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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

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Limit use and protect supplies of unproven but widely prescribed COVID-19 treatment

There was an upsurge last week in prescribing hydroxychloroquine and chloroquine, both antimalarial agents, after review of several recently published studies. One study from China showed in vitro benefits of chloroquine against SARS-CoV-2, the virus causing COVID-19 disease (www.ismp.org/ext/359). Also, two uncontrolled clinical trials, one from China (www.ismp.org/ext/360) investigating chloroquine and another from France (www.ismp.org/ext/361) investigating hydroxychloroquine, showed benefit. Neither drug is approved by the US Food and Drug Administration (FDA) for this purpose. However, according to the Centers for Disease Control and Prevention (CDC), in some other countries, hydroxychloroquine or chloroquine is currently recommended for treatment of hospitalized COVID-19 patients (www.ismp.org/ext/362).

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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.

In light of these developments, ISMP implemented a remote work environment on March 16. During this time, the ISMP office is closed, but we remain open for business and any questions you may have, and we will continue to support you via phone calls, emails, and other technologies.

Please know that during this unsettling time, our number one priority remains you and ensuring uninterrupted delivery of the information and resources you need to safely care for your patients and yourselves. In that regard, starting with the March 26 issue, we will be publishing a SPECIAL EDITION of the *ISMP Medication Safety Alert!* focusing

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showed varying levels of bacterial contamination on disinfected mouthpieces, from no growth up to 5% with contamination.

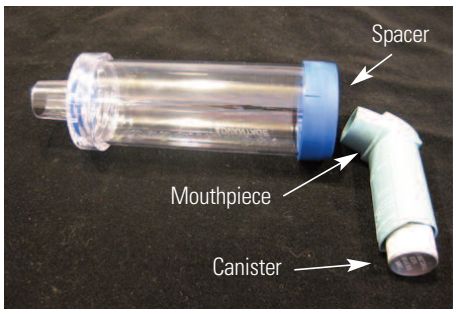

Figure 1. MDI with spacer device.

Deciding whether to implement a common MDI canister protocol during the COVID-19 pandemic requires thoughtful analysis and deliberation. Importantly, even in 2009, we pointed out three critical risk factors that still exist today: 1) Using a common canister may not be appropriate for patients on isolation precautions or for immunocompromised patients; 2)The methods used for disinfecting the mouthpiece (using alcohol wipes) in 2009 were aimed at preventing bacterial contamination, which would not be considered adequate for the COVID-19 virus; and

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Table 1. Components of a common MDI canister protocol from Spectrum Health Butterworth Hospital

Task	Component
Dispensing	New MDI is dispensed from the pharmacy or via an automated dispensing cabinet
	Nurses or pharmacy staff label the MDI for the specific patient when dispensed
Initiation	All patients prescribed an MDI medication receive a patient-specific spacer device
	Nurses or respiratory therapists (RTs) label the spacer device for the specific patient
Administration	Nurses or RTs attach the patient-specific MDI to the patient-specific spacer to deliver each dose
Storage	Labeled patient-specific spacer is stored in a plastic bag at the bedside between uses
	Labeled patient-specific MDI is stored in a plastic bag in the patient's medication storage bin
Discontinuation (or Discharge)	Nurses or RTs remove the patient-specific label from the MDI
Cleaning # 1	Nurses or RTs separate the canister from the plastic mouthpiece, thoroughly wipe the canister and plastic mouthpiece with appropriate disinfection wipes (www.ismp.org/ext/384) for 2 minutes
	After thorough MDI drying, nurses or RTs place the canister and mouthpiece back together, place the MDI in a clean plastic bag, and return it to an identified bin in the medication room for pharmacy pick-up
Pharmacy reuse assessment	MDI is returned to a designated area in the pharmacy (spacers are not reused or sent to the pharmacy; MDIs that have not been disinfected are not returned to the pharmacy)
	Pharmacy staff completes an assessment for re-dispensing (e.g., review of expiration dating, number of doses remaining on counter [MDIs with fewer than 5 doses are not re-dispensed])
Cleaning # 2	If MDI is appropriate to re-dispense, pharmacy staff re-cleans the canister and plastic mouthpiece using the same process as above
	Once cleaned, pharmacy places the canister and plastic mouthpiece back together, seals the MDI in a plastic bag with tamper-evident tape, and applies product labeling
Discharge	MDI used during hospitalization is not sent home with patients
	If appropriate, patient-specific spacers are sent home with patients

