

Nurse Advise ERR®

Educating the Healthcare Community About Safe Medication Practices

Patients with low health literacy make more errors interpreting instructions and warnings

According to the US Department of Education, National Center for Education Statistics (NCES), National Assessment of Adult Literacy (NAAL), more than half of adults (53%) are classified as having intermediate health literacy, followed by basic (22%), and below basic (14%), with only a small percentage (12%) considered health literacy proficient. Whether limited by knowledge, socioeconomic factors, emotional or clinical state, or cultural background, the patient's level of health literacy—the ability to read, understand, and act in a well-informed manner on healthcare information—is a concern for many patients. This issue is compounded by the fact that healthcare information is increasingly available via digital healthcare portals. People who have difficulty reading or understanding health information may be embarrassed and hide the problem, often masking their underlying fear of misunderstanding. In addition, low health literacy is not always obvious, and practitioners may not be aware that some patients need additional support to understand their care plan. Researchers have reported poor reading skills in some of the most poised and vocally articulate patients. Regardless of their level of intelligence, ability to read or write, or reading comprehension, most patients need help understanding information about their health and medications.

Definition of Health Literacy

Healthy People 2030, an initiative led by the Centers for Disease Control and Prevention (CDC), describes health literacy in terms of both personal and organizational aspects. They define personal health literacy as the degree to which individuals can find, understand, and use information and services to inform health-related decisions and actions for themselves and others. Healthy People 2030 defines organizational health literacy as the degree to which organizations equitably enable individuals to find, understand, and use information and services to inform health-related decisions and actions for themselves and others. Patients should be able to make "well-informed" decisions rather than "appropriate" ones. These definitions emphasize the patient's ability to use health information, not just understand it, and acknowledge that organizations have a responsibility to address health literacy with everyone.

Outcomes of Low Health Literacy

Patients with low health literacy are more likely to make errors when interpreting medication instructions and warning labels.¹ This is especially true when instructions involve a titration or taper. Not understanding how to take their medication may result in the patient taking a sub-optimal dose or overdose of medication, which can lead to an increased risk of adverse events.² Low health literacy can also contribute to decreased medication adherence.³ Furthermore, patients who do not understand their disease state and how medication can help, may be less likely to take their medication as prescribed to minimize disease progression or complications.⁴

Organizations and individual practitioners may not have the proper resources to assess or support varying levels of health literacy in patients they treat. Medical information may be difficult to understand even for patients whose primary language is English. Patients with limited English proficiency (LEP) may struggle with both linguistic and other cultural barriers that affect comprehension of medical language. Due to time constraints, lack of available interpreters, or convenience, practitioners may choose to "get by" without an interpreter. Staff may use family members, friends, or even colleagues as interpreters, but these people may not have the ability to understand or translate the information appropriately.

continued on page 2 — Low health literacy >

SAFETY wires-

- Some products continue to present risks of needlestick injuries. Over the last two years, we reported the potential for accidental needlestick injuries with the use of manufacturer prefilled syringes that do not come with a needle safety guard. The products mentioned included the following:
 - **EVENITY** (romosozumab-aqqg), indicated for the treatment of osteoporosis in postmenopausal women at high risk for fracture, or patients who have either failed or are intolerant to other available osteoporosis therapies;
 - KINERET (anakinra), indicated for rheumatoid arthritis, neonatal-onset multisystem inflammatory disease (NOMID), and deficiency of interleukin-1 receptor antagonist (DIRA); and
 - HUMIRA (adalimumab), indicated for rheumatoid arthritis, psoriatic arthritis, Crohn's disease, as well as other autoimmune diseases.

Additionally, we received a report of another prefilled syringe with the same issue—**LEQVIO** (inclisiran). Leqvio is supplied in a carton with one single-dose prefilled syringe containing 284 mg/1.5 mL (189 mg/mL) of inclisiran. The medication is intended to be administered by a healthcare practitioner as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease, who require additional lowering of low-density lipoprotein cholesterol.

