ISMP
Institute for Safe Medication Practices
An ECRI Affiliate

Managing Medication Safety During the COVID-19 Pandemic and Learning from Errors

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World Health Organization
Global Patient Safety Network Webinar
Medication Safety: Implementing the Challenge

ISMP Mission

How does ISMP accomplish its mission?

Collect and Analyze	reports of medication-related errors and hazardous conditions
Disseminate	timely medication safety information
Educate	the healthcare community and consumers
Collaborate	with other organizations
Advocate	for the adoption of safe medication standards
Conduct Research	to provide evidence-based safe medication practices

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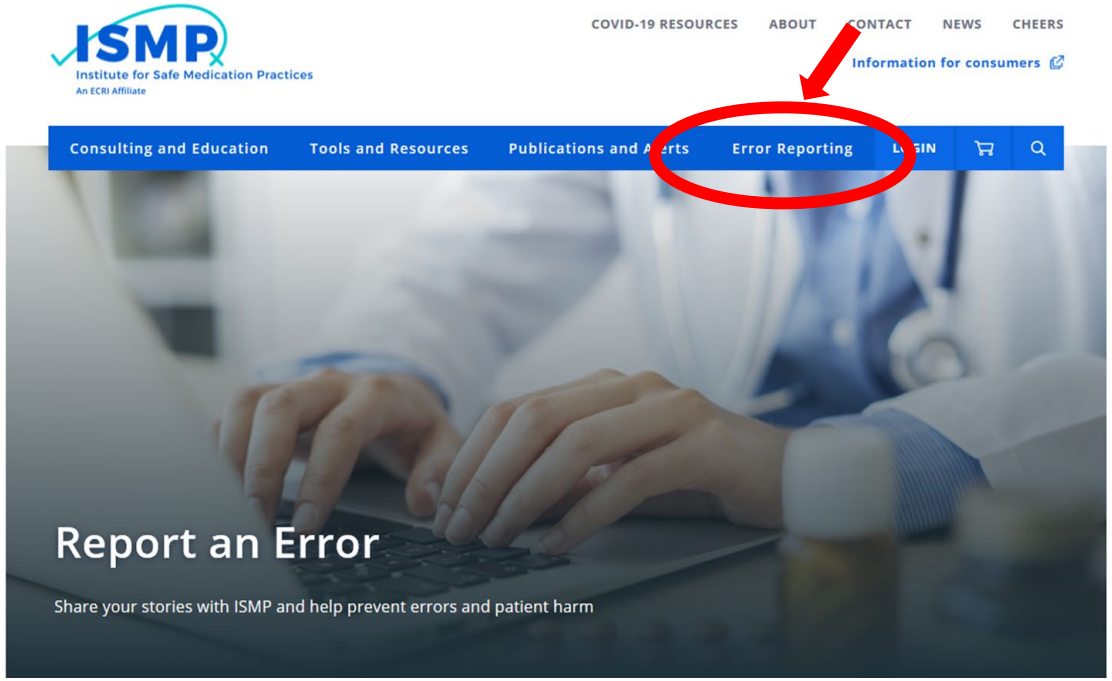
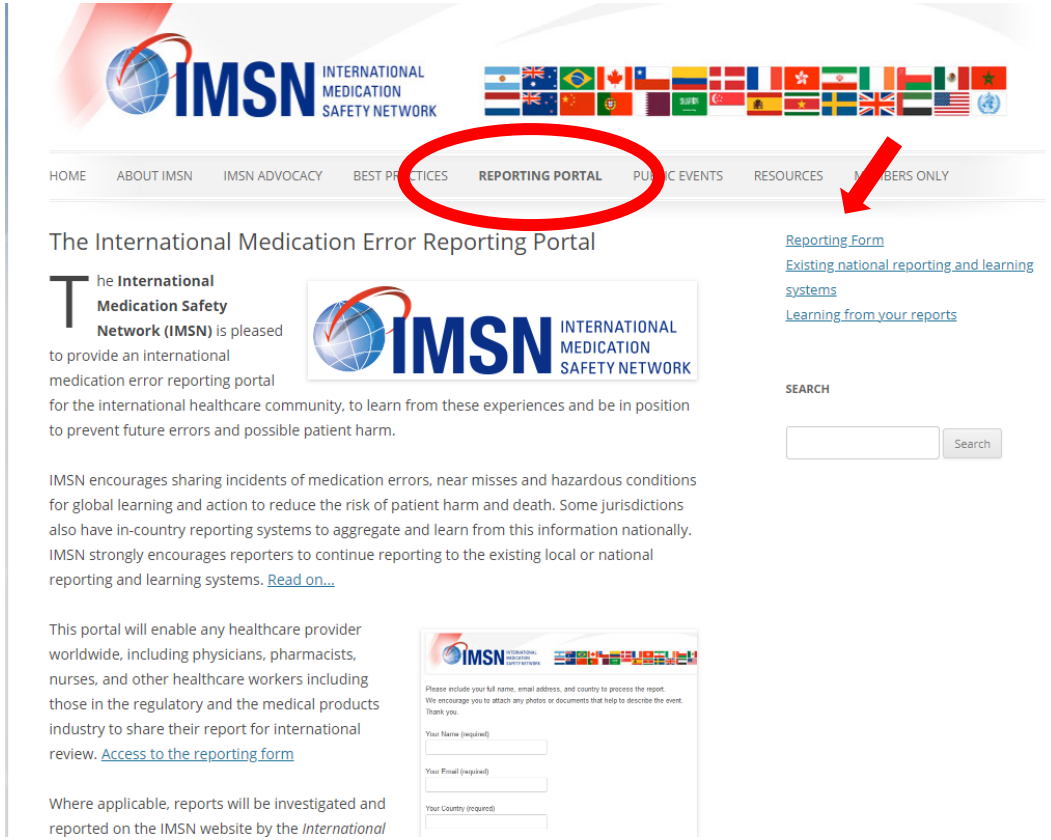
https://ismp.org/about/mission

