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Educating the Healthcare Community About Safe Medication Practices

Multiple error pathways with the monoclonal antibodies, casirivimab and imdevimab

PROBLEM: On November 21, 2020, the monoclonal antibodies, casirivimab and imdevimab (**REGEN-COV**), received initial Emergency Use Authorization (EUA) from the US Food and Drug Administration (FDA). The two monoclonal antibodies are authorized to be administered together for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults and children (12 years and older weighing at least 40 kg) with positive results of direct, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death. The monoclonal antibodies are not authorized for use in patients who are hospitalized due to COVID-19 or require oxygen therapy (or an increase in oxygen therapy if already receiving chronic oxygen therapy).

The EUA has been revised several times to address new safety information and to allow use for post-exposure prophylaxis of COVID-19 in adults and children (12 years and older and weighing at least 40 kg) who are at high risk for progression to severe COVID-19, including hospitalization or death, and are not fully vaccinated or are not expected to mount an adequate immune response to vaccination. The EUA also allows post-exposure prophylaxis in individuals at high risk of exposure to another person infected with SARS-CoV-2 in the same institutional setting (e.g., nursing homes, prisons). Under the current EUA, the monoclonal antibodies can be administered either subcutaneously or intravenously (IV). While the IV route is the preferred treatment route, either route is recommended for post-exposure prophylaxis. The subcutaneous route takes less time, facilitating administration and allowing for more widespread availability.

On September 23, 2021, we wrote about the possible confusion with a new alternative packaging for casirivimab and imdevimab (www.ismp.org/node/28427). Due to high demand for the monoclonal antibodies, Regeneron (manufacturer of REGEN-COV) is distributing co-packaged cartons of the antibodies that are manufactured by Regeneron's development partner, Roche Pharmaceuticals. The Roche co-packaged products are for distribution outside the US and use labeling that differs from Regeneron's other REGEN-COV products. In the article, we warned about possible confusion with the foreign Roche label because it lacks a National Drug Code (NDC) number, the product is labeled "For Pandemic Use" instead of "For EUA Use," and a barcode may not be present or functional. We also warned about confusion among the various presentations of the product.

Available Product Presentations

Currently, casirivimab and imdevimab are available in the US in a **co-formulated** vial containing both casirivimab and imdevimab together in the same vial, **co-packaged** in cartons containing one vial of casirivimab and one vial of imdevimab, and in **Dose Pack bags** containing individual vials of casirivimab and imdevimab (**Table 1**, page 2).

Risk of Errors

We are hearing that many nurses have been tasked with selecting these monoclonal antibodies from automated dispensing cabinets (ADCs) to prepare and administer them. Furthermore, the locations where casirivimab and imdevimab are administered (e.g., infusion

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SAFETY wires

Age-related COVID-19 vaccine mix-ups. Ever since the US Food and Drug Administration (FDA) authorized the emergency use of a specific formulation (10 mcg/0.2 mL) of the Pfizer-BioNTech coronavirus disease 2019 (COVID-19) vaccine for children ages 5 through 11 years, reports of mix-ups with the Pfizer-BioNTech COVID-19 vaccine formulation intended for individuals 12 years and older (30 mcg/0.3 mL) have been pouring in. Based on reports sent to us that involve hundreds of children, and the fact that adverse event reporting programs are known to receive only a fraction of actual cases, it's likely that many thousands have been impacted. Some children ages 12 and older received the formulation intended for children 5 to 11 years, resulting in underdoses. Other children ages 5 to 11 years received the formulation for individuals 12 years and older, which resulted in overdoses.

Figure 1. The vaccine vial label for ages 5 through 11 years has an orange border, and the vial (not pictured) has an orange cap.

Some errors are due to vial or syringe mix-ups. The label on the pediatric formulation states: "Age 5y to < 12y" (**Figure 1**), but this information is not as prominent as the instructions to "**DILUTE PRIOR TO USE**" and could be easily missed. Surprisingly, only the injection volume is listed on Pfizer-BioNTech COVID-19 vaccine labels. The dose in mcg is not listed, which would have been helpful in differentiating this product from the 30 mcg/0.3 mL formulation for patients 12 years and older. The 30 mcg/0.3 mL adult formulation vial has a purple cap,

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centers, clinics, emergency departments, long-term care facilities, prisons) are extremely busy, and staff are often rushed, increasing the risk of an error. Under these conditions, we have received numerous reports of confusion, as well as actual errors. Most of the errors are associated with preparing and administering only one component of the two monoclonal antibodies, or prescribing, preparing, and/or administering the wrong dose. Common causes of confusion and examples of the error reports we received are summarized below.

