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ISMP
An ECRI Affiliate

Acute Care
ISMP Medication Safety Alert!®
Educating the Healthcare Community About Safe Medication Practices

The dark side—Safety issues when protecting medications from light

Problem: The phrase, "protect from light," is poorly defined in prescribing information and many drug references. Inconsistencies exist in understanding what "protect from light" means and the necessary measures that should be taken during the various phases of the medication-use process. ISMP recently researched this topic to "shed more light" on it for our readers. Our findings and recommendations are presented below.

Types of light vulnerabilities

There are different types of light (e.g., the visible spectrum, infrared, ultraviolet) that can affect pharmaceutical products. Certain medications, such as biologics, chemotherapeutics, and protein-containing and -derived products (e.g., vaccines, immune globulin) are particularly susceptible to wavelengths from ultraviolet or blue light. Medications that require prolonged intravenous (IV) infusion time are also most vulnerable to light.

Few medications need protection from light during administration

We recently searched Lexicomp monographs for "protect from light" and found more than 800 results mentioning the phrase—sometimes referring to when being stored, sometimes during administration, and sometimes specifically for both. Of those, less than 2% specified that protection from light was needed during administration.

Light protection testing

According to the US Food and Drug Administration (FDA) *Guidance for Industry: Q1A (R2) Stability Testing of New Drug Substances and Products* (www.ismp.org/ext/1304), photostability testing is recommended during product development to determine appropriate manufacturing conditions and container closure systems. The FDA *Guidance for Industry: Q1B Photostability Testing of New Drug Substances and Products* (www.ismp.org/ext/1305) further recommends that it may be appropriate to test certain products (e.g., infusions) to support their photostability in-use. However, this is left to the manufacturer's discretion. Medication labeling often does not provide adequate information on the duration of light exposure that may result in medication degradation to assist practitioners in determining if medications require protection from light exposure during specific parts of the medication-use process (e.g., administration).

Light protection responsibility

Several light-protective mechanisms exist, such as foil-shielding blister packaging, amber vials, overwrap bags, and tablet film coatings. Some of these mechanisms are put in place by the manufacturer, while in other cases, pharmacy or the practitioner administering the medication may need to implement them to limit light exposure during each applicable step in the medication-use process. Without specific information, medications that degrade with short exposure to light may not be sufficiently protected. On the other hand, overuse of light-protective containers (e.g., bags, overwraps) that hinder the practitioner's ability to read the medication label, or other related processes (e.g., affixing labels with barcodes to the outer bag) can increase the risk of error.

continued on page 2 — Protecting from light >

Worth repeating...

RSV vaccines are not approved for children; Arexvy is not approved during pregnancy!

A ***Safety* brief** in our November 30, 2023 newsletter, *Do not confuse these respiratory syncytial virus (RSV) products* (www.ismp.org/node/110336), warned about the potential for mix-ups with the various RSV products now available. **BEYFORTUS** (nirsevimab-alip) and **SYNAGIS** (palivizumab) are monoclonal antibodies indicated for use in certain infants and children, while **AREXVY** (respiratory syncytial virus vaccine, adjuvanted) and **ABRYSVO** (respiratory syncytial virus vaccine) are indicated for use in certain adults. Both Arexvy and Abrysvo are indicated for active immunization of adults 60 years and older, but only Abrysvo is also indicated for pregnant individuals at 32 through 36 weeks gestational age.

ISMP has received reports in which pregnant women, between 32 through 36 weeks gestational age, have received injections of Arexvy instead of Abrysvo. At the time of the reports, no outcome data was available. In addition, a January 22, 2024 *Centers for Disease Control and Prevention (CDC) Clinician Outreach and Communication Activity, Information on Respiratory Syncytial Virus (RSV) Vaccine Administration Errors in Young Children and Pregnant People* (www.ismp.org/ext/1296), warned that several errors have been reported through the Vaccine Adverse Event Reporting System (www.ismp.org/ext/592) operated by the US Food and Drug Administration (FDA) and CDC. This includes 25 reports involving children younger than 2 years who received Abrysvo or Arexvy (adult vaccines), and 128 reports of pregnant women mistakenly getting Arexvy (not approved during pregnancy).

continued on page 2 — Worth repeating >

> Protecting from light — continued from page 1

Medication safety examples

Below are a few examples of medication safety issues reported to ISMP that involved protecting medications from light.

