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ISMP An ECRI Affiliate

Community/Ambulatory Care

ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

Support health literacy to enhance medication safety for patients

Problem: Whether limited by knowledge, socioeconomic factors, emotional or clinical state, or cultural or language background, the patient's level of health literacy—the ability to read, understand, and act in a well-informed manner on healthcare information—is often dangerously low. This issue is compounded by the fact that healthcare information is increasingly available via digital healthcare portals. According to the US Department of Education, National Center for Education Statistics (NCES), National Assessment of Adult Literacy (NAAL) (www.ismp.org/ext/1238), 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. People who have difficulty reading or understanding health information may be embarrassed and hide the problem, often masking underlying fear due to the misunderstanding. In addition, low health literacy is often not obvious, and practitioners may not be aware that some patients need additional support to understand their care plan. Also, researchers have reported poor reading skills in some of the most poised and vocally articulate patients. Furthermore, most patients need help understanding information about their health and medications, regardless of their level of intelligence, ability to read or write, or reading comprehension.

Definition of Health Literacy

Healthy People 2023 (www.ismp.org/ext/1237), 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 2023 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 rather than just understand it and acknowledge that organizations have a responsibility to address health literacy with everyone.

Problems with 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 the medication may result in inadvertently taking a suboptimal 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 or the benefit of the medication are less likely to take precautions which may include being less likely to take their medication as prescribed to minimize disease progression or complications.[4]

Organizations and individual practitioners may not have the right resources to help assess or support varying levels of health literacy in the patients that they treat. To complicate the matter, medical information is difficult to understand even for patients whose primary language is English. Comprehension of medical language is even more difficult for patients with limited English proficiency (LEP) as they may also struggle with both linguistic and other cultural barriers. Due

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SAFETY briefs

No, not always 3 lidocaine patches at a time! A prescriber ordered a lidocaine 5% patch for an elderly patient with instructions to "apply 1 patch daily, for 12 hours on and then remove for 12 hours." However, the patient applied three patches daily instead. Rather than following the instructions on the prescription label, the patient followed the "usual dosage" information on the outer package, which states, "Apply up to 3 patches. See package insert for complete prescribing information." While the manufacturer was not reported, there are several lidocaine patch products that have similar statements on the label (**Figure 1**). The organization did not report whether there was any patient harm. However, excessive dosing or prolonged exposure to lidocaine patches may lead to lidocaine toxicity, with dose-related adverse effects such as central nervous system excitation and/or depression, as well as bradycardia, hypotension, and cardiovascular collapse.

The lidocaine 5% strength is available only by prescription; therefore, patients should refer

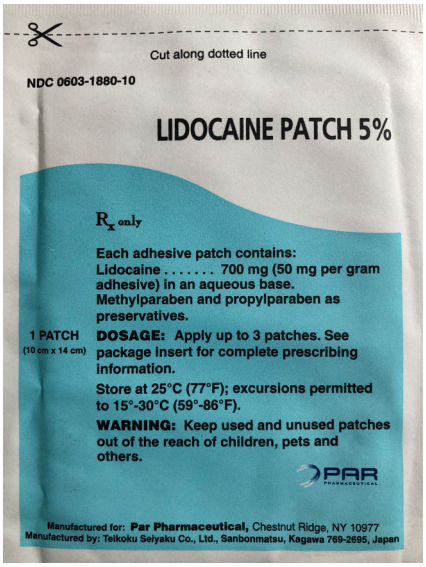

Figure 1. Example of lidocaine patch "DOSAGE" instructions that state, "Apply up to 3 patches. See package insert for complete prescribing information."

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to time constraints, lack of available interpreters, or convenience, practitioners may choose to "get by" without an interpreter.[5] 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 in medical terms.

Errors Related to Health Literacy

Below are recent events reported to ISMP that involve gaps in health literacy.

A Spanish-speaking patient misinterpreted the directions (in English) for DisposeRx, 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 glass of water. Fortunately, a home care nurse who was counseling the patient using a Spanish-language interpreter intercepted the error.

*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 they 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 1**), which the patient had described as a "syringe."*

Figure 1. 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.

Safe Practice 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. Consider the use of assessment tools. The Test of Functional Health Literacy in Adults (TOFHLA) and the Rapid Estimate of Adult Literacy in Medicine (REALM) are the most widely used instruments to measure health literacy (www.ismp.org/ext/1241).

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. Never assume being articulate and confident equates to adequate reading skills and other proficiency. Patients who cannot read will likely try to mask their lack of skill 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).

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 information 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, depend on visual clues to reinforce learning and spark memory. Consider using the Patient Education Materials Assessment Tool (PEMAT) (www.ismp.org/ext/1236) to evaluate how understandable and actionable your organization's medication education materials are to the general public. To promote better patient understanding of labeling instructions and information on prescription containers, review the USP General Chapter <17> *Prescription Container Labeling*.