Reporting Errors to ISMP

ISMP National Medication Errors Reporting Program



International Medication Safety Network Error Reporting Portal



https://ismp.org/report-medication-errorr
https://www.intmedsafe.net/the-international-medication-error-reporting-portal//

ISMP Medication *Safety Alert!* ® Newsletters

Managing Medication Safety During COVID-19

Once a Week

March 26, 2020 ▪ Volume 25 Issue 6

SPECIAL EDITION COVID-19

ISMP An ECRI Affiliate

Acute Care

ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

Revisiting the need for MDI common canister protocols during the COVID-19 pandemic

Patients infected with the coronavirus (COVID-19 virus) often require inhaled bronchodilator medications (e.g., albuterol, levalbuterol). Because nebulizer therapy with bronchodilators for presumptive or confirmed COVID-19 patients may not be safe due to the generation of aerosols, which increases the risk that respiratory droplets will remain in the air and spread the virus, delivery of these drugs via metered-dose inhalers (MDIs) is preferred. As a result, use of these inhalers has skyrocketed during the pandemic and there is concern about inhaler drug shortages. Supply chain disruptions are already being experienced in some areas, leaving some hospitals with just a few days supply. MDI canisters usually contain enough medication to last 2-4 weeks, while patients are often hospitalized for shorter periods, frequently leading to drug waste. As a result, hospitals are considering the best way to conserve MDI supplies.

Some organizations are asking patients to bring in a prescribed MDI to use throughout their hospitalization. Or, when the pharmacy dispenses an MDI for a specific patient, they are immediately labeling it for home use so the MDI can be sent home with the patient at discharge. Others are considering, or have implemented, a common MDI canister protocol as another way to address possible shortages. ISMP has been asked about our position on the latter topic.