*A patient who was undergoing surgery began decompensating due to vasodilation. The patient was given a dose of **ADRENALIN** (**EPINEPH**rine) from a 1 mg/mL injection vial, with no clinical effect. A practitioner noted that the vial used, along with several others, were discolored, indicating degradation of the product. **EPINEPH**rine solution is light sensitive and deteriorates rapidly when exposed to light, turning pink, and then brown. **EPINEPH**rine vials are available in clear glass that may not protect the medication from light (**Figure 1**). A subsequent dose was administered from a vial of **EPINEPH**rine that was not discolored with good clinical response.*

Figure 1. Adrenalin (**EPINEPH**rine) 1 mg/mL injection by Par Pharmaceutical should be protected from light, but it comes in a clear vial.

*A patient was prescribed a ni**CAR**dipine infusion to control blood pressure, but a norepinephrine infusion prescribed for a different patient was accidentally administered. The pharmacy dispensed both infusions in brown opaque bags to protect them from light. The pharmacy system was set up to print two patient-specific labels with barcodes; one to affix to the compounded infusion, and the other to be placed on the brown bag. At some point, the IV bags were accidentally switched. The nurse who inadvertently administered norepinephrine to the patient reviewed the label and scanned the barcode on the brown bag prior to administration but did not notice a different patient's medication inside the bag. The patient recovered, but the organization reported that similar events have occurred.*

Safe Practice Recommendations: Organizations should consider the following strategies to safeguard medications that need to be protected from light.

Develop a "protect from light" list based on phases that require light protection. Review prescribing information, published literature, and drug information resources to identify medications on your organization's formulary that require protection from light during storage, preparation, and/or administration. Refer to resources such as *Hospital Pharmacy's Light-Sensitive Injectable Prescription Drugs—2022* (www.ismp.org/ext/1248), which includes a comprehensive list of medications that require protection from light during specific steps of the medication-use process. Ensure there is a process to routinely review the list as manufacturers and prescribing information are continually modified and updated. Include this designation on monograph templates for new formulary requests.

Evaluate light-protective products and usage. Bags available to reduce the amount of light transmission to medications have various opacities. Consider purchasing products (e.g., amber bags) that meet the requirements for light protection but allow practitioners to read the medication label through the bag and still have visibility of the inner product for monitoring the infusion during administration. For medications that are recommended to be stored in the original carton to "protect from light" until preparation, consider using amber-lidded bins to contain the vials if the carton is to be disposed of on receiving (e.g., disposal of the carton before stocking due to USP <800> policy/procedure).

Label the product directly. Practitioners should scan the manufacturer's barcode directly on the product to prevent the risk of a false positive barcode scan from a pharmacy-applied or patient label. If a pharmacy-generated label with a barcode is needed (e.g., compounded infusion), affix it

continued on page 3 — Protecting from light >

>Worth repeating

continued from page 1

Most events occurred in outpatient settings where barcode scanning prior to vaccine administration is often lacking.

The CDC communication also provides recommendations for practitioners who have administered incorrect RSV vaccine products to their patients. For children who are recommended to receive nirsevimab-alip but received either the Abrysvo or Arexvy vaccine in error, administer a dose of nirsevimab-alip. For pregnant patients who have received Arexvy in error, do not give them a dose of Abrysvo; instead, their infant (if younger than 8 months) should receive nirsevimab-alip during RSV season (October through March in most of the continental United States).

To prevent mix-ups with RSV products, we think it is ***Worth* repeating** the error prevention strategies presented in our previous article.

Based on your patient population, determine which RSV products should be available in your organization. Verify and document the patient's age and pregnancy status. Create order sentences to guide prescribers to the appropriate formulation based on the patient population (e.g., age, pregnancy status). Confirm that clinical decision support systems will provide an alert if a practitioner orders a vaccine for a patient in an age group or pregnancy status outside of its approved indication. Use barcode scanning to verify the correct vaccine and dose are being administered to the correct patient prior to vaccine administration. Expand barcode scanning beyond inpatient care areas to offer a greater layer of protection to ensure the patient receives the correct vaccine formulation, as recommended in the 2022-2023 ISMP ***Targeted Medication Safety Best Practices for Hospitals***, *Best Practice #18* (www.ismp.org/node/160). Store products separately and clearly label prepared vaccine syringes (e.g., vaccine name, dose). Educate staff about the differences in indication, formulation, and dosage. Involve the parent, caregiver, or patient in verifying the vaccine, formulation, and dose by reviewing the label to confirm the correct vaccine.