Recently, we learned of another product that poses the same risk. This time it is a kit—the leuprolide acetate 14 mg/2.8 mL kits which are used in the palliative treatment of advanced prostate cancer. The kits come with a vial containing 14 mg/2.8 mL of leuprolide acetate, 14 syringes with affixed needles, and 28 alcohol swabs. The needles do not have a safety device. In the case reported

continued on page 2 — **SAFETY** wires >

> Low health literacy — continued from page 1

Errors Related to Health Literacy

Below are examples of events reported to ISMP that involve gaps in health literacy:

A Spanish-speaking patient misinterpreted the directions (in English) for DisposeRx (Figure 1), a product intended to facilitate safe drug disposal. The patient thought the contents were to be ingested, partly due to the photo on the packet of the powder being dispersed in what looked like a glass of water. Fortunately, a home care nurse who was counseling the patient using a Spanish-language interpreter intercepted the error. The company has since updated the package labeling to clarify that it is a medication disposal packet.

A non-English speaking patient was discharged from a hospital with a new prescription for albuterol 2.5 mg/3 mL nebulization solution. During a post-discharge phone call, the patient told a nurse that she had been given a liquid medication to drink from a "syringe." The nurse contacted the patient's pharmacy and realized that the patient was drinking the albuterol from the plastic container (**Figure 2**), which the patient had described as a "syringe."

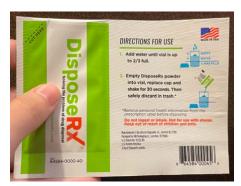


Figure 1. A patient thought they were supposed to ingest the contents of the DisposeRx packet, in part due to the picture that was on the packet.



Figure 2. Albuterol nebulization solution comes in a plastic container that is to be used with a nebulizer machine for inhalation. The patient referred to it as a "syringe" and drank the contents.

Recommendations

Health literacy has a critical impact on informed decision-making, including safe medication use. Consider the following recommendations to support both personal and organizational health literacy.

Assess literacy level. As part of the admission process, consider using health literacy assessment tools, if possible. The Test of Functional Health Literacy in Adults (TOFHLA) and the <u>Rapid Estimate of Adult Literacy in Medicine (REALM)</u> are the most widely used instruments to measure health literacy.

Provide health literacy-friendly materials. Organizations should strive to offer written materials (e.g., medication handouts, prescription labels) in the patient's preferred language, at a fifth grade reading level or lower. Simplify materials and offer small amounts of information at a time. Use clear captions, pictures, diagrams, or videos to help explain concepts. Most patients, even those who read well, rely on visual clues to reinforce learning and spark memory. Consider using the <u>Patient Education Materials Assessment Tool (PEMAT)</u> to evaluate how understandable and actionable medication education materials are to the public. To promote better patient understanding of labeling instructions and information on prescription containers, pharmacies should review and follow USP, General Chapter <17> Prescription Container Labeling (December 1, 2021).

Gather feedback. Seek feedback from patients (e.g., focus groups, targeted satisfaction survey questions), patient advocates, and healthcare educators to ensure that written materials effectively communicate the most vital information in concise, familiar language, and update as necessary.

Provide patients with tools. Provide resources to prepare patients on how to be more involved in their health including their medication regimens. Make medication education information available for patients within an online portal, a smartphone application, and/or handouts. Ensure information on the portal is patient-friendly, especially if making highly technical documents available digitally

continued on page 3 — Low health literacy >

>**SAFETY** wires continued from page 1

to ISMP, a nurse accidentally stuck herself with the needle attached to the included syringe after administering the medication to a patient.

These injectable products have been designed to be administered by patients or their caregivers after receiving proper training. However, they are also administered by practitioners in the inpatient and long-term care settings where the use of needles with safety mechanisms is common and expected. Also, if the patient does not have a proper sharps container, these syringes, with their exposed needles, may make their way into garbage bins and other forms of common waste, exposing children, animals, and others to unintended needlestick injuries.

