A Guide to Home-Based CONTRACTOR Treatment

Step-By-Step Doctors' Plan That Could Save Your Life



An educational resource from the Association of American Physicians and Surgeons (AAPSonline.org) 1

A Guide to Home-Based COVID Treatment

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Disclaimer: This booklet does not provide individual medical advice or prescribe treatment but is provided as an educational service for patients and their families to know what options are available and widely used for many conditions. Patients should consult the physicians of their choice for individual medical evaluation and recommendations for treatment tailored to individual needs. If you need emergency care, call 911. Medical knowledge is evolving rapidly. Although the efforts are taken to keep the information contained in this booklet current, authors cannot guarantee that it reflects the most up-to-date research. The authors make no warranties, expressed or implied, regarding errors or omissions and assume no legal liability or responsibility for loss or damage resulting from the use of information contained within this booklet.

Disclosure: All physicians consulted for developing this Guide are actively treating COVID patients and are focused on early, home-based delivery of medical treatment options unless critical care in hospital is determined to be urgently needed. Some of them offer products that they recommend for prevention or treatment. We have not evaluated these products. Jane M. Orient, M.D., an internist, is executive director of the Association of American Physicians and Surgeons. All contributors have volunteered their time and expertise as a community service in view of the COVID-19 national emergency and its consequences to help inform patients of their options. Contributors have received no remuneration for their contributions. The opinions expressed in this guide are those of the physician contributors and not those of any of the institutions with which they have or have had affiliations.

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An educational resource from the Association of American Physicians and Surgeons (AAPSonline.org) 3

INTRODUCTION

A Guide to Home-Based COVID Treatment is built on the rapidly accumulating and changing peerreviewed published medical research and the clinical experience of practicing physicians who have decades of experience treating patients with all kinds of illnesses. In this guide, we provide a step-bystep guide to medically sound early *treatments of COVID-19 in outpatient settings* that in the opinion of the authors have a reasonable probability of therapeutic success.

A new coronavirus that was named *severe acute respiratory syndrome coronavirus 2* (SARS-CoV-2) suddenly appeared at the end of the year 2019, causing the global pandemic of the illness known as **COVID-19** (<u>Co</u>rona<u>vi</u>rus <u>d</u>isease 2019).

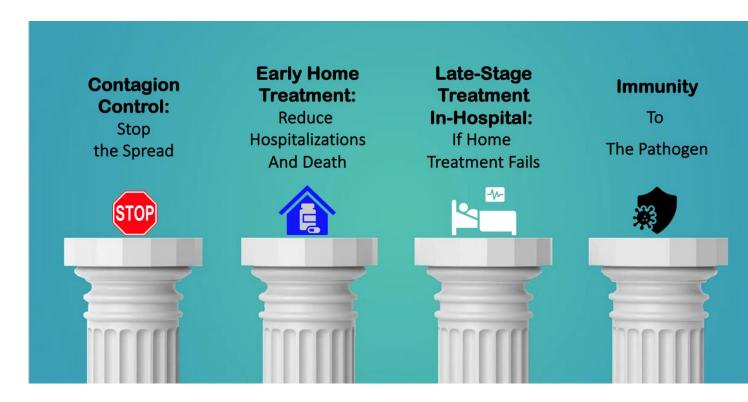
The severity and course of this illness varies from asymptomatic infection, with no symptoms at all, through mild respiratory symptoms to severe pneumonia that can cause a dangerous condition known as the acute respiratory distress syndrome (ARDS). ARDS may become complicated by damage to many organs of the body leading to death. The recovery from COVID-19 is variable as well, with some patients recovering fast and completely, while others struggle with a chronic prolonged disease called "long COVID-19."

COVID-19 was a brand new disease and our knowledge about its manifestation and possible treatments has been changing very fast. Taking proper care of COVID-19 patients remains complicated, especially with the appearance of new variants of the SARS-CoV-2 virus. As it happens frequently in medicine, opinions among physicians about which treatment works best for COVID-19 patients were divided. In the setting of a deadly pandemic such disagreements led to heated discussions about the effectiveness of various drugs proposed as COVID-19 treatments. Typically, such arguments are eventually settled by the results of large-scale randomized clinical trials, which are the gold standard of proof where the best treatments is concerned. Initially, during the global pandemic emergency, performance of those complex studies was not possible in the face of such critical illness.

However, with time clinical trials started to be performed and their results analyzed. At the time of this update some physicians claim that the outcomes of the trials already performed are conclusive, but others question such opinions and believe that more studies should be done. Patients may find the information about the ongoing trials and enroll to participate in them at https://clinicaltrials.gov/ct2/results?cond=COVID-19.

Dealing with the infectious disease during pandemic rests upon four major pillars:

- 1) Contagion control (stop the spread of the virus);
- 2) Early ambulatory, home-based treatment;
- 3) Late-stage treatment in hospital;
- 4) Immunity, which can be acquired by going through the infection or through vaccination.



This Guide will focus on the second pillar: early, ambulatory, home-based medical treatment overseen by your physician, using various medications. Some of those medications discussed below like remdesivir (Veklury™) are approved by the U.S. Food and Drug Administration (FDA) for the outpatient treatment of COVID-19. Others like nirmatrelvir-ritonavir (Paxlovid™) or (convalescent plasma) are not FDA approved but have been authorized by FDA under an Emergency Use Authorization (EUA). Yet others are approved but for medical conditions other than COVID-19 and were safely used for them in clinical medicine. According to the FDA's own opinion: "From the FDA perspective, once the FDA approves a drug, healthcare providers generally may prescribe the drug for an unapproved use when they judge that it is medically appropriate for their patient."

Faced with a horrifying emergency, humans typically respond in one of two ways. Some follow the "Don't Just Stand There, Do Something!" principle, while others stand and watch. With regard to the second pillar of pandemic response, physicians aligned with the government advocated *extreme restraint* about any type of home-based treatment of COVID-19 since this disease was new and no proven drugs to treat it were known. Therefore, for many months governmental health agencies simply advised patients to: *isolate themselves, drink a lot of fluids, rest in bed, and wait* to see whether the disease would pass or worsen to the point that hospitalization was needed.

