medication materials are too difficult for most patients to read.<sup>17</sup> As a result, the patient information leaflets and Med Guides that accompany many prescription medications may be ignored.

## A System Failure

The 2004 Institute of Medicine of the National Academies report on health literacy, *A Prescription to End Confusion*, aptly identified the problem of health literacy as encompassing more than limitations in individual abilities.<sup>13</sup> Rather, the complexity of demands placed upon the individual by the health care system must clearly be addressed. While patients must have adequate cognitive capacity and proficiency to read, understand, and act on medication label instructions to ensure proper and safe use, the manner in which the current health care system delivers necessary medication information to patients is clearly inadequate. Physicians, who are legally responsible for delivering important drug information directly to patients, frequently miss opportunities to adequately counsel their patients on how to self-administer their medicines.<sup>19</sup> Pharmacists, next in line to counsel patients, also frequently fail to verbally communicate detailed information to patients at the point of dispensing medicines.<sup>20</sup>

In light of these failures, patients must depend more on the print drug labeling materials (ie, the container label, consumer medication information, Med Guides, patient information leaflets) that are challenging for patients across all health literacy levels.<sup>17,18</sup> With the exception of Med Guides and a very limited set of similar patient package inserts that are available for only a select number of drugs, no national standards or regulations exist for the development and oversight of consumer medication information or container drug labels. Informational leaflets are industry-generated, and state laws minimally govern content and format on prescription container vials. This all leads to what can best be described as a fragmented system of patient information.

## Taking Action

Improving the readability and understanding of instructions and supplementary information for prescription drugs is warranted as it may ultimately stimulate appropriate and safe medication use among patients. Evidence is available now supporting the design of better drug labeling.<sup>21</sup> This includes considerations for both the container label and accompanying materials. Based on recent health literacy studies and work by

the American College of Physicians Foundation (ACPF) on prescription drug labeling, certain general recommendations can be issued that espouse the importance of promoting health literacy as a medication safety issue.<sup>22</sup>

First, seemingly simple dosage instructions printed on the container label should be written in the most clear and concise manner. Previous research has found that patients have more difficulty understanding vague medication directions as compared to more explicit ones.<sup>23,24</sup> The less a patient is required to make inferences, the more easily medication schedules can be comprehended (ie, “take every 6 hours” vs “take at 8am, 2pm and 8pm”). This is especially important for more complex dosing schedules, where patients may become easily confused or more prone to errors if instructions are read in haste.

Second, Shrank and colleagues examined the variability in content and format on prescription drug container labels.<sup>25</sup> They found that pharmacies consistently emphasized provider-directed content versus information most pertinent to the patient. The use of bolding, highlighting, and larger font should be directed solely to label content that is most salient to the patient. Information such as prescription number or the pharmacy logo should be de-emphasized and segregated from dosage instructions, warnings, or indications so as to not detract from the most important label content detailing its appropriate use. Every effort should be made to organize the container label in the most patient-friendly manner. It likely will be the most tangible source of drug information repeatedly used by patients.

Third, accompanying materials should abide by core principles upheld by adult literacy practitioners.<sup>17,26</sup> Consumer medication information should keep to simple language and avoid medical jargon. The scope of information should be limited and summaries more frequently used to highlight actionable messages. Shrank and colleagues further describe the type of content that is desired by patients to support appropriate use.<sup>21</sup> Surveys have shown that patients want to know, in addition to dosage instructions, the indications for use of a prescribed medicine, any precautions, and the duration of treatment. Information on the benefits and side effects of drugs is also sought after by patients, and providing this information has been found to improve adherence.<sup>20</sup>

Finally, steps should be taken to ensure that these separate elements of drug labeling, the container label and accompanying materials, are developed together as an integrated and complimentary set of information sources. Patients should be included in this process so materials are appropriately organized, and they accurately reflect the common schemas imposed by patients of all literacy levels when seeking to understand how to use prescribed medicines.

## Conclusion

System change is urgently needed to promote health literacy for greater medication safety. Patients must be able to easily understand how to use prescription drugs correctly. Standardizing and integrating drug labeling must be a central goal to ensure that best practices are implemented because

evidence is already available to target improvements. This should be viewed as a short-term goal for policymakers, and some states have already made progress to this end.

In the long term, additional challenges for drug labeling include efforts to seek labeling concordance in other languages because not all prescription drug information and instructions are currently available to non-English speakers. A formative response to labeling problems would also extend to addressing how health care providers communicate to patients the

information that is necessary to safely administer prescribed medicines. More broadly, health technology used by an increasing number of providers at the point of writing the prescription should be integrated with the software used by dispensing pharmacies to fill it and print out the labeling components. This would provide another layer of quality assurance that could minimize variability and the risk that instructions become lost in translation. **NCMJ**

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