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only on information you may find helpful for further planning and discussion during the COVID-19 pandemic. Appreciating that our readers are likely struggling just to keep up with the rapidly changing conditions and information about this pandemic, we will refrain from publishing medication safety information external to this area of focus (unless communicating the risk is critical). The length and frequency of newsletters might vary, depending on the information we need to communicate. However, **at a minimum**, a SPECIAL EDITION *ISMP Medication Safety Alert!* will be published every other week on the same schedule.

We hope you understand our need to contribute only to the discussion around COVID-19 at this time. For more than 25 years, ISMP has lived by the enduring values to "empower the healthcare community," "disseminate timely information and tools," "educate the healthcare community," and "collaborate with others" to improve medication and patient safety. We feel these enduring values will guide us as we face the difficult challenge of responding to the COVID-19 pandemic together.

COVID-19 *Collaboration*

ISMP has received many questions related to medication safety during the COVID-19 pandemic. We have also been monitoring professional listservs, blogs, and social media to learn from frontline practitioners about the challenges they face and how they are being met. Our goal is to share these challenges and mitigation strategies with readers to stimulate discussion and assist with planning, as you likely will face similar challenges during this crisis. While ISMP is neither an expert in COVID-19 nor a regulatory or standards-setting organization, we will provide our thoughts on the challenges and shared mitigation strategies. Every organization is unique, with variable infrastructures and resources; thus, what works for one organization may not be feasible in another. Please follow the guidance from experts, regulators, and evidence-based medicine to make the best possible decisions.

Behavioral drift

Challenge: With the COVID-19 pandemic, healthcare workers are dealing with

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Please report medication safety challenges, ideas, and errors associated with COVID-19 to ISMP via email (ismpinfo@ismp.org), phone (215-947-7797), or online at: www.ismp.org/merp.

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3) Individual noncompliance with always following the mouthpiece disinfection protocol is a concern. Safer protocols used today call for dual cleaning between nursing or respiratory therapy and pharmacy to reduce the risk of individual staff noncompliance with disinfecting the mouthpiece. In addition, segregation of disinfected MDIs to delay their reuse and/or sterilization procedures are used in some hospitals before an MDI can subsequently be reused for another patient.

Unfortunately, ISMP is not in a position to develop timely guidelines for a common canister protocol or to endorse individual hospital protocols currently available or being considered. However, we have alerted the Centers for Disease Control and Prevention (CDC), the Association for Professionals in Infection Control and Epidemiology (APIC), and the American Association for Respiratory Care (AARC) about the need for clear guidance on this subject. Meanwhile, we recognize that many hospitals are facing a shortage of MDI bronchodilators.

Until such guidance occurs, we have provided a summary of the important components of an MDI common canister protocol recently developed by **Spectrum Health Butterworth Hospital** in Grand Rapids, MI, in response to the COVID-19 pandemic and the impending drug shortage (**Table 1**, page 2). We greatly appreciate the hospital's willingness to explore this topic with ISMP and share key components of its emerging protocol, which can be used by other hospitals to develop or review a similar protocol. Instead of disinfecting the MDI for reuse between doses, this hospital's policy calls for a dual disinfection process and reuse only after the MDI has been discontinued and/or the patient has been discharged.

If a decision is made to move forward with a common MDI canister protocol, we encourage organizations to carefully analyze the process being considered to prevent inadvertent sources of transmission and to emphasize in the protocol the importance of hand hygiene and dual canister disinfection. Organizations should consider excluding patients with presumptive and confirmed COVID-19 infection, or at least segregating common canisters used by presumptive and confirmed COVID-19 patients from those used for the general patient population. ISMP continues to encourage manufacturers to provide smaller "institutional" containers of MDIs to prevent unnecessary waste and lower the cost.