Throughout the pandemic, governmental agencies recommended a very limited number of medications for home treatment. Those were *brand new, expensive*, and sometimes *hard to administer*. In general, they were to be used only for *special risk* categories of patients. The most recent NIH recommendations for outpatient treatment of COVID-19, issued on Dec 28, 2022, advised that all patients should be offered *symptomatic treatment* and only patients who are at high risk of progressing to severe COVID-19 should be treated with the new antiviral oral drug **Paxlovid™**, which is discussed in detail below.

As circumstances can change rapidly, patients who are interested in up-to-date information about government-approved out-patient treatment options could consult the following official web pages:

- COVID-19 Therapeutics Locator
- National Institutes of Health
- Centers for Disease Control and Prevention COVID-19 Treatment and Prevention

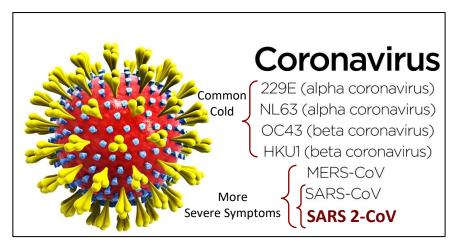
While most government-affiliated physicians advocated **watchful waiting**, many other doctors disagreed with that approach. They claimed that they simply could not just "stand there" watching their patients get very ill and die. They suggested doing what physicians have done for decades: namely, to judiciously use known safe drugs, which either improved the course of diseases similar to COVID-19 or had properties that could theoretically stop the COVID-19 virus. That was a **common sense** approach for them.

This is the approach taken in this Guide. It is written to help you understand your options and to TEACH you how to work with your doctor. Treatment administered outside of the hospitalized setting should be under the supervision of a physician or licensed medical professional who is knowledgeable in the use of medications and the monitoring approach for home-based treatment. Patients who worsen in any way should seek emergency room evaluation immediately.

Be aware that this issue has been seriously affected by the <u>politicization of medicine</u>. Most doctors are under severe pressure to conform to government guidelines and may risk their livelihood if they deviate.

Chapter 1 Overview: SARS-CoV-2 Coronavirus

What Is Coronavirus?



Coronavirus is a family of common respiratory viruses. There are seven different strains of coronavirus. Four can cause symptoms many people experience in the fall/winter seasons: from the common "cold" with cough and runny nose to flu-like body aches and possibly a low-grade fever.

SARS-1 (Severe Acute Respiratory Syndrome), MERS (Middle East Respiratory Syndrome) and most recently,

SARS-2 COVID-19 are newer coronaviruses that have emerged since about 2002-2003, and may cause more serious illnesses.

Diseases that spread widely are called an *epidemic* if they are mostly confined to one region of the world. *Pandemics* refer to diseases that rapidly spread out of a region, around the world. SARS-1 first appeared in China in 2002-2003. It was classified as an epidemic, even though it spread to 26 countries beyond China, but it was not considered serious enough to be a pandemic. It had a case fatality rate of about 9.6%.

SARS-1 lasted about two seasons, and then subsided. However, because of its infectious properties, various research labs began to study the SARS-1 virus for different reasons. During these years, the virus was known to have escaped several times from several virology labs in China, causing illness outbreaks.

MERS was first reported in Saudi Arabia in 2012. Contagion reports were similar to SARS-1, but the disease was much more deadly, with a fatality rate of 34.4%. MERS subsided, and there have been few cases reported since the outbreak.

SARS-2 COVID-19 (the actual infecting virus has been named SARS-2 or SARS-CoV-2) is reported to have a genetic sequence that is 79% identical to that of SARS 1. **SARS-2 COVID 2** is classified as a *pandemic* because of its rapid, global spread.

Coronaviruses are one of many types of virus that contribute to the yearly cough, cold, "flu" season. *Rhinoviruses* account for 35-70% of all symptoms, followed by *coronaviruses* at about 12-15% and then *adenoviruses* and *influenza* viruses (7-12%). Rates for each type of seasonal respiratory virus syndrome vary year to year. Influenza varies widely each year in severity of symptoms, how easily it spreads to others, and death rates. *Respiratory syncytial virus (RSV)* was typically causing predictable seasonal moderate outbreaks throughout the world. Those outbreaks were usually occurring from October to May, with a peak in January/February. However, recently after 2 years of COVID-19 pandemic the unusual, intense inter-seasonal

RSV activity (for instance occurring in the spring and early summer) has been described in both the Northern and Southern hemispheres. The reason for this change is unknown.

How Deadly Is COVID 19?

When a serious infectious disease breaks out, we naturally worry "Am I going to die?"

The vast majority of deaths from this COVID virus occur in those 75 years old and older, with most of those already sick with other illnesses. A large percentage of patients who die are over 80 years old, live in nursing care facilities, and have an average of 2.5 other medical conditions, called *comorbidities*, such as obesity, diabetes, heart disease, lung and/or kidney disease.

The chance of someone *under 50 years old* who has COVID symptoms dying from COVID-19 is 0.05%. The chance of someone under 18 years old dying from COVID is near 0%. Those that do die have severe underlying medical conditions. About seven times more children die from the flu than from COVID-19.

To put it another way, approximately 99.9%+ of individuals who contract COVID will have mild to moderate symptoms and recover, just like with the flu. The majority of deaths are coming from the 0.62% of the population who are in nursing home facilities.

The bottom line? This virus looks and acts very much like the flu, but with one caveat: *Unlike the usual seasonal influenza*, COVID-19 illness can become profoundly serious in *unpredictable* ways.

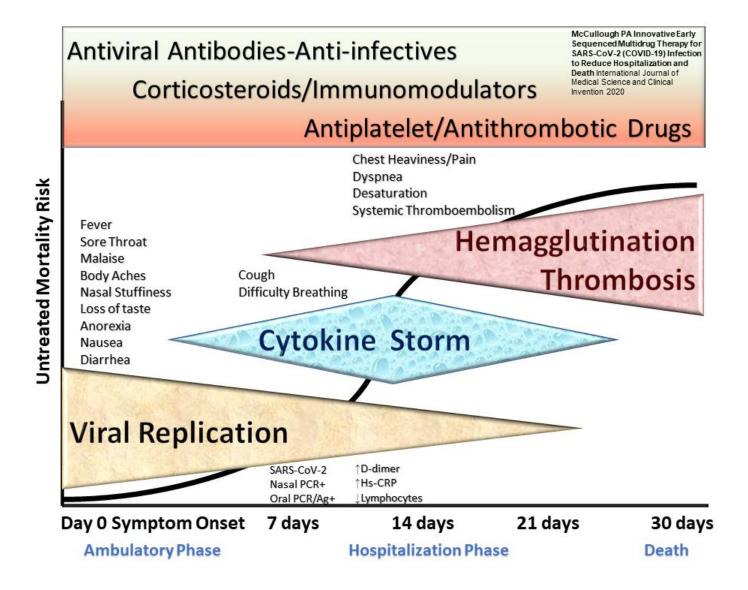
COVID-19 can very rapidly become critical illness for two primary reasons: this virus triggers two responses in the body much worse than seasonal flu: an *exaggerated inflammatory response* causing damage to critical organs, and an *exaggerated blood-clotting response* leading to multiple blood clots in the lungs, brain, and other organs. Doctors have even found blood clots in large arteries like the aorta.