Offer language services. Make formal medical interpreter services available, including in person, by telephone, and/or by video call. Interpreter services benefit not only the patient but also staff

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to the specific instructions on the prescription label rather than the product's label or carton's principal display panel. We have notified the US Food and Drug Administration (FDA) about this concern and recommended removing the dosage instructions from the outer package label or principal display panel. Ensure patients receive counseling when dispensing this product. Use the teach-back method to educate patients about their prescribed dosage, which may differ from the instructions on the product's label.

Humatrope pen and cartridge mismatch. A patient's parent notified the pharmacy that they were running out of **HUMATROPE** (somatropin), a growth hormone, much earlier than expected. They brought the product to the pharmacy for the pharmacist to examine. The pharmacist was able to confirm that the dose, medication cartridge strength (i.e., 12 mg), and quantity were correct. However, it was noted that they did not have the correct Humatrope Pen to use with the medication cartridge. To use and dose Humatrope accurately, the cartridge strength (e.g., 12 mg) must be used with the matching pen device (e.g., Humatrope Pen 12 mg). In this case, when the patient was changed from 6 mg to 12 mg cartridges, the family was not provided with the Humatrope 12 mg pen. The parent had been using the 6 mg pen with the 12 mg cartridges, resulting in more medication being administered than prescribed.

While specialty pharmacies typically dispense the medication cartridges, they do not dispense the corresponding pen device. Patients must obtain the pen device from the provider or directly from the manufacturer. Unfortunately, this creates a situation where the specialty pharmacies will likely not know what pen device the patient has when they dispense the medication cartridge, as happened in the case above. Also, while the package insert states that the pen and cartridge must match in order to deliver the correct dose, this information may be easily missed.

Ensure your treatment protocols and counseling guidelines for Humatrope

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members who otherwise struggle to ensure the provision of high-quality care (www.ismp.org/ext/1242). Use caution with interpretation services from bilingual 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.

Provide patients with tools. Provide resources to prepare patients on how to be more involved in their health including their medication regimens (www.ismp.org/ext/1240). Make medication education information available for patients within an online portal, on handouts (www.ismp.org/node/1055), QR codes printed on handouts or the pharmacy label, or via a smartphone application. Ensure information is patient-friendly.

Document in the pharmacy dispensing system, clinical management system, and electronic health record (EHR). Build required fields to document preferred patient language and interpreter service needs in electronic systems. Ensure this information is easily accessible to staff.

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

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.

References:

1) Wolf MS, Davis TC, Tilson HH, Bass PF 3rd, Parker RM. Misunderstanding of prescription drug warning labels among patients with low literacy. *Am J Health Syst Pharm*. 2006;63(11):1048-55.
2) Zhang NJ, Terry A, McHorney CA. Impact of health literacy on medication adherence: a systematic review and meta-analysis. *Ann Pharmacother*. 2014;48(6):741-51.
3) Fox D, Rowlands G, Kapadia N, Chinemana F, Ubhi V, Shaw A. The impact of low literacy on patient health: a qualitative study of United Kingdom primary care practitioners' views. *Health Issues*. 2007;92:15–19.
4) Orom H, Schofield E, Kiviniemi M, et al. Low health literacy and health information avoidance but not satisficing help explain don't know responses to questions assessing perceived risk. *Med Decis Making*. 2018;38(8):1006-17.
5) Diamond LC, Schenker Y, Curry L, Bradley EH, Fernandez A. Getting by: underuse of interpreters by resident physicians. *J Gen Intern Med*. 2009;24(2):256-62.

Don't confuse products used to prevent infections from respiratory syncytial virus

Problem: Most patients who develop a respiratory tract infection from the respiratory syncytial virus (RSV) will have mild illness and recover in a week or two. However, RSV can be dangerous for infants and young children, and for certain adults (e.g., older immunocompromised adults) (www.ismp.org/ext/1282). With all the publicity about new RSV products, and RSV outbreaks in many areas, it is easy to confuse product names, dosages, and schedule differences between the two monoclonal products or confuse the two RSV vaccines. So, be prepared! **Beyfortus and Synagis are indicated for use in certain infants and children, while the Arexvy and Abrysvo vaccines are indicated for use in certain adults.**

Pediatric RSV Products

In July 2023, the US Food and Drug Administration (FDA) approved the monoclonal antibody **BEYFORTUS** (nirsevimab-alip), to prevent RSV in neonates and infants, and in certain children

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(and other similarly packaged somatropin products) include prompts to verify with the patient/parent/caregiver which pen device they have. If the pen does not match the prescribed cartridge strength, work with the patient/parent/caregiver and their provider to obtain the correct device. Reinforce during patient counseling the need to verify that the cartridge and pen strengths match. Ideally, the company should design cartridges and pens such that the cartridge and pen can only connect if they are the same strength.