In 2009, we published an article about the risks and benefits of using a common MDI canister, a patient-specific spacer, and a disinfection procedure between patients to administer doses from the same MDI to multiple patients (www.ismp.org/node/838). At that time, common canister policies were being utilized by respiratory therapists and nurses who disinfected the MDI after administering each dose, and then reused it for a different patient's dose, primarily as a cost-savings measure, not for conserving inhalers to help alleviate drug shortages. The common canister protocols called for disinfecting the mouthpiece with an alcohol prep pad before inserting it into a patient-specific spacer with a one-way valve (**Figure 1**, page 2), administering the medication, and then disinfecting the mouthpiece after use. In our 2009 newsletter article, we cited studies that

SPECIAL EDITION: COVID-19

Dear colleagues,

Has it really been only a few weeks since our world was turned upside down by COVID-19? It feels like a lifetime ago, as the entire world continues to respond to this global pandemic that demands strong leadership and every person's commitment to, and cooperation in, containment and mitigation. Our hearts and thoughts go out to all the people who have been affected by this unprecedented event. We especially want to recognize the hard work and dedication of all healthcare workers who are selflessly serving on the front lines of this public health emergency. We know that healthcare workers are often taking on additional risks to their own safety, and that of their families, given widespread shortages of personal protective equipment (PPE) and COVID-19 tests, as well as looming shortages of staff and hospital beds. We are also grateful for our colleagues in federal agencies, including the US Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC); they are all-hands-on-deck in this war against COVID-19. From all of us at ISMP, we sincerely thank every one of you for all that you do.

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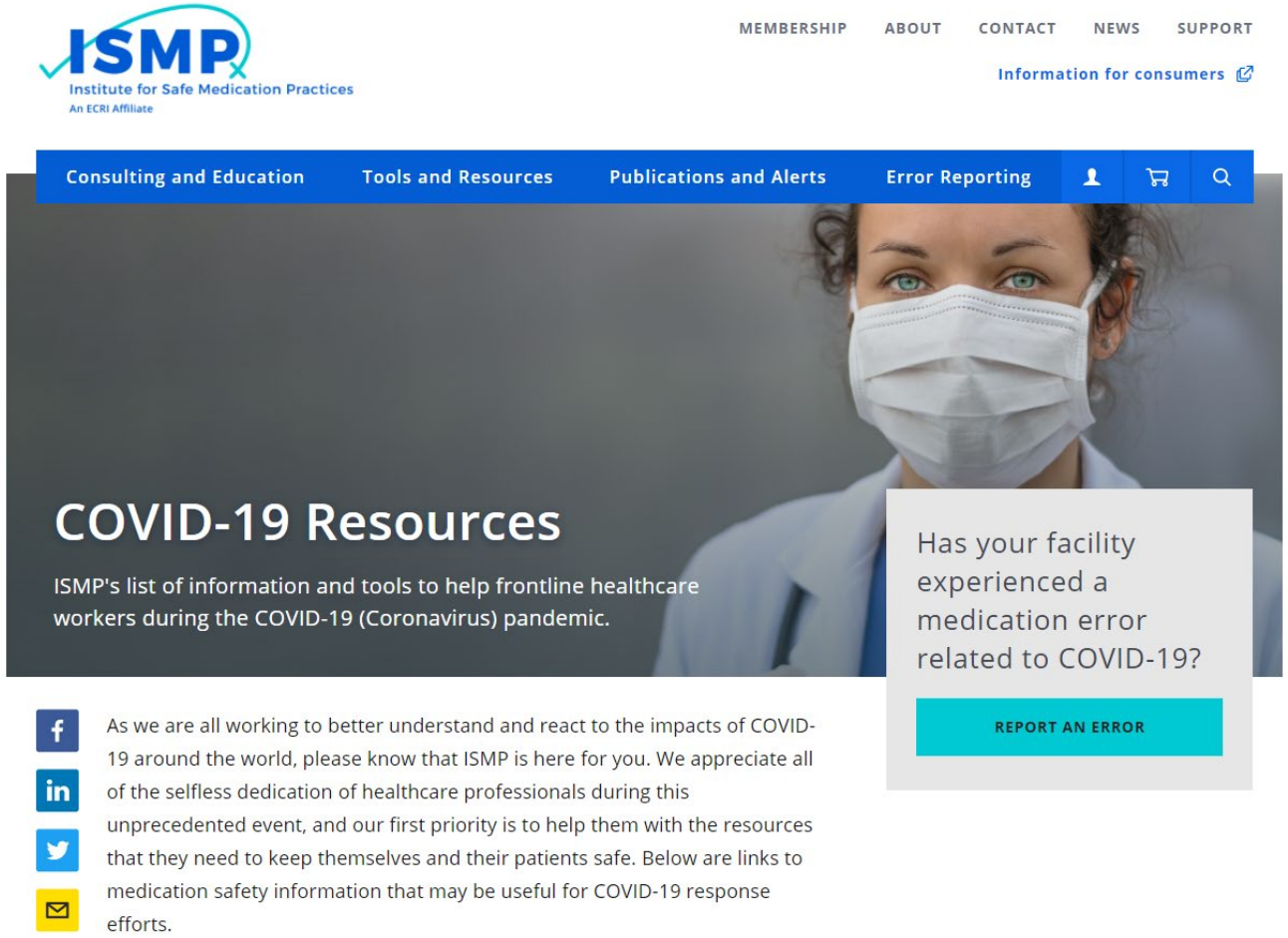
Managing Medication Safety During COVID-19