Contagion control remains the first step in reducing the spread of illness. Public health authorities, such as CDC, WHO, and state and local health departments, issue guidelines as new information becomes available. As doctors treating patients, our responsibility is to focus on treatment, which is our purpose in writing this Guide.

CDC recommends calling your doctor if you develop symptoms. This guide helps you recognize symptoms and when to call your doctor, and what options are available to discuss with your doctor for early treatment.

Stages of COVID

This diagram represents the three stages of COVID-19, showing symptoms, findings, pathogenetic mechanism, and rationale for treatment.



Chapter 2 I Have Flu-Like Symptoms: What Should I Do?

What Should I Do First?

Consult your primary physician with the **first onset** of COVID-19 symptoms. If you are experiencing severe, life-threatening symptoms call 911 or go to your nearest emergency department for evaluation. **Difficulty breathing or severe chest pain is a sign of serious illness and needs medical attention promptly.**

The most important reason to contact your physician right away is that studies show *early treatment* is the KEY to success with COVID. *Early treatment is especially critical for people at high-risk*.

HIGH RISK PATIENTS: over age 50, with one or more other medical conditions:

- Obesity
- Diabetes, or pre-diabetes ("metabolic syndrome")
- Lung disease (COPD, pulmonary fibrosis, asthma, cystic fibrosis)
- Kidney disease
- Hypertension
- Autoimmune disorders
- History of cancer treatment
- History of taking corticosteroids regularly

What Are the Symptoms of COVID?

For most people, the first symptoms are not that different from those you have had before at the beginning of a cold or flu. The difference is that COVID can progress rapidly and in unpredictable ways into very severe *respiratory difficulties*, marked *inflammation damage*, and intensified risk of *serious blood clots*. These last three complications of COVID are different from what we see with typical colds or seasonal flu episodes, and are what cause the most serious, potentially life-threatening damage to critical organs.

The three most critical symptoms of possible COVID are *fever, shortness of breath/difficulty breathing/ pressure in your chest, and severe cough*. Shortness of breath can mean shortness of breath doing daily activities or even at rest.

Keep a journal of your symptoms. A daily record of your symptoms by time and date and description of your illness can be lifesaving since an accurate record of your symptoms, the timeline of when they started, how they progressed, and how intense they are can help your doctor make better decisions about what treatment you need.

Fever: The most accurate way to check for fever is to use an oral/mouth thermometer for home use. You can buy these inexpensively at any local pharmacy or on-line. Forehead digital thermometers are easy to use, but they are also expensive and are not as accurate. For young children, you can place the thermometer in the armpit, since it is difficult to have a sick child hold a thermometer in the mouth.

Typical Symptoms You May Experience

(but keep in mind, not everyone has all of them):

- Runny nose, sneezing
- Sudden onset of marked fatigue
- Loss of energy, malaise
- Body aches, muscle aches, headaches
- Cough, though in COVID it is usually a dry cough. You may not produce mucus (sputum). Color of sputum is not necessarily a reliable indicator of severity or type of illness.
- If your cough is causing you to have increased shortness of breath or interfering with your sleep pattern, this could mean the disease is worsening.
- Feeling "feverish," even if fever (defined as temperature >101 degrees) is not present.
- Chills at night
- Sudden onset of sweats during the day that are unrelated to exercise
- Loss of taste or smell (tends to occur after the other symptoms have been there 1-3 days, but can occur earlier or later)
- Loss of appetite, nausea, GI upset
- Diarrhea may occur, though is not common. It can quickly lead to dehydration and electrolyte imbalances when it does happen.
- After about day 5, when the inflammation gets worse, there is often chest heaviness or tightness, difficulty breathing, shortness of breath.
- Drop in blood oxygen concentration (measured with a finger oximeter you can purchase at your local pharmacy) indicates serious respiratory problems
- Rapid heart rate, palpitations
- Loss of focus, difficulty with concentration and memory

Immediate Home Care Recommendations

If you suspect COVID or have tested positive for COVID, isolate yourself from other people to minimize spread of the virus. Quarantine time ranges from 7-14 days, depending on the symptoms and your age and medical risks. Consult CDC for the most recent guidelines on isolation.

Good hygiene reduces spread of the virus. Remember to wash hands and body with soap and water. Maintain good disinfecting procedures throughout your room/home. According to some clinicians and scientists who studied this matter, nasal sprays and mouthwashes containing dilute povidone iodine or hydrogen peroxide have been shown to help prevent infection or transmission of COVID-19, and even to speed recovery—when used judiciously and under supervision of a physician. However, as with any treatment—individual results can vary.

Sunlight and fresh air are key components to good health and fighting COVID. Direct sunshine for 10-20 minutes twice a day is a good source of vitamin D. Studies are clear that low vitamin D is a risk factor for getting COVID and having a worse outcome and higher risk of dying. Vitamin D3 in oil in capsules is better absorbed than tablets and is an excellent source of supplemental vitamin D if you cannot be outside in the sunshine, or your blood level of vitamin D is too low. We will describe in upcoming chapters more about doses and how to check your blood levels of vitamin D and other laboratory studies that are helpful.

Plenty of fluids—preferably water, not beverages with sugars and additives—is key to keep your immune system working well and keeping your body healthier to fight off the virus. *Adequate hydration is crucial*—the amount will vary by body weight, but a good rule of thumb is that your urine should be the *color of pale straw*.

