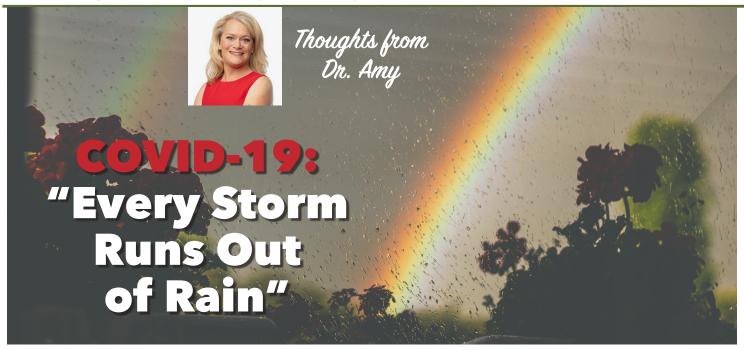
Heart GALK

Heart-healthy and Stroke-free Living with Dr. Amy L. Doneen, DNP, ARNP

April 2020



Paradoxically, as COVID-19 dominates the headlines The Guardian reports, "Never before have some many journalists cast around for silver linings. Never before has so much optimism been published — and read." Reports of good news emerging from the pandemic (some accurate and some not) are circulating on social media, and people are finding inspiration in song and poetry, including Maya Angelou's famous line, "Every storm runs out of rain."

What kind of progress is being made on the scientific and medical fronts? What are the most encouraging, positive and hopeful developments around the world as we battle this invisible enemy? Here's a look at some bright spots, great and small, and how the worst of the times is bringing out the best in people:

• Most people who get COVID-19 will recover. The <u>CDC estimates</u> that in many affected areas, about 99 percent of people with the virus survive and some have no symptoms at all. That 1 percent overall death rate is far lower than that of MERS (about 34 percent), SARS (about 11 percent) or Ebola (90 percent), but higher than seasonal influenza (0.1 percent), reports <u>Harvard</u> <u>Health</u>. Globally, more than 150,000 patients are reported to have recovered.

- A <u>103-year-old grandmother in</u> <u>China, a 102-year-old woman and</u> <u>a 101-year-old Italian man have</u> reportedly made full recoveries from the new coronavirus. Doctors have nicknamed the Italian woman, Italica Grondona, "Highlander — the Immortal," and say that she offers hope for all of the elderly facing the epidemic. The three centenarians were born around the time of the Spanish flu pandemic that ravaged the world in 1918.
- The first potential COVID-19 vaccine is now being tested on volunteers in Seattle. Scientists at the Kaiser Perma-

nente Washington Research Institute have started giving healthy volunteers the first doses of a potential coronavirus in an early-stage safety study with 45 participants. They will receive two doses of the experimental shot, given one month apart. One participant, Jennifer Haller, 43, a mom of two teens, <u>told PBS</u>, "This is an amazing opportunity for me to do something." A safety study of another potential vaccine, made by Inovio Pharmaceuticals, is expected to start in the U.S. and Asia next month — and dozens of other research teams around the world are also racing to develop COVID-19 vaccines.

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Are Malaria Drugs Hydroxychloroquine and Chloroquine an Answer to COVID-19?

n March 29, the Food and Drug Administration (FDA) granted an emergency use authorization for experimental coronavirus treatment with two anti-malaria drugs, hydroxychloroquine and chloroquine, stating that the potential benefits of the unproven therapy outweigh the risks for seriously ill patients. In a news release, the Department of Health and Human Services (HHS) stated that the drugs can "be distributed and prescribed by doctors to hospitalized teen and adult patients with COVID-19, as appropriate, when a clinical trial is not available or feasible."

HHS also stated that "anecdotal reports suggest that these drugs may offer some benefit in the treatment of hospitalized COVID-19 patient. Clinical trials are needed to provide scientific evidence that these treatments are effective."

Both of these oral medications can have serious side effects in patients who have certain heart conditions or take certain drugs, so it's important for medical providers to screen patients carefully before prescribing these medications. Moreover, the CDC warns against taking a toxic, nonpharmaceutical form of chloroquine that is used to clean fish tanks because it "can cause serious health consequences, including death." In countries where malaria drugs are available without a prescription, there are reports of poisonings in people who self-treated with these medications, which can be toxic if taken at even slightly higher doses than those prescribed for medical purposes. In the U.S., these drugs are only available by prescription and should only be taken under the supervision of a medical provider.