Common Causes of Confusion and Errors

Prescribing errors. The monoclonal antibodies have been prescribed using an ambiguous dose designation of "600 mg" instead of the recommended "600 mg of casirivimab and 600 mg of imdevimab" (or "300 mg of casirivimab and 300 mg of imdevimab" for certain post-exposure prophylaxis circumstances). A common contributing factor associated with these prescribing errors is misleading order entry fields that do not make it clear that

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Table 1. Casirivimab and imdevimab packaging presentations

Presentation	Image	Contents
Co-formulated product in a single vial (REGEN-COV)		One single 10 mL vial contains 600 mg of casirivimab and 600 mg of imdevimab co-formulated (60 mg/60 mg per mL)
Co-packaged carton with one vial of casirivimab and one vial of imdevimab*		Two vials per carton: One vial of casirivimab One vial of imdevimab Co-packaged cartons include either 2.5 mL vials (300 mg each) **or** 11.1 mL vials (1,332 mg each) Concentration of the product in each vial is 120 mg/mL
Dose Pack bag with individual vials of casirivimab and imdevimab (REGEN-COV)		Contains two, five, or eight cartons, providing at least a total of 2,400 mg of casirivimab and imdevimab (1,200 mg of casirivimab and 1,200 mg of imdevimab) and a one-page informational document† Concentration of the product in each vial is 120 mg/mL

* *The co-packaged cartons are manufactured by Regeneron's development partner Roche Pharmaceuticals and are being distributed by Regeneron to increase the availability of doses of casirivimab and imdevimab.*

† *The included one-page informational document contains inaccurate dosing information per the current Health Care Provider Fact Sheet. The QR code on the document can be used to obtain the most current Fact Sheet.*

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while the 10 mcg/0.2 mL pediatric formulation has an orange cap. While different color caps might help prevent some mix-ups, once the cap is removed and discarded, doses may be prepared one at a time rather than all at once, which will render the cap color irrelevant. Also, it is unlikely that the vial will accompany prepared syringes, so the vial label cannot be verified by those administering the vaccine or parents/patients receiving the vaccine.

In other errors, healthcare providers incorrectly thought it was acceptable if only 10 mcg of the formulation intended for individuals 12 years or older was administered to children 5 to 11 years, either as 0.1 mL (10 mcg) or by diluting the 10 mcg dose in a syringe to 0.2 mL. Neither method would be correct, though, since the pediatric vaccine is specifically formulated to be less concentrated to ensure accurate measurement. Withdrawing 0.1 mL of the 30 mcg/0.3 mL vaccine in a 1 mL syringe will result in an inaccurate volume, as it is recommended that no less than 20% of the nominal syringe capacity is measured. Also, if needles are changed between preparation and administration, some of the 0.1 mL dose would likely be lost to dead space in the needle. If a 0.1 mL dose is drawn up and the same needle and syringe are used to draw up a 0.9% sodium chloride diluent, then any vaccine occupying the dead space of the needle and syringe hub would be drawn into the syringe as it is pulled back to withdraw the diluent. Depending on how evenly the vaccine is distributed in the syringe, this could result in too much or too little vaccine reaching the patient upon injection.

The media reported that some parents have expressed vaccine hesitancy after hearing about these COVID-19 vaccine errors (www.ismp.org/ext/804). We certainly do not want mix-ups between these vaccine formulations to raise concerns even more.

If clinics, physician practices, and/or pharmacies in your health system will be administering adult and pediatric COVID-19 vaccines, develop a plan for segregating and storing these in refrigerators and

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600 mg (or 300 mg) of EACH monoclonal antibody is required for appropriate dosing. Based on error reports we have received, a knowledge deficit about the recommended dose has infrequently been an underlying cause of prescribing errors.

Selection errors. Organizations may not have a choice of which product presentation they receive. Thus, given the various presentations of the monoclonal antibodies and the fact that they are often stored together, selection errors among the different presentations have been occurring in both the pharmacy and in patient care areas where the antibodies might be prepared. For example, mix-ups between vials of the co-formulated antibodies and vials of the individual antibodies have been reported.