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Controversial use of hydroxychloroquine and chloroquine

Use of these drugs is still controversial because the results are not based on controlled clinical trials and thus lack solid evidence of safety and effectiveness. According to a *Bloomberg* news article this week (www.ismp.org/ext/382), there is even a small study showing no benefit (www.ismp.org/ext/383). However, hope was raised, perhaps prematurely, about the benefits of these drugs during a Presidential news conference last week, drawing public attention to the treatment and likely further increasing off-label prescribing. According to *The Washington Post* (www.ismp.org/ext/364), drugs have also been used prophylactically. Several state boards of pharmacy have limited prescriptions for the drugs, preventing prophylactic use. Prescriptions require a diagnosis and documentation of a positive COVID-19 test, and limits have been placed on the quantity dispensed. Some retail pharmacies are refusing to fill prescriptions unless there is a legitimate indication (e.g., lupus, malaria, rheumatoid arthritis, porphyria cutanea tarda).

Current clinical trials

According to the CDC, hydroxychloroquine is currently under investigation in clinical trials for pre-exposure or post-exposure prophylaxis of SARS-CoV-2 infection, and treatment of patients with mild, moderate, and severe COVID-19. In the US, several clinical trials of hydroxychloroquine for prophylaxis or treatment of SARS-CoV-2 infection are planned or will be enrolling soon.

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considerable stress and anxiety. They are routinely dealing with staffing issues, physical and psychological fatigue, and concern for their patients' health and their own well-being. They are encountering frequent distractions, time-urgent tasks, and constant system failures, such as lack of adequate personal protective equipment (PPE). Behavioral drift and violation of safety practices that would otherwise be normal operating procedures are concerns.

Shared mitigation strategies: One organization is measuring key critical, historically stable safety metrics to determine areas of behavioral drift that might benefit from coaching and reinforcement, such as compliance with engaging the drug library when infusing high-alert medications via a smart infusion pump. Another organization is using a messaging technique, STAR, to help staff remember to Stop, Think, Act, and Review before initiation of critical patient tasks.

ISMP thoughts: Behavioral drift during this unprecedented time is expected and most likely reflects the difficult decisions and creative solutions that staff must make to work around unfixable system failures on a daily basis to achieve the best possible outcomes for their patients. Without going to the trenches and living in their shoes, we should not harshly judge healthcare workers who violate safety practices under these circumstances, as many of these violations may be justified given current stressors. On the other hand, leaders and peers should not simply turn a blind eye to safety violations. With all that is happening, ISMP agrees with selecting just a few critical safety metrics that are currently under the control of staff, measuring their compliance, and using consistent messaging to coach staff to follow them. Leadership support, teamwork, and a sense of collective responsibility are important during the crisis.

Smart infusion pumps outside of rooms

Challenge: To reduce staff exposure to COVID-19 and conserve PPE, some organizations are situating infusion pumps closer to glass doors or windows (limiting entering the room), or outside of the patient's room using extension tubing (similar to extension tubing used in magnetic resonance imaging [MRI] suites without MR-conditional pumps).

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Hoarding, overdoses, and drug shortages

Unfortunately, there is a tendency to hoard medications in situations like this, and there may be some practitioners or managers who feel "entitled" to access the drugs. There were reports last week about prescribers ordering the drugs for themselves or family or friends, even though they may not have been diagnosed with COVID-19 and do not exhibit symptoms. Some may just want to keep the drug on hand in case they need it. That should not be allowed.

There were also several reports from poison centers about consumers self-administering the drugs in toxic doses. This has also been reported in other countries (www.ismp.org/ext/366). And, this week, in Arizona, one man died and his wife has been hospitalized after the couple, both in their 60s, ingested chloroquine phosphate, an additive commonly used at aquariums to clean fish tanks (www.ismp.org/ext/378).

Further complicating the situation, the American Society of Health-System Pharmacists (ASHP) announced there is a shortage of both drugs, with some manufacturers stating the products will be unavailable until next month.

