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SPECIAL EDITION COVID-19

ISMP An ECRI Affiliate

Community/Ambulatory Care

ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

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

There has been an upsurge in prescribing hydroxychloroquine and chloroquine, both antimalarial agents, after review of several recently published studies. One study from China (www.ismp.org/ext/359) showed in vitro benefits of chloroquine against SARS-CoV-2, the virus causing COVID-19 disease. 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).

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. For example, earlier this month, researchers published the results of a small study (www.ismp.org/ext/383) showing no benefit. However, hope was raised, perhaps prematurely, about the benefits of these drugs during a Presidential news conference two weeks ago, drawing public attention to the drugs and likely further increasing off-label prescribing. According to *The Washington Post* (www.ismp.org/ext/364), the drugs have also been used prophylactically.

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 have also been reports 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, earlier this month in Arizona, one man died and his wife was 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.

State regulatory decisions

State governors and professional licensing boards are monitoring the prescribing and dispensing of hydroxychloroquine and chloroquine in response to concerns of

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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 your-

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inappropriate use and hoarding. In fact, many states 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). Make sure you are regularly checking for updated information from your state regulators.

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.

Protocols for use and secure storage

A protocol containing patient criteria, use criteria, and standardized dosing will help appropriately limit access and prevent dosing errors. ASHP provides a table (www.ismp.org/ext/380) with dosing information. Pharmacies may want to 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 location. 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.

Another combination: hydroxychloroquine and azithromycin

In the French study (www.ismp.org/ext/361) mentioned earlier, 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, which may be difficult or impossible to do on an ongoing basis in outpatient settings. 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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selves. In that regard, starting with the March issue, we will be publishing a SPECIAL EDITION of the *ISMP Medication Safety Alert!* focusing 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 monthly 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.

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 (www.ismp.org/ext/371), the World Health Organization (www.ismp.org/ext/372), their state and federal US Department of Health & Human Services (www.ismp.org/ext/375), and the US Food and Drug Administration (www.ismp.org/ext/373; www.ismp.org/ext/374). These sites are the primary resources, with the most accurate information, for preventing expo-

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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.

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 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

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

One organization is measuring key critical, historically stable safety metrics to determine areas of behavioral drift that might benefit from coaching and reinforcement. Another organization is using a messaging technique, STAR, to help staff remember to **S**top, **T**hink, **A**ct, and **R**eview before initiation of critical patient tasks.

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.

Communication challenges

Close, unobstructed, face-to-face communication poses risks with COVID-19. Physical distancing, installation of plastic or plexiglass barriers at pharmacy counters, and wearing masks make verbal communication more difficult. Additionally, some pharmacy organizations are recommending prescriptions only be communicated electronically or by telephone. The same goes for refills as patients are asked to not bring their old prescription vials into the pharmacy. It is essential to remind healthcare workers of the medication error risks with verbal communication and strategies to reduce those risks.

When taking orders over the telephone, the prescriber (or authorized agent) should be queried about comorbid conditions, allergies, date of birth, patient weight (if applicable), and purpose. Then, the prescription, purpose of the medication, patient's name and date of birth, and prescriber information should be read back to the prescriber or agent for verification. Spell drug names back to the caller and state numbers in digits

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sure and transmission as well as reporting, testing, and specimen collection during the pandemic.

The following 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.
- **IBM Micromedex and DynaMed COVID-19 Resource Catalog** (www.ismp.org/ext/389). Access the curated drug and disease content from IBM Micromedex and DynaMed in a single and comprehensive search. IBM Micromedex and DynaMed are providing free public access to their referential database for medication information as well as their peer-reviewed clinical content, including systematic literature reviews in 28 specialties for comprehensive disease topics, health conditions, and abnormal findings. Users will be able to access drug monographs, drug consults, disease monographs, and patient education materials.
- **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 asso-

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for strengths and doses when receiving spoken orders (i.e., 16 is stated "one-six," 60 is stated "six-zero"). Also, as the number of incoming telephone orders increases, the likelihood that prescribers will use the pharmacy's integrated voice response (IVR) system to communicate prescriptions increases. Consider adding prompts to the IVR system that direct the prescriber or agent to stop and spell all names (prescriber, patient, and drug) and sound out numbers. Finally, 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 communicating verbal orders.

Changes in prescription delivery and error prevention

To help protect their staff and patients while still fulfilling their mission to treat their patients, pharmacies are shifting delivery of prescriptions away from the pharmacy counter. Instead, they are using a drive-thru window (if the store already has one), curbside delivery, or home delivery, including via mail. While these strategies may be effective at maintaining physical distancing, they can make patient identification and patient education more difficult.

It is important to continue to use at least two patient identifiers—the patient's full name and full date of birth. Take steps to ensure this information is attached to prescriptions delivered by pharmacy staff to the curbside or the patient's home to enable staff to verify the patient's identity. When packaging prescriptions for home and mail delivery, implement a verification process to ensure only one patient's medications are packaged together and the delivery address on the shipping/delivery label matches the shipping address in the patient's profile. When enrolling patients into a delivery service, confirm the shipping address on file is correct. We have received reports in the past of deliveries sent to an outdated address as well as packages containing medications for a different (incorrect) patient.

Patient education at the point-of-sale will not be possible if prescriptions are delivered to a location outside of the pharmacy or if someone other than the patient obtains the medication(s). However, that does not mean patient education should be abandoned. A reasonable effort should be made to contact the patient directly to provide medication counseling (e.g., call the patient at home, place a written suggestion in or on the bag for the patient to call the pharmacy for counseling).

One of the most effective ways to intercept errors is to open the bag of filled prescriptions with the patient to verify that the medications are correct. While it may not be possible to do that at the pharmacy counter today, it is still important for patients to do this. Before the patient leaves the drive thru or the curb, have the patient open the bag in the car and conduct their own verification. If a friend or caregiver picks up the prescription or the prescription is delivered to the patient's home, the patient should be notified to open the package at home, check the contents before taking any of the medication, and call the pharmacist with any concerns or questions.

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ciated 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.

US Environmental Protection Agency (EPA) Disinfectants for Use Against SARS-CoV-2 (www.ismp.org/ext/384). This site includes a list (List N) of disinfectants that meet EPA's criteria for use against SARS-CoV-2, the virus that causes COVID-19 disease. The list includes each disinfectant's active ingredient, product name and company, amount of time the surface must stay wet (contact time) for disinfection, which disinfection and preparation directions to follow, and more. Disinfectants that meet EPA's criteria will have an EPA registration number that matches those on the list. The site links to CDC cleaning and disinfection recommendations for COVID-19.

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.

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

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