Preparation errors. Some preparation errors have been related to label confusion. Displayed on the front panel of the Roche label for the co-packaged cartons containing 2.5 mL or 11.1 mL vials of casirivimab and imdevimab is "2 vials of 6 mL" or "2 vials of 20 mL," respectively (see the red arrows on the images in **Table 1**, page 2), which refers to the vial size, not the contents of each vial or the sum of the two vial contents. Confusion about the volume in each vial could lead to preparation of incorrect doses. ISMP has received several reports regarding this particular label confusion. One reported error involved a pharmacy technician who withdrew the contents of both casirivimab and imdevimab from the Roche co-packaged 2.5 mL vials. Upon discovering that the total volume was only 5 mL instead of 6 mL (which was listed on the front label panel), the technician thought she did not have enough medication to prepare a 600 mg total dose (300 mg of each monoclonal antibody) for repeat dosing intended for post-exposure prophylaxis.

Confusion has also been reported regarding the total contents of the 10 mL vial of the co-formulated monoclonal antibodies. Some have mistakenly thought that the co-formulated product contains 300 mg of each antibody (600 mg total), when it actually contains 600 mg of each antibody (1,200 mg total). In one reported error, a nurse retrieved the co-formulated product and misunderstood "600 mg/600 mg per 10 mL" on the label to mean that each 10 mL vial contained 600 mg in total (300 mg of casirivimab and 300 mg of imdevimab). She then retrieved a second vial of the co-formulated product and mixed the two 10 mL vials in a 100 mL infusion bag of 0.9% sodium chloride injection, thus administering an overdose. Confusion has also been reported regarding whether each vial contains the co-formulated monoclonal antibodies (both antibodies) or contains a single antibody.

Errors related to the various instructions for preparation following Regeneron's *Fact Sheet* (www.ismp.org/ext/779) have also been reported. For the recommended IV infusion route of administration, a 10 mL (600 mg/600 mg) vial of the co-formulated product, or 5 mL of casirivimab (600 mg) and 5 mL of imdevimab (600 mg) from individual antibody vials, must be injected into a 50 mL, 100 mL, 150 mL, or 250 mL, single 0.9% sodium chloride or 5% dextrose infusion bag, each with a different minimum infusion time and the 50 mL bag with a different rate of infusion. We have heard about nurses who have prepared each monoclonal antibody in a separate infusion bag, rather than preparing them together in a single bag. We also learned about a nurse who selected two of the 2.5 mL vials of imdevimab (each labeled 300 mg/2.5 mL) and prepared and administered them without the casirivimab component, misunderstanding the "600 mg" dose designation that was listed on the patient's medication administration record.

The various presentations of these monoclonal antibodies, and the fact that some co-packaged dose packs contain enough product for two full doses instead of just one full dose, increases the risk of an error. Also, we are not confident that vials of the monoclonal antibodies that are stored under refrigeration are consistently being brought to room temperature as directed for 20 minutes prior to dilution or subcutaneous injection.

For administration by the subcutaneous route, different preparation directions are provided in the *Fact Sheet*. If using a casirivimab and imdevimab co-formulated 10 mL vial, four

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freezers that are organized and properly labeled. Store the adult (12 years and older) and pediatric COVID-19 vaccines apart from one another, such as in separate labeled plastic bins. Make it a policy to clearly label all individual syringes containing vaccines. To facilitate proper labeling, the pharmacy should print labels for each patient or provide vaccine preparers with strips of preprinted labels that differentiate adult and pediatric doses. Ideally, prior to administration, barcode scanning should help confirm the correct vaccine again.

Also, only bring the intended and labeled vaccine syringe(s) for one patient into the vaccination area at a time. Although it may impact efficiency, involve the parent or patient in verifying and confirming the correct vaccine by reading the label aloud, which will go a long way to alleviate fears. Document the lot number and date of manufacture prior to vaccine administration. Then document administration afterwards in the patient's profile, on vaccination records, and via state or other immunization registries. Report all vaccine errors internally as well as externally to the FDA/CDC (Centers for Disease Control and Prevention) Vaccine Adverse Event Reporting System (VAERS, https://vaers.hhs.gov/), which is mandatory for COVID-19 vaccine errors under an Emergency Use Authorization (EUA). ISMP also asks providers to report vaccine errors to the ***ISMP National Vaccine Errors Reporting Program*** (ISMP VERP; www.ismp.org/VERP). Additional vaccine information can be found at: www.cvdvaccine-us.com, and in the latest vaccine *Fact Sheets* (www.ismp.org/ext/803, www.ismp.org/ext/813).