Protocols for use and secure storage

We hope you have been working with infectious disease experts through your Pharmacy and Therapeutics (P&T) Committee to place restrictions on any remaining supplies of hydroxychloroquine and/or chloroquine, and to standardize the dosing. (ASHP provides a table with dosing information at: www.ismp.org/ext/380.) You should even consider locking up supplies of these (and other drugs associated with COVID-19 therapy) with your controlled drug inventory. We understand why these medications might be prescribed, but they are already scarce and may not even be available at your facility. The drugs may have benefits in treating COVID-19, but they need to be reserved for appropriate patients, including those who rely on them for treatment of rheumatoid arthritis, systemic lupus erythematosus, and porphyria cutanea tarda. A protocol approved by your P&T Committee containing patient criteria, use criteria, and standardized dosing will help appropriately limit access and prevent dosing errors.

Another combination: hydroxychloroquine and azithromycin

In the French study mentioned earlier (www.ismp.org/ext/361), patients received a combination of hydroxychloroquine and the antibiotic azithromycin to prevent bacterial super-infection. This was not a randomized controlled study, and the sample size was small, with many patients lost to follow-up. Nevertheless, researchers reported that all patients treated with the combined therapy were virologically cured according to their measures, compared to 57.1% of patients treated with hydroxychloroquine only, and 12.5% in the control group. So, practitioners are probably seeing patients prescribed this combination.

Keep in mind, patients taking this combination should have electrocardiogram (ECG) monitoring. While there is limited experience reported so far with patients taking this drug combination, post-marketing cases of life-threatening and fatal cardiomyopathy have been reported with the use of hydroxychloroquine and chloroquine. Ventricular arrhythmias and torsades de pointes have been reported, and drug labeling warns against administering these drugs with other drugs that have the potential to prolong the QT interval. Azithromycin itself may prolong the QT interval, so taking the drug in combination with hydroxychloroquine or chloroquine may enhance the overall QTc-prolonging effect. Patients with additional risk factors for QTc prolongation may be at even higher risk. Thus, patients taking this combination should be monitored for QTc interval prolongation and ventricular arrhythmias. Additionally, elderly patients with other serious underlying diseases, who are already vulnerable to complications from COVID-19 infection, may be at higher risk for cardiac and hepatic side effects from these agents. Also, there are other serious side effects and drug interactions for both drugs.

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Shared mitigation strategies: Organizations that are positioning pumps outside of patient rooms with long extension tubing recommend the following to verify the patient, reduce the risk of infections and tubing misconnections, and ensure medications and solutions reach the patient at the correct rate of infusion: 1) Implement a process for cleaning pumps that are moved from inside to outside a patient's room; 2) Establish criteria for allowing pumps to be positioned outside the room (e.g., not for insulin infusions as the medication adheres to the tubing); 3) Ensure all tubing is secure, unkinked, off the floor, and not a tripping hazard; 4) Implement IV push, secondary infusion, low-flow infusion, and flush administration processes that consider the dead space in long extension tubing and ensure the medications and solutions reach the patient in a timely manner at the prescribed rate; 5) Describe the process for barcode scanning of the medication/solution/pump, and how the patient will be verified.

Additional thoughts: Check with your pump vendor about administration via extension tubing. In 2015, ECRI published a guidance on the use of pumps in the MRI environment, which identified some additional concerns with using long microbore extension tubing on pumps: 1) Occlusion alarms may be delayed at low flow rates (<5 mL/hr); and 2) At high flow rates (>300 mL/hr), some pumps tested showed increasing resistance to fluid flow and were unable to operate due to frequent occlusion. Thus, it may be appropriate to exclude infusions at very low and high flow rates from being delivered by pumps with long microbore extension tubing. Also, there is concern about compromising the negative air flow in isolation rooms when a door is left open to accommodate the pump. In addition, we recently learned that some manufacturers' administration sets may require manual allocation to ensure equitable distribution. All pumps require proprietary administration sets to function correctly.

Other quick points of sharing

Swab shortage. Some organizations are no longer testing for influenza to conserve swabs needed for COVID-19 testing.

Facility smart pump shortage. Plan now for a potential internal shortage of smart infusion pumps as use skyrockets. Prioritize high-

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Worth visiting...