Here is a look at the latest research on the use of malaria pills as potential treatments for COVID-19 patients.

Does this mean that chloroquine and hydroxychloroquine are now the first FDA-approved drugs for COVID-19?

In its statement about the emergency use authorization (EUA), HHS emphasizes that, "there are no currently approved treatments for COVID-19," adding that when the Secretary of HHS declares that issuing a EUA is appropriate, "the FDA has the regulatory emergency use authority to facilitate access to unapproved medical countermeasures or unapproved uses of approved medical countermeasures... A EUA may be issued if the FDA determines that, among other criteria, the known and potential benefits of the product, when used to diagnose, prevent, or treat the identified disease or condition, outweigh the known and potential risks of the product, and there are no adequate, approved, available alternatives."

Also known as chloroquine phosphate and hydroxychloroquine sulfate, these medications have been FDA-approved for about 70 years for the treatment of malaria and are also approved to treat lupus and rheumatoid arthritis. Hydroxychloroquine (brand name Plaquenil) is also approved to prevent malaria. In advance of the EUA, a number of hospitals in the US have already added these drugs to their COVID-19 treatment protocols, and some doctors have started hoarding them, leading to shortage of the pills for people with lupus or arthritis.

For possible use in treating hospitalized COVID-19 patients or in clinical trials of treatments for the virus, German pharmaceutical company Sandoz has donated 30 million doses of hydroxychloroquine to HHS and Bayer Pharmaceuticals has donated 1 million doses of chloroquine (brand name Resochin). The HHS statement also says, "We'll continue working around the clock to get American patients access to therapeutics that may help them battle COVID-19, while building the evidence to evaluate which options are effective." Under the EUA, patients and providers must be given <u>fact sheets</u> describing the known risk and drug interactions of the medications.

Is there any scientific evidence that these medications help COVID-19 patients?

There have only been a few small studies reporting possible benefits. A letter from three Chinese scientists, published in <u>BioScience Trends</u>, hailing

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April Recipe

Frozen Vegetarian Chocolate Banana Sushi

Patients are often surprised — and delighted — when we "prescribe" a daily dose of dark chocolate (in small amounts) to enhance cardiovascular health. Studies suggest that compounds in dark chocolate called flavanols may reduce risk for heart disease and diabetes, reduce blood pressure, improve cholesterol levels and perhaps even improve brain health. Bananas are an excellent source of potassium, which also helps enhance heart health and reduce blood pressure.

This easy, no-bake, vegetarian frozen banana recipe offers a delicious way to satisfy your sweet tooth that the entire family is sure to love. It's filled with heart-healthy nutrients but is a bit high in calories and fat, so we recommend limiting yourself to one half-banana serving or less as a "treat" dessert for special occasions, not a daily indulgence. For a flavor variation, substitute other fruits of your choice for the bananas.

INGREDIENTS

- 4 firm, slightly underripe bananas, peeled
- 1/2 cup smooth nut butter (peanut, cashew, almond, sunflower seed)
- ¼ cup mini dark chocolate chips
- 1 cup puffed rice cereal (unsweetened)
- 1/4 cup chopped nuts, seeds, dried fruit or other toppings
- 2 teaspoons chia seeds (optional)

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chloroquine phosphate (another name for chloroquine) as a "breakthrough" states that the medication has shown "apparent efficacy and apparent safety against COVID-19 associated pneumonia in multicenter clinical trials conducted in China," based on results from "more than 100 patients." Compared to a control treatment, the malaria drug was reportedly superior for preventing the worsening of pneumonia, improving lung imaging findings, and shortening the disease course. The letter's authors attribute these findings to "a news briefing held by the State Council of China," NOT their own research.

A letter by nine Chinese scientists, published in *Cell Research* in February, reported that the team had compared



PREPARATION

In a small, shallow bowl, warm nut butter in the microwave for 30 seconds to soften and make it easier to spread. In another bowl, combine chocolate chips, cereal and nuts, seeds or dried fruit, and chia seeds, if using. Dip bananas into nut butter or spread it on the fruit with a spoon. Coat bananas with the chocolate chip/cereal/topping mixture, then allow bananas to set in the freezer for 10 minutes or in the refrigerator for 20 minutes. Slice into 1-inch slices, serve and enjoy!