Safe use of parenteral nutrition. The American Society for Parenteral and Enteral Nutrition (ASPEN) has published recommendations on the safe use of lipid injectable emulsions (ILEs). Part 1 of this two-part series (www.ismp.org/ext/807) provides a comprehensive review of ILEs and considerations for use in adult patients, while part 2 (www.ismp.org/ext/808) focuses on neonatal- and pediatric-specific information. ASPEN also has published a position paper

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separate syringes (2.5 mL each) must be prepared for 600 mg of casirivimab and 600 mg of imdevimab (or two syringes for 300 mg doses of each antibody). If using casirivimab and imdevimab individual vials, two separate syringes (2.5 mL each) must be prepared for both casirivimab and imdevimab (a total of four syringes) to provide a 600 mg dose of each antibody (or one syringe of each for a total of two syringes for 300 mg doses of each antibody). While we have not received error reports regarding preparation of the monoclonal antibodies for the subcutaneous route of administration, we worry that errors might be occurring and syringes might not be labeled during preparation in patient care areas.

Administration errors. Most of the reported administration errors we received have been noted above (e.g., wrong doses, administering just one monoclonal antibody instead of both, wrong rates of infusion [dependent on bag size]). We have also received reports where the four syringes prepared for subcutaneous administration were administered at the same injection site instead of different injection sites as recommended. It is also unclear how the most up-to-date information in the current casirivimab and imdevimab *Fact Sheet* is being conveyed to frontline practitioners who prepare and administer the monoclonal antibodies, particularly since the *Fact Sheet* has been revised multiple times.

SAFE PRACTICE RECOMMENDATIONS: To reduce the risk of errors when prescribing, preparing, dispensing, or administering casirivimab and imdevimab, consider the following:

Clarify dosing during order entry. In order entry systems and on standardized order sets, make it clear that 600 mg (or 300 mg under certain conditions) of each antibody is required for appropriate dosing. Consider requiring the entry of an indication (e.g., treatment, post-exposure prophylaxis, repeat dose of post-exposure prophylaxis) and default to the appropriate dose based on the indication.

Require pharmacy preparation. Whenever possible, outside of emergencies, have the pharmacy prepare and label patient-specific subcutaneous doses and IV infusions of the monoclonal antibodies, and dispense them to the appropriate patient care areas. If practitioners must prepare the doses in patient care areas, provide them with clear preparation instructions and preprinted labels for the subcutaneous syringes and the IV infusions.

Update EHRs with current information from the *Fact Sheet*. While it is not easy, for all EUA drugs, including casirivimab and imdevimab, it is important to assign an individual to regularly check the *Fact Sheets* for the most current information and to keep all electronic health record (EHR) systems updated with the most current information so it is readily available to all frontline practitioners. If questions arise, it is equally important for all practitioners prescribing, preparing, dispensing, and administering casirivimab and imdevimab to refer to the current *Fact Sheet* in case it has been revised. Revision dates and recent major changes are described within the first few pages of the *Fact Sheet*. Do not use the dosing and administration information on the one-page document in the Dose Packs because this information is not current.

Create separate storage. Separate the different presentations of the monoclonal antibodies in sequestered storage containers in the refrigerator and other storage locations, and clearly label each storage container. Consider packaging each complete dose in a separate, labeled, clear plastic bag.

Use auxiliary warnings. Include bold, colorful, critical warnings on the product storage containers and on electronic screens or menus where these products are listed, based on the type of errors that have been reported. At a minimum, consider using these auxiliary warnings: "**Co-formulated casirivimab and imdevimab**," "**Co-packaged casirivimab and imdevimab** (must be **administered together**)," and "**Dose Pack** of **casirivimab and imdevimab** (must be **administered together**)."

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covering recommendations for photoprotection of parenteral nutrition (PN) for premature infants (www.ismp.org/ext/809). The paper reviews the scientific literature on the formation of quantifiable peroxides and other degradation products when PN admixtures and ILEs are exposed to light and reports of adverse clinical outcomes in premature infants subjected to light-exposed PN. Recommendations are provided for photoprotection of PN admixtures and ILEs along with challenges in achieving complete photoprotection with the equipment, supplies, and materials currently available in the US. In addition, there is an invited commentary (www.ismp.org/ext/810) on the international perspective on photoprotection.

Labeling of transdermal scopolamine products. A pharmacist was replacing transdermal scopolamine in an automated dispensing cabinet (ADC) and noticed that the replacement product (from Perrigo) expressed the amount of drug in terms of how much was released over 3 days (1 mg/3 days). In the past, the transdermal scopolamine product they had purchased (from Sandoz) had been labeled in terms of the total amount of scopolamine contained in the patch (1.5 mg) (**Figure 1**). Also, the hospital's electronic order entry system listed transdermal scopolamine as 1.5 mg and displayed this amount on the medication administration record (MAR) and the ADC screen, which is inconsistent with the current package labeling from Perrigo. The pharmacist thought that perhaps this was a new strength of scopolamine, but he noticed that online drug references such as *Lexicomp* and *Micromedex* indicate that a 1.5 mg

Figure 1. TRANSDERM SCŌP (scopolamine) on the left (Sandoz) lists the strength as total drug content (1.5 mg), while a generic product on the right (Perrigo) expresses the strength by release rate (1 mg/3 days), as per an FDA draft guidance.