Worth repeating...

Safeguard your return-to-stock (RTS) process

Recently, a patient reported an error in which they received a prescription vial that had been previously returned to stock. The patient's prescription was for 90 tablets of **FLU**oxetine 20 mg. When the prescription bottle was close to empty, the patient realized that the label was for the correct drug but the wrong quantity (45 tablets) and was labeled as a "return-to-stock vial." The correct patient-specific pharmacy label had not been affixed to the prescription vial. The patient called the automated refill line to order more medication. When they entered the prescription number listed on the affixed label, the system indicated the prescription was for a different patient. Thankfully, this error did not result in any harm as the patient received the correct medication and dosage strength.

We wrote about an error and the potential vulnerabilities in RTS processes in our March 2017 issue. In that case, a pharmacist was verifying a prescription for rif**AMP**in 150 mg capsules. They noticed capsules with very slight differences in appearance when they opened the prescription vial to visually inspect the contents. Some capsules had different capsule markings. The prescription had been filled with rif**AMP**in 150 mg and rif**AMP**in 300 mg capsules. It was thought that a previous prescription for rif**AMP**in 300 mg capsules had been returned to stock

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up to 24 months of age. Beyfortus is available in 50 mg/0.5 mL and 100 mg/mL single-dose prefilled syringes for intramuscular (IM) administration (**Figure 1**). See the prescribing information (www.ismp.org/ext/1235) for the recommended dose based on age, weight, RSV season, and for children who undergo cardiopulmonary bypass surgery. In October 2023, the Centers for Disease Control and Prevention (CDC) distributed an advisory from their Health Alert Network, *Limited Availability of Nirsevimab in the United States—Interim CDC Recommendations to Protect Infants from Respiratory Syncytial Virus (RSV) during the 2023–2024 Respiratory Virus Season* (www.ismp.org/ext/1276) with interim recommendations for those who should receive the vaccine. However, it is important to continually check the CDC website for the most up-to-date recommendations as to which patient population meets the current criteria for receiving immunization against RSV.

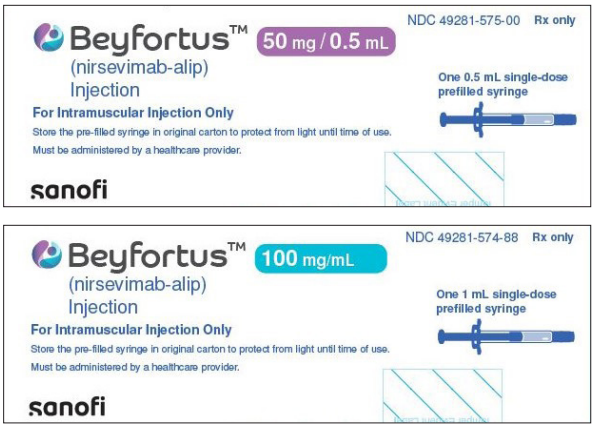

Figure 1. Beyfortus is available in 50 mg/0.5 mL (top) and 100 mg/mL (bottom) prefilled syringes.

Practitioners may already be familiar with **SYNAGIS** (palivizumab), which was approved in 1998. Like Beyfortus, Synagis is a monoclonal antibody but is only recommended for children less than 24 months with certain conditions that place them at increased risk for severe RSV disease (www.ismp.org/ext/1264). Synagis is available in 50 mg/0.5 mL and 100 mg/mL single-dose vials for IM use. The dose of Synagis is 15 mg/kg IM, given once a month throughout the RSV season, which typically lasts for about 5 months, meaning 5 doses are needed.

Adult RSV Products

In 2023, the FDA approved two vaccines for RSV prevention in adults. **AREXVY** (respiratory syncytial virus vaccine, adjuvanted) (**Figure 2**) is indicated for active immunization of adults 60 years and older. **ABRYSVO** (respiratory syncytial virus vaccine) (**Figure 3**) is for active immunization of pregnant individuals at 32 through 36 weeks gestational age, as well as individuals 60 years of age and older. Both Arexvy and Abrysvo need to be reconstituted and are administered IM as a single dose, currently without recommendations for revaccination with additional doses.

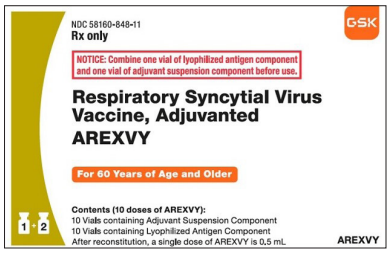

Figure 2. The Arexvy carton includes vials of lyophilized antigen (powder) and vials of adjuvant suspension (liquid). After reconstitution, a single dose is 0.5 mL.