> **Protecting from light** — continued from page 2

directly on the product (e.g., syringe, infusion bag). Do not include barcodes on pharmacy-generated labels placed on the outer containers or bags to force scanning of the product.

Additionally, for drugs that require protection from light, FDA should consider revising labeling to require more detailed information on the duration of light exposure that may result in medication degradation to ensure appropriate light protection of medications during the medication-use process.

Special Announcement

Virtual MSI workshops

Join us for our first ***ISMP Medication Safety Intensive (MSI)*** workshop in 2024. The unique 2-day virtual program will be held **March 7 and 8, 2024**. Please visit: www.ismp.org/node/127.

ECRI top 10 health technology hazards for 2024

ISMP's affiliate, ECRI, recently released the ***Top 10 Health Technology Hazards for 2024*** (www.ismp.org/ext/1301). Now in its 17th year, ECRI's annual report identifies health technology concerns that warrant attention by patients, healthcare leaders, and industry. ECRI's team of biomedical engineers, clinicians, and healthcare management experts, along with ISMP medication safety experts, follow a rigorous review process to select topics for the annual list, drawing insight from incident investigations, reporting databases, and independent medical device testing. Below are the medication-related hazards included in the list.

Coming in at number three is how sterile drug compounding without the use of technological safeguards increases the risk of medication errors. Compounding errors that are not identified before the medication leaves the pharmacy have a high likelihood of reaching the patient. For this reason, we recommend implementing technological safeguards (e.g., intravenous workflow management systems) to minimize opportunities for human error in the sterile compounding process. For additional information, review the ISMP ***Guidelines for Sterile Compounding and the Safe Use of Sterile Compounding Technology*** (www.ismp.org/node/31362).

On the list at number eight, is how infusion pump damage remains a medication safety concern. Damage to an infusion device can impact its ability to control medication flow or communicate with other modules. Infusion pumps are routinely subjected to circumstances that can lead to damage, whether through mishandling, exposure to improper cleaning chemicals or methods, or normal wear and tear. The report can help healthcare providers identify signs of damage and reduce the likelihood of harm. A review of the ISMP ***Guidelines for Optimizing Safe Implementation and Use of Smart Infusion Pumps*** (www.ismp.org/node/972) and our recent newsletter article, *Smart infusion pump investigations after an unexplained over-infusion* (www.ismp.org/node/77008) can also help mitigate this concern within your organization.

SAFETY brief

Limit ketorolac therapy to 5 days. The nonsteroidal anti-inflammatory drug (NSAID) ketorolac, which is indicated for short-term acute pain, has a Boxed Warning to avoid exceeding 5 days of therapy, otherwise, serious adverse effects (e.g., peptic ulcer, gastrointestinal bleeding, perforation) may occur. One organization recently told us that a patient received a total of 85 doses of ketorolac over a 4-week timeframe. The organization's electronic health record (EHR) defaulted to an automatic stop time of 48 hours; however, prescribers continued to reorder the medication for additional doses. Fortunately, no harm was reported.

In a second report, a patient inadvertently received ketorolac for more than 5 days. Although the original order was discontinued, it fell outside of the hospital's 72-hour standard view timeframe in the EHR and was not visible to practitioners. Not being able to see the previous doses of ketorolac, and lacking any clinical alerts, a prescriber ordered a second course of ketorolac therapy.

To prevent this from happening again, the first organization is working with the EHR vendor to develop an alert to warn practitioners when a patient has received a total of 20 doses of ketorolac. The second organization has expanded its order view timeframe in the EHR so that practitioners can see previously administered doses and recently discontinued orders.

Review ketorolac order sentences to ensure appropriate limits are set. Check your EHR settings to determine how long discontinued orders are visible to practitioners Consider enabling a cumulative dose calculation, similar to those utilized for acetaminophen or chemotherapy, to alert practitioners if the maximum dose has been reached. Educate staff that ketorolac therapy should not exceed 5 days.

Editors: Shannon Bertagnoli, PharmD; Ann Shastay, MSN, RN, AOCN; Rita K. Jew, PharmD, MBA, BCPPS, FASHP; Editor Emeritus, Michael R. Cohen, RPh, MS, ScD (hon), DPS (hon), FASHP. ISMP, 5200 Butler Pike, Plymouth Meeting, PA 19462. Email: ismpinfo@ismp.org; Tel: 215-947-7797.