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Reduce confusion with the Roche co-packaged product. If you receive the Roche co-packaged monoclonal antibodies, educate staff about the label differences. Also, before product use, either place (if absent) or replace the barcode on the product with a pharmacy-prepared barcode, or test any available barcodes on the product and manually input the product information, including the NDC number, into your EHR system to ensure the barcodes do not provide incorrect information when the product is scanned. If questions arise, ensure staff know to reference the *Fact Sheet* intended for US administration rather than the package leaflet in the carton (which is not approved for use in the US and should be discarded). Also consider clarifying the volume of product contained in each vial using auxiliary labels.

Educate staff. Educate practitioners who prepare and administer the monoclonal antibodies, with a particular focus on the various presentations available, reported label confusion, the types of errors reported nationwide, and preparation and/or administration instructions from the most current *Fact Sheet*.

what's in a Name?

The "–penem" drug stem name

Medications with the suffix "–penem" belong to a class of beta-lactam antibiotics referred to as carbapenems (**Table 1**). These antibiotics are similar to penicillins and cephalosporins in that they kill bacteria by binding to penicillin-binding proteins. In addition, due to their similar structure to penicillin antibiotics, allergic cross-sensitivity is possible. Individuals with an allergy or sensitivity to penicillin need to be carefully screened before carbapenems are used.

Table 1. Carbapenems available in the US

Generic (BRAND) Name
ertapenem (**INVANZ**)
imipenem and cilastatin (**PRIMAXIN**)
imipenem, cilastatin, and relebactam (**RECARBRIO**)
meropenem (**MERREM**)
meropenem and vaborbactam (**VABOMERE**)

Carbapenems have a broad spectrum of activity and work well against highly resistant bacteria. Therefore, they are used for hospitalized patients with more severe infections or as a last-line treatment against a number of bacterial infections, including intra-abdominal, bloodstream, and skin and soft tissue infections; pneumonia; and complicated urinary tract infections.

Carbapenems are poorly absorbed if given via the oral route, so they are administered intramuscularly (IM) or intravenously (IV). If ertapenem is administered IM, the drug needs to be reconstituted with lidocaine and administered deep into the gluteal muscles or lateral thigh. The IM route of administration is contraindicated for patients with a known hypersensitivity to local anesthetics. If ertapenem is administered IV, it should be reconstituted with sterile water or normal saline, diluted in a minibag, and dispensed by pharmacy for IV administration.

Caution should be used in patients with compromised renal function. Imipenem is rapidly inactivated by the kidneys and can be toxic. Therefore, it is combined with cilastatin, which helps to protect the kidneys by limiting renal metabolism of the drug. Relebactam and vaborbactam are beta-lactamase inhibitors used in combination with imipenem-cilastatin and meropenem, respectively. They help boost the efficacy of imipenem-cilastatin and meropenem by blocking the breakdown of the carbapenem by enzymes that are released from the bacteria.

After administering the first dose of a carbapenem, patients should be closely monitored for anaphylaxis. Common side effects of "–penem" drugs include injection site reaction, diarrhea, nausea, vomiting, skin rash, pruritus, and anemia. In addition, carbapenems can cause

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patch delivers 1 mg of scopolamine over 3 days.

This situation has the potential to confuse pharmacists and nurses. However, a US Food and Drug Administration (FDA) draft guidance (www.ismp.org/ext/774, lines 340-341) calls for the strength of transdermal products to be expressed as a rate (e.g., 1 mg/3 days), instead of the total drug content (e.g., 1.5 mg). FDA has been working to change all transdermal scopolamine product labeling to 1 mg/3 days rather than 1.5 mg.

Until the labeling of all transdermal scopolamine products displays the new strength expression and older stock has been exhausted, the potential for confusion will exist. Consider editing order entry systems, order sets, and MARs to indicate the drug delivery rate of 1 mg over 3 days, and during the availability of mixed labeling of these products, consider including a default note on the order that states, "1.5 mg = 1 mg/3 days."

what's in a Name? — continued from the left

central nervous system adverse effects including confusion, agitation, and seizures. They can decrease the serum concentration of valproic acid in patients requiring antiseizure medications, which increases the risk of breakthrough seizures. Thus, if the patient is taking valproic acid, alternative antimicrobial treatment should be considered.

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