If your urine is *dark yellow or gold*, you are definitely not drinking enough water. If your urine is *colorless*, you are drinking too much plain water, and this can make you lightheaded or confused from electrolyte imbalance.

Healthy food intake also gives the vital nutrients for your immune system to work well. Fresh fruits and vegetables are good choices, along with healthy protein options like meats and beans. Avoid excess sugar, excess intake of "convenience" foods high in fat, sugars, salt and additives because these foods cause inflammation and weaken the immune system.

Make sure you talk with your physician about increasing your intake of immune-boosting vitamins and minerals: Vitamin D, vitamin C, zinc, and others as your physician may recommend.

For Fever: Remember, fever is both a warning of infection that could be serious, and one of our body's defenses against infection. Not all physicians agree that every fever should be treated, since it may signal a superinfection that needs aggressive antibiotic treatment, not just a fever-reducing medicine.

For high fever, treatment can be with acetaminophen (Tylenol™), ibuprofen, and/or ice packs. Ice packs are easy to use and a good option to keep fever down. Just fill a bag of ice and apply to your back/tummy/flank. Acetaminophen has side effects of oxidative stress on the liver. One study has suggested it may increase risk of oxygen desaturation.

One option is to alternate ibuprofen and acetaminophen every 4-6 hours. For example, use ibuprofen at 12 PM and then try acetaminophen at 6 PM, if the fever persists. Do not exceed recommended doses on the package.

Should I Get a COVID Test?

Home tests may be available. Both false positives and false negatives can occur.

The <u>CDC provides extensive information on testing</u>. Many questions have been raised. Population-wide testing including asymptomatic persons may be useful for epidemiologic purposes, but be aware that testing of low-risk individuals likely has a large percentage of false positives. Many agencies have been running <u>polymerase</u> <u>chain reactions (PCR) at such a high cycle threshold</u> (Ct > 35) that virus is very unlikely to be present.

Because rapid treatment is so crucial in COVID, many outpatient physicians elect to treat their patients based on *clinical symptoms*, *risk factors*, *and other objective findings from a physical exam or blood work*, so as not to lose the "window of opportunity" for early treatment by waiting several days for a COVID test report. That is a very reasonable option, since the tests have been at times hard to get and may take too many days for results. Also, reliability of the tests has been a serious problem. We have patients who tested negative but had the cardinal features of the COVID illness and needed treatment. If you have symptoms of COVID illness, but a negative test result, most physicians still recommend early treatment to help reduce the risk of requiring hospitalization.

There are several basic types of tests:

- 1. Diagnostic tests: an "antigen" test and a "molecular" test. An antigen test detects certain proteins on the surface of the virus. A molecular test, called RT-PCR or rRT-PCR detects fragments of the virus' genetic material. PCR tests with a high cycle threshold may often be finding non-infectious viral fragments instead of active infection with SARS-CoV-2.
- 2. Antibody tests: (after recovery from COVID): These tests check for antibodies made by your immune system in response to an infection, such as a viral illness. Antibodies help fight infections, and antibodies "remember" what the infection-causing organism looks like to help our bodies fight similar infections in the future.
- 3. Antibody tests are *not* used to *diagnose* an active infection. These tests tell your doctor you had the illness and recovered and have developed immunity. Commonly used antibody tests are not specific to COVID. People may have similar antibody responses to other viral infections, such as the coronavirus that is responsible for the common cold and even the flu virus. The test can only say that you have had a viral infection, not the specific type of virus.
- 4. Tests for immune cells (T cells), indicating memory of past infection and capacity to mount an immune response, are under development. The T-detect test is available under an EUA.

Should you get a COVID test when you develop symptoms? That is a choice between you and your doctor. If you do decide to test, be aware of the test's limitations.

But either way, if you develop symptoms, the key is to be evaluated by your physician promptly and decide whether you should have early treatment to reduce chance of having to be hospitalized or having serious complications.

We encourage you to follow the steps included here to keep yourself healthy, do your best to stay away from sick people, and learn about early treatment options.

Early Treatment Is the Key to Success

Seek early treatment and be your own advocate. All the physicians contributing to this booklet are on the frontlines treating outpatients at the first signs of COVID illness. Studies in the U.S. and many other countries clearly show that patients who are treated within the first 5 days of symptoms have better outcomes using the combination of medications in the algorithm below. Conversely, the death rate is about 12% by the time oxygen is needed, and about 40% for those requiring the intensive care unit. These death rates are unacceptably high. We have found that death rates can be significantly lower with early, outpatient treatment for high-risk patients over age 50, with one or more other medical conditions.

Do not wait until it is too late.

Steps to Take:

- 1. Be proactive.
- 2. Print the treatment algorithm that we included in this chapter.
- 3. Study this algorithm of medicines used and when they work the best. You will recognize many. They are in common use as anti-virals, anti-inflammatories, and anti-coagulants.
- 4. Schedule an appointment with your primary physician ahead of getting sick.
- 5. Find out if your physician is willing to treat you according to this peer-reviewed published protocol, developed by experts from major U.S. and Italian medical centers.
- 6. If your physician is not knowledgeable about treatment options or is not willing to treat you for COVID, start now to find one who is. Resources for physicians across the U.S. are listed in Appendix II. You need an advocate who will work to help you get well.
- 7. A "wait and see" approach is not adequate for high-risk patients (those over age 50 with one or more other medical conditions). "Wait and see" is a factor contributing to the high death rate in the U.S. Countries with the lowest death rates are treating *early at home* with the oral medicines listed in the algorithm that follows in this chapter.
- 8. Our medical knowledge on how to treat COVID is changing and improving daily, so please do not be afraid to seek professional help promptly if you develop symptoms.

What To Expect at Your Physician Consultation

Many of our physician contributors have patients fill out a questionnaire and/or a flow sheet of their symptoms describing what they are experiencing and how long they have been sick. See the COVID Screening Checklist and COVID Illness Tracking Log in APPENDIX III. Print these and use them to track your symptoms and progress. They are helpful for any doctor you may see.

Vital signs (blood pressure, pulse, height, weight, BMI, blood oxygen levels) are checked and recorded. A COVID test may be recommended. Our physicians typically do not wait for the test results to start treatment if in their medical judgment, symptoms and risk factors mean prescription medications should be started rapidly.