Adapted from <u>Dailyburn.com</u> and <u>Mindfulmom.com</u>.

the effects of five medications that had been used with patients with related illnesses, such as SARS (which is also caused by a coronavirus), by analyzing their effects on the SARS-CoV-2 virus (in a test tube, not actual patients). The team found that chloroquine and another antiviral drug, remdesivir, were "highly effective" in the laboratory and suggested that the two drugs should be evaluated in patients with coronavirus. They also reported that chloroquine had both antiviral activity and beneficial effects on immune system activity that might enhance its effects against the virus. Their study did not include hydroxychloroguine.

A controversial French study that reported improved outcomes in 20 patients who either received hydroxychloroquine on its own or in combination with the antibiotic azithromycin has been frequently cited by advocates of prescribing malaria drugs for COVID-19. That study, published in International Journal of Antimicrobial Agents in March, has been criticized because of its small size and lack of randomization, double-blinding and a control group, all of which are part of the gold standard of scientific research. A randomized study of 30 patients conducted in China found that adding hydroxychloroquine to standard care was no better than treatment with standard care alone for COVID-19.

What are the cardiac risks and potential side effects of hydroxychloroquine and chloroquine?

A paper by a group of cardiologists



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- Antibodies from recovered COVID-19 patients may help protect people at risk. Johns Hopkins University in Baltimore and Mount Sinai Hospital in New York are investigating if a century-old blood-derived treatment called plasmapheresis, which uses blood plasma or serum from people who have recovered from the virus, can help boost the immunity of newly infected patients or those at high risk. The idea is to see if antibodies in the plasma neutralize SARS-CoV-2, the virus that causes COVID-19. "Deployment of this option requires no research or development [and] could be deployed in a few weeks since it relies on standard blood-banking practices," wrote Hopkins immunologist Auturo Casadevall, MD, PhD in an article in Journal of Clinical Investigation. On March 24, Mount Sinai announced plans to use the treatment in critically ill patients. This technique has reportedly been used successfully in China, which states that some patients improved within 24 hours, with decreased inflammation and viral loads and higher levels of oxygen in their blood, according to a news release from Mount Sinai.
- Acts of kindness and community spirit — are flourishing! In the UK, more than 500,000 people have volunteered to help that country's National Health Service in its battle against COVID-19, twice the government's recruitment target. In the US, volunteers in many towns and cities are sewing and donating face masks for healthcare workers at hospitals and many businesses are providing supplies for home crafters who want to join this effort. In North Carolina, one local group has started using 3-D printing to make plastic face shields.
- Charities are stepping up with emergency grants related to COVID-19. Programs for children undergoing treatment at MD Anderson Cancer Center used to include visitors from the Houston Ballet for bedside dance classes, the Houston Symphony for a program in collaboration with the hospital's music therapist and a bedside theater program called Books Alive, all of which had to be



canceled due to infection control concerns. To help young patients feel better without volunteers at bedside, the Texas-based Alice Kleberg Reynolds Foundation has arranged for the children to receive special age-appropriate arts and crafts kits to brighten their spirits.

- The pandemic has decreased air pollution dramatically. Some reports estimate that China's quarantine has reduced carbon dioxide emissions by more than 100 metric tons — and large decreases have also been seen over other quarantined areas around the world. Paul Monks, former chair of the UK government's science advisory committee on air quality, says this could have some health benefits. "It seems entirely probable that a reduction in air pollution will be beneficial to people in susceptible categories [for COVID-19], for example some asthma sufferers," he told The Guardian. "It could reduce the spread of disease. A high level of air pollution exacerbates viral uptake because it inflames and lowers immunity."
- Healthcare workers are being applauded globally. People around the world are going to their doorsteps

PHOTO BY LOGAN WEAVER ON UNSPLASH and windows to clap for the health heroes on the frontlines of fighting the invisible enemy in our midst and to shout or sing their encouragement and gratitude. We join them in saluting every researcher and medical provider who is working to combat COVID-19!