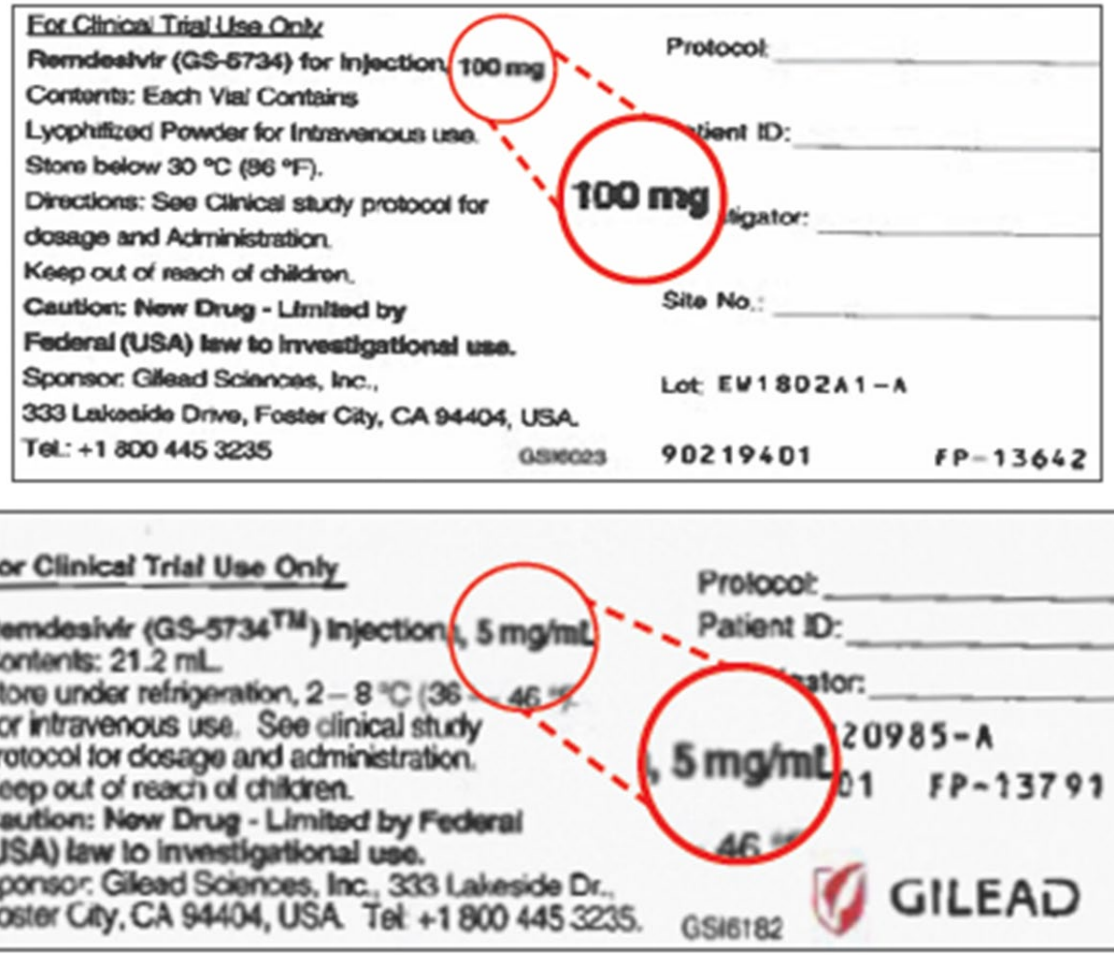


MSOS
at the Institute for Safe Medication Practices

Medication Safety Officers Society (MSOS)

https://www.ismp.org/covid-19-resources
https://www.medsafetyofficer.org/

Learning from COVID-19 Medication Errors



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Managing Medication Safety During COVID-19

- Many hospitals positioned infusion pumps outside of COVID-19 patients' rooms to conserve personal protective equipment (PPE) and reduce staff exposure

Managing Medication Safety with COVID-19 Vaccines

January 14, 2021 ▪ Volume 26 Issue 1

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Acute Care

ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

Learning from errors with the new COVID-19 vaccines

PROBLEM: In mid-December, the US Food and Drug Administration (FDA) granted emergency use authorization (EUA) to both the Pfizer-BioNTech and Moderna coronavirus disease 2019 (COVID-19) vaccines. Since then, ISMP has received numerous voluntary reports of COVID-19 vaccine errors or hazards through the ISMP National Vaccine Errors Reporting Program (VERP), the ISMP National Consumer Medication Errors Reporting Program (C-MERP), and via email correspondence from professional colleagues. (See the last recommendation on **page 5** regarding a mandatory requirement to report all COVID-19 vaccine errors and adverse reactions to the Vaccine Adverse Event Reporting System (https://vaers.hhs.gov). The following highlights a few of the missteps happening across the nation