Other laboratory tests may be ordered, and might include these basic tests: metabolic profile to check glucose, electrolytes, liver enzymes, etc; a complete blood count; C-reactive protein (general inflammatory marker); D-Dimer (a marker of blood clot risk); 25-OH vitamin D level; serum zinc level; and ferritin.

Additional specialty laboratory tests, such as markers of possible heart attack, may be ordered if the physician thinks necessary after evaluating the patient.

Some of our physicians recommend an EKG initially to check heart rhythm and look for any other abnormalities, including a prolonged QT interval that might increase the risk of arrhythmia from certain drugs such as hydroxychloroquine. Chest X-rays may be ordered if the physician is concerned that lung damage or pneumonia may already be present.

Most of our physician contributors recommend patients purchase a device worn on the finger to measure blood oxygen saturation, called an *oximeter*, available at local pharmacies for about \$40-\$50.

Follow-up appointments (in person or by telemedicine) are typically scheduled at about 3, 5, or 7-10 days from start of treatment, and thereafter at intervals determined by the physician, based on the patient's response and risk factors.

Chapter 3 PHYSICIANS' GUIDE TO EARLY HOME-BASED TREATMENT

In countries around the world, doctors have found that treating COVID patients at home quickly when symptoms develop leads to better outcomes and dramatically lower death rates than if doctors send people home to wait until they are so sick they need hospitalization, ICU admission, mechanical ventilation, and even dialysis when kidneys fail.

Hospital care for critical patients has a much higher death rate, and far higher risk of long-term lung, heart, neurological, and other complications for those who survive.

Home-based treatment makes sense for another reason: *reducing the spread of the illness*. COVID-19 is a highly contagious virus. TeleMedicine allows us a safer option to evaluate patients remotely and assess how they look and sound in addition to evaluating their symptoms and vital signs (which can easily be taken at home).

Note that the protocol outlined below is not the only one used successfully. Physicians are encouraged to think independently and be guided by their own experience, reading of the literature, and patient circumstances and values.

Advantages of Home-based Treatment:

- Home care is safer because it reduces the risk of picking up other infections from sick people in the hospital.
- Home care also allows people to have family members with them for love and support. It can be terrifying to be seriously ill in the hospital, and even worse to have family unable to visit.
- Home care can quickly use widely available, low cost, generic oral medicines and help avoid risks of intravenous medicines needed when people are critically ill in the hospital.
- Physicians can prescribe home-based oxygen therapy with oxygen concentrators available through homehealth services.
- Most treatment modalities used in hospitals, except for mechanical ventilators, can be implemented at home—faster, and better tailored to the individual patient.

It makes sense to go back to our basic principles in medicine:

- Control spread of the virus with careful disinfecting procedures in the home.
- Use prescription medicines targeted to the specific problems COVID-19 causes.
- TREAT EARLY when medicines work best for infections.
 None of our medicines work as well in the critical late stages of COVID illness.
- Start with the right drugs at the right time, based on the patient needs.
- Be ready to treat intensively with full combination of medicines before critical illness occurs.

Available Medicines, New Uses: Rationale for Combination Treatment

COVID-19 illness can become very serious, very rapidly, in *unpredictable* ways. While this does not happen to everyone, it is not possible to predict *who* will develop critical illness or how fast. Remember the two mechanisms that make COVID much worse than the seasonal flu:

- An exaggerated inflammatory response, causing damage to critical organs. In its most serious form, this is called cytokine storm.
- An exaggerated blood-clotting response, leading to multiple blood clots (thrombi) in the lungs, brain, kidneys, intestines and other critical organs. These blood clots in COVID can occur in both veins and arteries, which is unusual and potentially life-threatening if not treated rapidly.

These unique kinds of damage from the COVID virus mean we must use a *combination* of prescription medicines to block these dangerous effects rapidly. The use of prescription medications discussed in this guide should be considered clinically indicated, medically necessary, and appropriate "off-label" use of these products. "Off-label" use of older medicines for new uses occurs every day in doctors' offices around the country. In fact, about 20% of *all* prescriptions in the United States are written for "off-label" uses when a doctor thinks a medicine will benefit a patient.

As with any medicine you are prescribed, we encourage you to read the safety information and FDA-approved package insert and patient guide before deciding on the risks and benefits of the medication. Ask your physician for additional information/clarification. (Tip: Check <u>GoodRx.com</u> to comparison shop prices for your prescriptions.)

The basic groups of prescription medicines and other therapies used in COVID-19:

- Combination anti-viral medicines started as soon as symptoms occur
- Medicines to decrease inflammation, such as corticosteroids (called immunomodulators)
- Anticoagulant therapy to prevent blood-clots that can cause strokes, heart attacks, kidney shut-down, and death.
- Non-prescription supportive treatments with zinc, vitamin D, vitamin C, electrolyte drinks such as Pedialyte[™], and others.
- Home-based oxygen support, such as with an oxygen concentrator. These machines are available by physician prescription from home health medical supply businesses and are covered on most medical insurance plans.

I. Antiviral Agents:

These must be started quickly at STAGE I (Days 1-5):

Symptoms at this stage include sore throat, nasal stuffiness, fatigue, headaches, body aches, loss of taste and/or smell, loss of appetite, nausea, diarrhea, fever.

These medicines stop the virus from (1) entering the cells and (2) from multiplying once inside the cells, and they reduce bacterial invasion in the sinuses and lung:

*Hydroxychloroquine (HCQ) with azithromycin (AZM) or doxycycline

OR

Ivermectin with doxycycline or AZM**

Either combination above must also include zinc sulfate or gluconate, plus supplemental vitamin D, and vitamin C. Some doctors also recommend adding a B-complex vitamin.

Zinc is critical. It helps block the virus from multiplying.

Hydroxychloroquine is the carrier taking zinc INTO the cells to do its job.

Other ionophores such as quercetin may be used if hydroxychloroquine is unavailable.

II. Anti-inflammatory Agents—Corticosteroids ("Steroids"): Oral and Nebulized.

These are started at **STAGE II (Days 3-14)** to reduce *inflammation*, the cause of added damage to the lungs and critical organs.

Symptoms at this stage include worsening cough, difficulty breathing, chest heaviness/tightness or chest pain.

As inflammation damages the airways, interfering with normal oxygen-carbon dioxide exchange, blood oxygen levels drop and people experience loss of focus, drowsiness, confusion, difficulty concentrating, low energy, and severe fatigue.