Most healthcare providers have already bookmarked the usual credible resources to help guide them to reliable information during the COVID-19 pandemic, such as the Centers for Disease Control and Prevention (**CDC**) (www.ismp.org/ext/371), the World Health Organization (**WHO**) (www.ismp.org/ext/372), their state and federal US Department of Health & Human Services (**HHS**) (www.ismp.org/ext/375), and the US Food and Drug Administration (**FDA**) (www.ismp.org/ext/373; www.ismp.org/ext/374). These sites are the primary resources, with the most accurate information, for preventing exposure and transmission as well as reporting, testing, and specimen collection during the pandemic.

The following highlighted resources are also ***Worth* visiting...**

ECRI COVID-19 Resource Center (www.ismp.org/ext/368)

This site includes a wealth of resources and tools, from webinars and podcasts to assessments and equipment (e.g., ventilator) evaluations, including information about supply chain equivalents for personal protective equipment (PPE), special alerts, and resources for aging services.

American Society of Health-System Pharmacists (ASHP) Coronavirus Disease 2019 (COVID-19) (www.ismp.org/ext/370)

This site includes invaluable ASHP resources for both members and nonmembers, including a recently uploaded *Assessment of Evidence for COVID-19-Related Treatments*, advocacy efforts on behalf of pharmacists, clinical trial enrollment information, sterile compounding recommendations, and links to many other credible resources.

UW Medicine COVID-19 Resource Site (www.ismp.org/ext/381)

UW Medicine (Western Washington state) has posted more than 70 of its evolving policies, procedures, protocols, and templates associated with the COVID-19 pandemic. Since the outbreak began in Washington in February 2020, local and national colleagues have been reaching out to this health system as they start to see cases. UW Medicine has shared a variety of administrative and clinical documents, including: screening and testing algorithms; clinical protocols for general and specialty areas (e.g., neonatal, critical care, emergency department, long-term care); PPE and respiratory equipment conservation policies; guidance on rescheduling patients, visitor restrictions, and telehealth; and so much more. The site provides contact information (covid19@uw.edu) inviting questions and recommendations.

Medication Safety Officers Society (MSOS) Forum (www.medsafetyofficer.org/)

Join more than 2,000 MSOS members (membership is **FREE**) on a discussion board to ask questions, share your thoughts and ideas, and learn more about the medication safety challenges facing practitioners during the COVID-19 pandemic.

If you would like to subscribe to this newsletter, visit: www.ismp.org/node/10

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alert medication infusions and high-risk patients that require their use and establish procedures and safeguards for any gravity-flow infusions that might be required (e.g., chart for calculating flow rates in drops). Don't forget to assess the effectiveness and efficiency of pump disinfection procedures to avoid delays in returning pumps to use. Follow manufacturers' guidelines to determine a safe and effective disinfectant to use.

Communication challenges. Remind healthcare workers that communication is challenging when wearing masks and to speak clearly and loudly so they can be heard by the intended recipient, including when necessary to communicate verbal orders. Remind recipients to read back verbal orders for verification (or repeat back in emergencies or under sterile conditions), spelling drug names and stating each digit of the dose separately (e.g., one-five instead of fifteen, which can sound like fifty).

Social distancing. Many organizations have restricted visitors and are using video conferencing, FaceTime, and other technologies to stay connected to caregivers. Some organizations have initiated virtual patient rounds using similar technologies. Organizations continue to find ways to allow healthcare workers to work remotely. Pharmacists are conducting remote order verification. Pharmacy technicians are collecting medication histories via phone interviews with patients, caregivers, and pharmacies. Some organizations have suspended their "meds-to-beds" programs or are counseling patients by phone.

Standardizing times. To minimize the number of times practitioners, especially nurses and respiratory therapists, need to enter a patient's room, assessment, treatment, and medication administration times have been standardized to coordinate time as much as possible. For example, heparin administration three times daily might be changed to enoxaparin daily, and docusate three times daily could be changed to the full dose daily.

Increase in alcohol withdrawal. Plan for a potential increase in the demand for alcohol detoxification/withdrawal treatment as access to alcohol becomes limited, with liquor stores and bars closing, and social distancing enforced.