and internationally, from vaccine dilution errors to look-alike product mix-ups. There is much to be gleaned from these reports, as the same types of errors are likely happening globally, and similar risks exist in most settings. We conclude with safe practice recommendations to help prevent these types of errors in your practice setting.

Dilution Errors

Four dilution errors were reported with the Pfizer-BioNTech COVID-19 vaccine, which was granted EUA for immunization to prevent COVID-19 in individuals 16 years and older. After thawing, each Pfizer-BioNTech multiple-dose vaccine vial contains 0.45 mL, which must be diluted using 1.8 mL of preservative-free (not bacteriostatic) 0.9% sodium chloride injection. Once properly diluted, each vial contains 6, perhaps even 7, doses when using low dead-volume syringes/needles to extract each 0.3 mL (30 mcg) dose. The vaccine is administered intramuscularly (IM) as a series of 2 doses 3 weeks apart.

Dilution errors result in administering too much or too little vaccine. If you add too much diluent, doses may be ineffective; if you add too little diluent, doses may invoke stronger adverse effects (if one happens). In one reported case, mixing the vaccine with too little diluent was suspected when only 0.25 mL remained in the multiple-dose vial when attempting to access the fifth dose. As instructed in the *Fact Sheet*, the 0.25 mL of remaining vaccine was discarded (rather than pooled with excess vaccine from other vials). The previous four doses may represent overdoses.