The exaggerated Inflammation response in COVID further increases the risk of blood clots.

Prescription medicines and other support added now to Stage I medicines are:

- nebulized budesonide to help penetrate the lungs and reduce inflammation;
- oral prednisone, methylprednisolone, or dexamethasone;
- colchicine;
- full strength adult aspirin 325 mg (also reduces risk of blood clots).

^{*}FDA cautions against use of hydroxychloroquine or chloroquine for COVID-19 outside of the hospital setting or a clinical trial, citing risk of heart rhythm problems. Please consult with your physician before use. Both HCQ and AZM may prolong QT interval.

^{**}One source notes that AZM could cause an increased blood level of ivermectin of minor significance.

III. Prescription Anticoagulants ("Blood Thinners"):

These are needed at **STAGE III (Day 7 and beyond):**

Symptoms seen in Stage II intensify. Difficulty breathing becomes extreme, oxygen levels drop sharply, risk of heart attack or stroke increases. At this point, people are critically ill.

The medicines to be added to Stage I and II medicines now include:

- Low molecular weight heparin injections (e.g., enoxaparin [Lovenox™])
 OR
- apixaban (Eliquis[™]), or rivaroxaban (Xarelto[™]), or dabigatran (Pradaxa[™]) or edoxaban (Savaysa[™]) in standard doses for 5 to 30 days.

If these added steps do not lead to improvement, or the patient becomes unstable, a 911 call is warranted for ER evaluation and hospital admission so that more aggressive intravenous medications may be considered, and more intensive oxygenation regimens that require an intensive care setting.

IV. Vitamins, Supplements, and Oxygen.

Adequate nutritional elements are needed for prevention and at all stages of illness. These include:

- Zinc sulfate, gluconate, or citrate. These forms are available in pharmacies, health food stores, and online. Zinc sulfate 220 mg provides 50 mg elemental zinc, the recommended anti-viral dose. Zinc in the form of zinc picolinate form is not recommended following reports of liver damage and tumors from studies about 20 years ago. Following these reports, the German Commission E that regulates supplements used in medical practice in Germany banned this form of zinc.
- Vitamin D3, preferably in oil in capsules for better absorption. Recommended doses for anti-viral benefit vary up to 5000 IU (125 mcg or 0.125 mg) or more for 5-30 days.
- Vitamin C with bioflavonoids for antioxidant, anti-inflammatory effects. Dose recommendations from our contributors vary from 1000 mg (1 gram) once or twice a day up to 4 or more times a day.
- A word about quercetin. Some physicians are recommending this supplement to reduce viral illnesses because quercetin acts as a zinc ionophore to improve zinc uptake into cells. It is much less potent than HCQ as a zinc transporter, and it does not result in high concentrations of Zn in lung cells that HCQ does. Quercetin may help reduce risk of viral illness if you are basically healthy. But it is not potent enough to replace HCQ for treatment of COVID once you have symptoms, and it does not adequately get into lung tissue unless you take massive doses (3-5 grams a day), which cause significant GI side effects such as diarrhea.

V. Other Re-Purposed Drugs

To name a few, metformin, fenofibrate, cyproheptadine, famotidine, colchicine, anti-androgens, fluvoxamine, and melatonin have been investigated. Studies are compiled at c19study.com.

The McCullough Protocol

Dr. Peter McCullough led a team of international experts and published the first treatment protocol for ambulatory COVID-19 patients developed from experience treating patients in the U.S. and Italy and supported by the expanding medical literature at the time. The initial protocol was published in the highly respected American Journal of Medicine. An updated protocol is reproduced below.

If you or a loved one are ill or exposed to risk of COVID-19, read the article (abstract shown in image below) by Dr. McCullough and colleagues from leading U.S. and Italian medical centers, which was published in the American Journal of Medicine (link above) and the updated summary in Reviews in Cardiovascular Medicine. Print these resources for your medical records and take a copy to your physician to discuss these treatment options.

REVIEW McCullough PA, Kelly RJ, Ruocco G, Lerma E, Tumlin J, Wheelan KR, Katz N, Lepor NE, Vijay K, Carter H, Singh B, McCullough SP, Bhambi BK, Palazzuoli A, De Ferrari GM, Milligan GP, Safder T, Tecson KM, Wang DD, McKinnon JE, O'Neill WW, Zervos M, Risch HA. Pathophysiological Basis and Rationale for Early Outpatient Treatment of SARS-CoV-2 (COVID-19) Infection. Am J Med. 2020 Aug 7:S0002-9343(20)30673-2. doi: 10.1016/j.amjmed.2020.07.003. Epub ahead of print. PMID: 32771461; PMCID: PMC7410805.



Pathophysiological Basis and Rationale for Early Outpatient Treatment of SARS-CoV-2 (COVID-19) Infection

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Specialties

Internal Medicine Critical Care Nephrology Cardiology Electrophysiology Infectious Diseases Ophthalmology **Epidemiology Biostatistics**

ABSTRACT

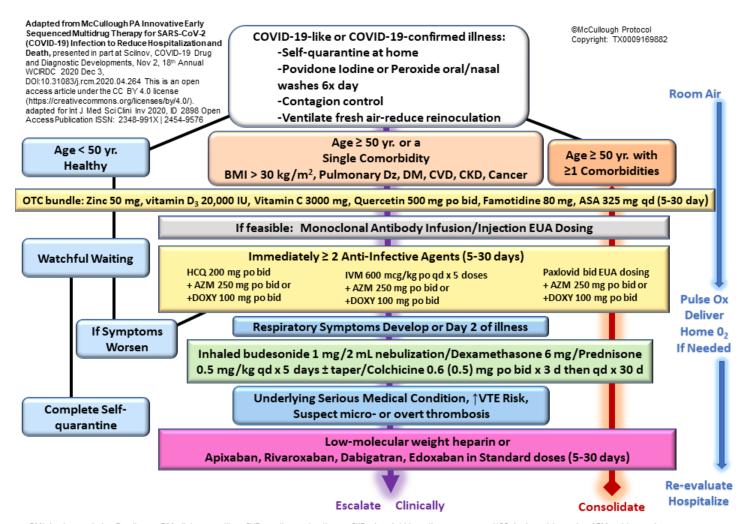
Approximately 9 months of the severe acute respiratory syndrome coronavius-2 (SARS-CoV-2 [COVID-19]) spreading across the globe has led to widespread COVID-19 acute hospitalizations and death. The rapidity and highly communicable nature of the SARS-CoV-2 outbreak has hampered the design and execution of definitive randomized, controlled trials of therapy outside of the clinic or hospital. In the absence of clinical trial results, physicians must use what has been learned about the pathophysiology of SARS-CoV-2 infection in determining early outpatient treatment of the illness with the aim of preventing hospitalization or death. This article outlines key pathophysiological principles that relate to the patient with early infection treated at home. Therapeutic approaches based on these principles include 1) reduction of reinoculation, 2) combination antiviral therapy, 3) immunomodulation, 4) antiplatelet/antithrombotic therapy, and 5) administration of oxygen, monitoring, and telemedicine. Future randomized trials testing the principles and agents discussed will undoubtedly refine and clarify their individual roles; however, we emphasize the immediate need for management guidance in the setting of widespread hospital resource