The Occupational Safety and Health Act (OSHA) of 1970 requires compliance with OSHA standards to institute safety measures in workplaces where there is occupational exposure to blood or other potentially infectious materials. Under the standard, as revised by the Needlestick Safety and Prevention Act, employers are required to evaluate, select, and use engineering controls (e.g., sharps with engineered sharps injury protections or needleless systems) to eliminate or minimize exposure to contaminated sharps. Technically, if an injectable does not allow the use of an engineering control such as a needle with a safety guard, then the product should not be used in that facility. Using injectables without safety needles when providing patient care puts organizations at risk, especially with products that have labeling stating it should be administered by a healthcare provider.

Much of this safety issue could be avoided if all prefilled syringes had engineering controls that protected people, not just healthcare professionals, against needlestick injuries. We will continue to communicate with the US Food and Drug Administration (FDA) and manufacturers of prefilled syringes to address this concern with a requirement for ALL prefilled syringes to have a safety guard. Alternatively, companies can make prefilled syringes without an affixed needle so that a safety

continued on page 3 — **SAFETY** wires >







> Low health literacy — continued from page 2

(e.g., CT scan summary interpretation by a radiologist, echocardiogram results written by a cardiologist).

Offer language services. Make formal interpreter services available, including in person, by video call, and/or by telephone. Interpreter services benefit not only the patient but also staff members who otherwise struggle to <u>ensure the provision of high-quality care</u>. Use caution with interpretation services from multilingual teammates, or family members of the patient, who may not be well-versed in healthcare translation. Ensure any communication beyond conversational discussions involves a trained professional.

Document in the EHR. Build required fields in the electronic health record (EHR) to document preferred patient language and interpreter service needs. Ensure this information is easily accessible to staff. Automatically schedule interpreters at clinical points of service for patients with LEP.

Educate patients. Implement the teach-back method and have patients show and tell how they plan to take their medications. Avoid closed-ended questions and never assume patients understand how to take their medications. Being articulate and confident does not necessarily equate to adequate reading skills and other proficiency. Patients who cannot read will likely try to mask their literacy challenges due to emotional reasons (e.g., embarrassment) or misunderstanding of the potential negative impacts on their care. Empower patients and families to report errors through the ISMP consumer website, www.consumermedsafety.org, so they can contribute to learning.

Coach practitioners. Instruct staff about best practices involving disease and medication information communication, interpreter service use, and cultural awareness. Create a policy or procedure for practitioner onboarding to ensure staff are aware of the available resources and when to use them. To minimize language barriers, the Agency for Healthcare Research and Quality (AHRQ) has several training programs available, including the TeamSTEPPS (Team Strategies and Tools to Enhance Performance and Patient Safety) LEP Module.

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> **SAFETY** wires continued from page 2

needle can be placed on the syringe before use. This would allow conformance with the OSHA requirement and help protect people against injury from an uncovered needle after administration.

Finally, it is important to provide patient counseling and make sure patients (or the family member or caregivers who will be administering the injection) have the information and supplies necessary to dispose of the products properly and safely. FDA has published advice for consumers about the best ways to dispose of needles and other sharps.

Hurricane Helene intravenous (IV) fluid update. ISMP has been in communication with Baxter and other organizations to help navigate the drug shortages in the aftermath of Hurricane Helene. In addition, the US Food and Drug Administration (FDA) is working to temporarily import some products to help meet patient needs.

As organizations implement conservation strategies that work best for their institution, we recognize that any change to procedures, workflows, or procuring new products because of the shortage may increase the risk of error; continued communication with frontline staff is key. The following represent safety concerns and practices during medication administration that must be addressed.

- Ensure staff understand how to administer medications via IV push that were previously administered by infusion (e.g., rate of antibiotic administration). The medication administration record (MAR) should include the rate of IV push administration.
- Maximize barcode scanning prior to administration. If a barcode is missing or unscannable (e.g., imported products), the practitioner must confirm the product's identity prior to administration.
- Implement a process to ensure staff know when a product has an extended expiration date that was FDA approved.
- Communicate changes to policies, systems, and workflow practices when new products are purchased.







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