• Our message about a homemade saline solution that could help abate COVID-19 is being adopted by patients. New science suggests that using a salt-water gargle and nasal wash daily is likely to help curtail the spread of the virus. This simple technique, described in our blog post, has been shown to reduce the rate of other respiratory infections by activating one of the body's natural defenses. As of March 22, 2020, the BaleDoneen Method recommends that everyone in the USA do this hypertonic saline nasal irrigation and gargle until the CDC no longer considers COVID-19 a serious threat in this country. For those with symptoms or a confirmed case of the new coronavirus, we recommend repeating the usage up to every two hours during the first few days. For complete instructions on how to perform nasal irrigation and gargling, click here.



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published in Mayo Clinic Proceedings in March states that while the safety profiles of these drugs "are relatively favorable," both medications block one of the potassium channels that regulate the heart's electrical recharging systems. This raises the risk that in people with heart arrhythmias, the heart's rhythm could become dangerously erratic, potentially resulting in sudden cardiac death, the paper's authors warn.

"Correctly identifying which patients are most susceptible to this unwanted, tragic side effect and knowing how to safely use these medications is important in neutralizing this threat," commented Mayo Clinic cardiologist Michael J. Ackerman, MD, PhD, in an accompanying news release. The paper's authors report people with an inherited heart rhythm condition called Long QT Syndrome (LQTS) may be at particular risk for this deadly side effect. Globally, this disorder affects about 3 million people, reports the paper.

The paper also states some of the other medications currently being used to treat COVID-19 — including the antibiotic azithromycin, which is often prescribed in combination with anti-malarial drugs — may further increase the risk for people with LQTS, some of whom are undiagnosed, as well as other patients

with disorders that affect the timing of electrical recharges of the heart. The paper says that about 10 percent of patients may fall into this category and about 1 percent are particularly high risk. To identify such patients, the paper advises medical providers to use electrocardiograms to check patients' QT interval as a vital sign and modify the treatment of those at risk as necessary.

Like all medications, chloroquine can have <u>side effects</u>. According to the FDA, the most common ones include stomach pain, nausea, vomiting and headaches. People who experience irregular heartbeats, fainting, seizures, yellowing of the eyes, blurred vision, muscle weakness or hives are advised to consult their medical provider immediately. Hydroxychloroquine is a slightly different drug but <u>has similar side effects</u>. Before taking any medication, discuss the risks and benefits with your medical provider.

What research is currently being done to find a cure for COVID-19?

On March 22, <u>a randomized double-blinded clinical trial</u> <u>called Discovery was launched in several European countries</u> to test the safety and effectiveness of four experimental treatments, including remdesivir, hydroxychloroquine and other drugs the World Health Organization has identified as top priorities for investigation. Ultimately, the study aims to include 3,200 hospitalized patients, including those in intensive care, from at least 20 participating centers.

The experimental treatments will be given in various combinations and the effects will be compared with outcomes in a control group of patients who receive conventional care. The trial is designed to be "adaptive," meaning that ineffective treatments will quickly be halted and replaced with other therapies that emerge from research efforts as part of an



ongoing effort to identify the best COVID-19 treatments as quickly as possible.

A <u>number of researchers around the world</u> are also working on developing new antiviral medications with the ultimate goal of finding a cure. Another approach that is being explored by Chinese researchers is to develop new drugs that shorten the time critically ill patients need to be on ventilators — or perhaps avoid the need for these devices in the first place — by improving immune system response to protect against potentially life-threatening lung complications.

Can malaria pills prevent COVID-19?

A team of researchers from University of Washington and New York University have launched a clinical trial that will ultimately include 2,000 volunteers who are close contacts of people with confirmed or suspected COVID-19 diagnoses. The volunteers will be randomly assigned to either take hydroxychloroquine or a placebo for two weeks and their health will be closely monitored to see if this medication provides protection against catching the virus. This clinical trial is one of three being funded by the <u>COVID-19 Therapeutics Accelerator</u>, a \$125 million initiative of the Bill & Melinda Gates Foundation and other organizations to speed up drug development.

Outside of clinical trials, the FDA has only authorized medical providers to prescribe hydroxychloroquine or chloroquine to hospitalized adults or teen patients as an experimental treatment in appropriate cases. **These medications are NOT currently advised for prevention of the virus. Instead patients should follow the CDC's recommendations about social distancing and hand hygiene as the best available ways to protect themselves during the pandemic.** We will continue to report major new developments in our blog and newsletter as they occur.