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KEYWORDS: Ambulatory treatment; Anticoagulant; Anti-inflammatory; Antiviral; COVID-19; Critical care; Epidemiology; Hospitalization; Mortality; SARS-CoV-2

US/Italian Multicenter Collaboration

Academic Medical Centers Public Heath Integrated Health Systems Community Practice Biotech Industry



BMI=body mass index, Dz=disease, DM=diabetes mellitus, CVD=cardiovascular disease, CKD=chronic kidney disease, yr=years, HCQ=hydroxychloroquine, AZM=azithromycin, DOXY=doxycycline, IVM=lvermectin, VTE=venous thrombo-embolic, EUA=Emergency Use Authorization (U.S. administration)

For more information on the safety and efficacy of HCQ and other medicines in the algorithm, check the c19study.com website that summarizes more than 374 studies of HCQ-based treatment, which are particularly favorable when HCQ is used in the first few days of COVID-19 symptoms as recommended in the above algorithm. C19study.com also includes an analysis of 47 early treatments and approvals in 80 countries.

Chapter 4 Emerging Prevention and Treatment Options

Monoclonal Antibodies

Natural Antibodies are produced by the body in response to foreign organisms, such as viruses and bacteria. Synthetic antibodies are those produced in a laboratory to mimic ones the body can make. When these synthetic compounds, referred to as "**monoclonal antibodies**," are made in the lab targeted for a new treatment in medicine, they are patented as new therapeutic agents. This is the type of experimental synthetic monoclonal antibody you heard described on the news that was given to President Trump as part of his treatment for COVID-19 when he was in the hospital at Walter Reed.

Monoclonal antibodies, which <u>received an EUA in November 2020</u>, were the first government-recommended home treatment. Previously recommended REGEN-COV2 is a combination of two monoclonal antibodies intended to fight off the virus SARS-CoV-2. To develop REGN-COV2, Regeneron scientists used antibodies from mice that have been genetically modified to have a human immune system, as well as antibodies identified from humans who have recovered from COVID-19. The EUA for Regeneron was withdrawn.

Efficacy of such products is variant dependent. Bebtelovimab-was the only one recommended in NHI guidelines as of Sept 26, 2022, but this recommendation was rescinded, and its use is no longer recommended. Check with local authorities about what is currently available. The Infectious Diseases Society of America (IDSA) maintains a <u>summary page</u> on this modality.

High-titer Convalescent Plasma

High-titer convalescent plasma, or CP, is the serum from blood donated by people who have had an infectious disease, recovered, and developed antibodies to the infectious organism so that their blood contains those antibodies that can be administered intravenously to another person with that disease to treat the infection. CP was using during the 1918 flu pandemic, and has also been used for measles, mumps, and polio early in the 20th century. When the COVID pandemic hit, physicians began considering this could be a therapy to help ill patients recover.

The FDA approved an Emergency Use Authorization to use CP to treat COVID patients in August 2020, and it has been given intravenously to COVID patients in the hospital. It has not been shown prevent disease progression in high-risk outpatients with COVID-19, when administered within the first week of their symptoms. The risk of getting COVID-19 from convalescent plasma has not been tested, but researchers believe that the risk is low because donors have fully recovered from the infection. CP might be used in certain patients, e.g. those with immunosuppression, but as of Dec 24, 2020, the NIH panel concluded that there is insufficient information to advocate for or against their use. If it is to be used, be sure it is designated to be high titer.

Convalescent plasma therapy has some risks, such as allergic reactions, possible lung damage and difficulty breathing, and infections such as HIV and hepatitis B and C though the risk of these infections is low because donated blood is tested for safety.

Prophylactic Medications

Since SARS-2 virus first appeared, there has been much media focus on vaccines to protect people from infection. But in addition to vaccines, there are several *prophylactic*, or preventive, medication protocols in use in various countries and in controlled trials in the U.S.

Prophylaxis means treatment designed to reduce risk of getting an illness. It is a basic approach to prevention, particularly with illnesses like malaria, herpes, HIV/AIDS, and some other illnesses. Pre-exposure or post-exposure prophylaxis (PrEP and PEP) is the standard approach to HIV/AIDS.

Very early in the COVID pandemic, physicians in India, South Korea, Japan, Costa Rica, Turkey (now Turkiye), and several other countries began using the safe, widely available and very potent anti-viral medicine hydroxychloroquine (HCQ) as a prophylactic (preventive) medicine in COVID-19.

The <u>India Council on Medical Research</u> (ICMR) published in March 2020 (updated in May 2020) their national guidelines for India using HCQ 400 mg once a week for health care workers, physicians, nurses, first responders, high risk patients, and family members of exposed or COVID-positive individuals. Nations that employed widespread prophylaxis and early treatment with HCQ have had death and hospitalization rates much lower than nations where prophylactic and early treatment use of HCQ has not been recommended or widely available.

Dr. McCullough's team in Dallas did a study in their health care workers using HCQ prophylaxis and found it to be effective and safe, with no adverse cardiac events or serious side effects.

The doses of HCQ for prophylaxis are far lower than doses patients with rheumatoid arthritis or lupus or malaria take daily for many years. Because the doses are so low, and not taken daily, risk of side effects is extremely low.