According to a second report, an inadequate volume of diluent (approximately 1 mL) was added to the vaccine vial. Before the error was discovered, a 60-year-old patient received a nearly 2-fold overdose during his first vaccine dose. The patient had no initial reaction to the overdose and was discharged after an hour, with follow-up calls planned for the next 48 hours. Clinic staff called a Pfizer representative to determine if the patient's second vaccine dose should be altered, but no immediate guidance was offered.

The third dilution error was similar to the previous error in that only 1 mL instead of 1.8 mL of 0.9% sodium chloride injection was used to dilute the vaccine. Again, only one clinic patient received the nearly 2-fold overdose before the error was caught. No details were provided regarding the patient's response to the overdose.

In the last case, which happened internationally, eight healthcare workers in a long-term care (LTC) facility received the entire vial contents (0.45 mL), without dilution, for their first dose of the Pfizer-BioNTech vaccine. Four of the eight workers were hospitalized as a

continued on page 2 — Vaccine errors >

SAFETY briefs

Bamlanivimab confused with belimumab. Four residents at a long-term care (LTC) facility received 700 mg of belimumab (BENLYSTA) instead of the intended bamlanivimab intravenously (IV). Belimumab is indicated for patients with active systemic lupus erythematosus or active lupus nephritis who are also taking other lupus medications. Bamlanivimab was granted emergency use authorization (EUA) 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) who are at high risk for progressing to severe COVID-19 and/or hospitalization. This event began when a nurse at the LTC facility called the offsite pharmacy with orders but either mispronounced or misread bamlanivimab. The pharmacist heard belimumab, which he prepared and dispensed. The preparations were infused over 60 minutes, but no adverse reactions were reported for any of the residents.

There are several elements in common with belimumab and bamlanivimab. Each drug is added to a 250 mL intravenous (IV) bag of 0.9% sodium chloride injection. Other diluents may also be used with belimumab, but 0.9% sodium chloride injection is one of the recommended base solutions. Also, the dosages can overlap. The pharmacist did not question the dose of 700 mg for belimumab because it aligned with the patients' weights and it fell within a safe dosing range. Both are infused IV over 60 minutes. Bamlanivimab is available in 700 mg vials, while belimumab comes in 120 mg and 400 mg vials for IV use, and in a prefilled syringe or autoinjector for subcutaneous injection. In this case, the pharmacist processing the order was not familiar with either drug. Apparently, the preparations, labeled as belimumab, did not raise a red flag at the LTC facility, either. The incident occurred just as bamlanivimab use was increasing for patients with early

continued on page 3 — SAFETY briefs >

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https://www.ismp.org/resources/learning-errors-new-covid-19-vacciness

Managing COVID-19 Vaccine Safety Internationally

International Medication Safety Network

IMSN Covid-19 Vaccine Safety Interest Group (CVSIG) | International Medication Safety Network (intmedsafe.net))

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Learning from COVID-19 Vaccine Errors

- Dilution errors leading to under- or overdose of vaccine
- Air injected into vial instead of diluent; air injected into patient
- Storage issues (unsegregated vaccine brands in refrigerator)
- Wrong vaccine given for 2nd dose (not checking/documenting in immunization information system)
- Administration outside of age indications
- Waste of vaccine; not taking advantage of over-fill in vaccine vials
- Errors in scheduling 2nd dose
- Look-alike vials (vaccine-monoclonal antibody mix-up)
- Shoulder injury related to vaccine administration (SIRVA)

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Preventing Errors with COVID-19 Vaccines

- Verify competency of preparers and vaccinators (many are volunteers)
- Dispense pharmacy prepared and labeled syringes when possible, or one person prepares and administers
- For mass vaccination, utilize a standard, organized process with independent double checks
- Maximize doses withdrawn from vials
- Separate vaccines in storage
- Plan for leftover vaccine
- Be prepared for allergic reactions
- Report vaccine errors and adverse reactions (in-country reporting systems); additional reporting to ISMP is voluntary
- Utilize immunization information systems

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Thank You!

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