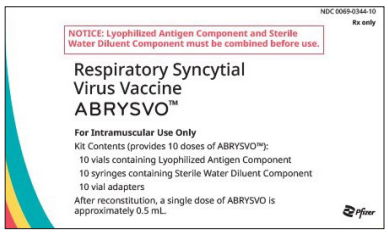

Figure 3. The Abrysvo carton includes vials of lyophilized powder, prefilled syringes containing sterile water diluent, and vial adapters. After reconstitution, a single dose is 0.5 mL.

Safe Practice Recommendations: Based on your patient population, determine which products should be available in your organization. Create order sets to guide practitioners in selecting the appropriate product and dosage based on the indication and the patient's age and/or weight. Patients may also receive other vaccines (e.g., influenza, coronavirus disease 2019 [COVID-19]) at the same time as Arexvy or Abrysvo, so clearly label prepared vaccine syringes (e.g., vaccine name, dose). Ensure barcode scanning is used prior to dispensing and at the time of administration. Educate staff about the differences in indication, preparation, and dosage. Confirm with the patient the product(s) they are expecting to receive.

>*Worth* repeating

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and added back into the manufacturer's bottle of rif**AMP**in 150 mg by mistake.

Given the recent error with a pharmacy's RTS process, we thought it was ***Worth* repeating** recommendations that can help prevent errors when returning medications to stock. Do not return medications into manufacturer stock bottles. Best practice calls for the pharmacy computer system to generate an RTS label that includes the drug name and strength, as well as a barcode that can be scanned during production and/or verification when used to fill a subsequent prescription. Enhance the RTS label by adding a description (e.g., tablet shape, color, imprint code) of the product. Conduct a visual inspection (i.e., verify the tablet appearance and markings) of the medication (if not in a sealed manufacturer bottle) to ensure it is the correct medication. Apply an RTS label to all vials or bottles of products that are returned to stock. Develop a process, ideally electronically, to include the medication's expiration date on the RTS label. When using an RTS bottle for a new prescription, transfer the medication to a new prescription vial and affix the patient-specific pharmacy label.

Call to Action! We want to learn more about your RTS process, including prescriptions dispensed by a robot, and any barriers you experience to generate an RTS label with a functional barcode. Please share your thoughts with us by sending an email to: medicationsafety@ecri.org.

To subscribe: www.ismp.org/node/126

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Report medication and vaccine errors to ISMP: Please call 1-800-FAIL-SAF(E), or visit www.ismp.org/report-medication-error. ISMP guarantees the confidentiality of information received and respects the reporters' wishes regarding the level of detail included in publications.

HITTING THE SAFETY HIGH NOTES

ISMP 26TH ANNUAL CHEERS AWARDS

Tuesday, December 5, 2023

House of Blues – Anaheim

Join us on Tuesday evening, **December 5, 2023**, at 6:00 pm for the ISMP 26th Annual **Cheers Awards** at the **House of Blues** in Anaheim. The awards will showcase medication safety stars who have set the tempo when it comes to developing innovative strategies that ensure progress.

You can help honor this year's **Cheers Award** winners by attending the awards dinner and/or supporting the event. Your participation helps bring attention to safety advances and enables ISMP to continue the core of its lifesaving work – preventing medication errors. For support opportunities and/or to register for the dinner, please visit: **www.ismp.org/node/83407**

Guest Speaker:
RaDonda Vaught, a former nurse who is a passionate advocate for system-based medication safety and second victims of errors

Lifetime Achievement Award Winner:
Susan D. Scott, PhD, RN, CPPS, FAAN
Nurse Scientist/Adjunct Associate Professor, University of Missouri Health Care/Sinclair School of Nursing

ISMP Activities at the 2023 ASHP Midyear Meeting

Workshop *(registration required)*

Thursday, November 30 & Friday, December 1
Medication Safety Intensive
7:30 am – 4:30 pm ET
Virtual format
To register, visit: www.ismp.org/node/76170

Symposium *(at Anaheim Convention Center North)*

Wednesday, December 6
Leveraging IV Robotics to Optimize Sterile Compounding Practices to Improve Safety
11:30 am – 1:00 pm PT, Doors open at 10:45 am
Room: 161, 100 Level
To register, visit: www.ismp.org/node/101371

Educational Sessions with ISMP Speakers

(at Anaheim Convention Center)

Sunday, December 3
2023 Health Technology and Patient Safety Hazards: Are You Playing at the TOP of Your Game?
4:00 pm – 5:00 pm PT
Room: 204b, Level 2

Tuesday, December 5
ISMP Medication Safety Update 2023
2:00 pm -3:00 pm PT
Room: 207b, Level 2

Wednesday, December 6
Look Outside! Safety Risks Outside the Pharmacy Walls
8:00 am – 9:15 am PT
Room: 204b, Level 2

Visit us at booth #621

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