HCQ has a long half-life of about 22 days, so it can be given just once weekly for 8-12 weeks, or longer if someone is continually exposed to COVID, such as people working in hospitals. A 2020 report, <u>Flattening the Risk: Pre-exposure Prophylaxis for COVID-19</u> examines this prophylactic treatment that is easy to use, already available, and inexpensive. They make the case for HCQ as the best candidate for this prevention strategy.

Prophylactic regimens are often recommended by the contributors to this guide, who are using several different dose and frequency regimens. Some use the regimen published by the India Council on Medical Research (ICMR), some use 200 mg of HCQ instead of 400 mg, some recommend the dosing every two weeks instead of once a week, and some doctors even use HCQ for prophylaxis only once a month.

As a result of the safety and significant reduction in risk of becoming ill with COVID-19, physician contributors to this guide are recommending more widespread use of the prophylactic regimens with HCQ that have been used in other countries.

<u>Some physicians prefer the anti-parasitic drug ivermectin</u> for both prophylaxis and treatment. The initial dose recommendation was 0.2 mg/kg, but some are suggesting 0.4 to 0.6 mg/kg. As more information becomes available, recommendations may change.

We believe that in the face of a public health crisis, it is important to consider life-saving approaches based on scientific logic, available safety data, and clinical availability, even if definitive results are not yet available pending more extensive clinical trials.

Vaccines

Three vaccines have received Emergency Use Authorization in the U.S. Two use messenger RNA and one uses a DNA virus vector to introduce genetic information that causes your cells to produce a SARS-2-like viral antigen ("spike protein"). Your immune system then reacts to that to develop immunity to the virus. More vaccines are under development. Although studies were not scheduled to be completed before the end of 2022, FDA granted approval to two mRNA vaccines, BioNTech's Comirnaty™ (said to be interchangeable with the Pfizer product) and Moderna's SpikeVax™. These brand-name products are not generally available in the U.S., and the EUAs are extended for the available Pfizer and Moderna products.

The most important consideration before approving a vaccine for human use is to make sure that the vaccine is safe and effective. Developing safe and controlled infection models for humans normally takes many years of phased testing in the lab, in animals, and then in humans. Many physicians and scientists have been concerned that vaccine manufacturers, with government support, are speeding up this process in ways that are not allowing adequate time for the usual phased testing leading up to human clinical trials. Many groups of people, including pregnant women, were excluded from the clinical trials. It is unprecedented to pressure such people to receive the vaccine.

No RNA-based vaccines were previously approved for human use. Vaccines for RNA viruses are notoriously challenging and difficult to develop. We still, after all these years since AIDS emerged in the 1980s, do not have a vaccine for the AIDS virus, or the SARS-1 coronavirus that emerged in 2002-2003.

Several previous attempts to create vaccines for coronavirus and other respiratory viruses did not survive the testing phases. The vaccine trial for SARS-1 from 2003, for example, was shut down because it produced autoimmune hypersensitivity reactions when exposed to the natural virus after immunization in animal studies.

Another problem is that the SARS-CoV-2 virus already has many variants, against which vaccines may be less effective.

Even the best vaccines for influenza are only about 30-60% effective. Compare that with an effectiveness for improvement ranging from 64% to more than 90% in more than 100 new studies showing early, outpatient treatment for COVID-19 with existing medications described in chapter 3.

Breakthrough infections are occurring, so early treatment options are also needed in vaccinated persons.

Epidemics end when the pathogen runs out of susceptible individuals who can transmit infection—in other words with "herd immunity." Throughout history, this has meant natural immunity because it has taken years to develop effective vaccines. The only disease believed to have been eliminated through vaccination is smallpox, which, unlike most viruses, does not have an animal reservoir but only affects humans. Still, the "Fourth Pillar"—immunity—is now being taken to mean "vaccine-induced immunity."

It is hoped that modern biotechnology will allow rapid development of vaccines to emerging pathogens, based on genetic sequencing. A "payload" might be attached to an existing "platform" and deployed without specific clinical trials. Emerging evidence about adverse consequences of such products may dash this hope.

Information about immunity, blood clotting, myocarditis, and other issues is posted on the <u>Information</u> <u>Heals substack</u>.

New Drugs

FDA has issued EUAs for two new oral drugs that show some benefit for early treatment. Both are quite expensive, though the government may provide them at taxpayer expense. Supplies are extremely limited. However, hospitals and employed physicians might be willing to prescribe them to patients meeting risk criteria, while denying access to older, long-approved re-purposed drugs.

Paxlovid™ by Pfizer is a combination of a protease inhibitor and the HIV drug ritonavir, which is needed to prevent its rapid breakdown but has many serious adverse effects. Ivermectin is also a protease inhibitor and has numerous other mechanisms of action. Paxlovid takes months to manufacture.

Paxlovid has many dangerous interactions with commonly used drugs. Hence, if Paxlovid cannot be used for that reason it can be replaced with intravenous-only antiviral preparation remdesivir (**Veklury™**).

The FDA provides an eligibility screening checklist and a compendium of drug interactions for Paxlovid.

NIH suggests that if neither Paxlovid™ nor Veklury™ can be used, another new antiviral medication molnupiravir (Lagevrio™) can serve as substitute. Molnupiravir by Merck is, like remdesivir, a nucleoside analog. It can be made available more quickly, but its mutagenic action poses a risk of birth defects. Lagevrio™ still has an EUA for mild to moderate symptomatic COVID-19 in patients at risk for progression, but most academic physicians don't advise using that drug. Recent studies showed it does not prevent hospitalization or death as much as it was expected.

APPENDIX I: Medical Resources

- <u>Early Home-based Treatment:</u> peer-reviewed algorithm by Dr. Peter McCullough and colleagues
- <u>Dr. Brian Tyson's First Person Account</u> of treating COVID-19 with hydroxychloroquine
- <u>Information Heals</u>: Immunity, post-vaccination syndromes, politicization of medicine
- Journal of American Physicians and Surgeons
- Truth for Health Foundation

APPENDIX II: Contributors and Physician Resources

Principal contributors to this guide were Peter A. McCullough, M.D., M.P.H. (internist, cardiologist, and epidemiologist) and Elizabeth Lee Vliet, M.D. (preventive and climacteric medicine). Other physician contributors include Stella Immanuel, M.D., (family physician), Lionel Lee, M.D., (emergency physician), Sheila Page, D.O., (neuromusculoskeletal medicine), and Tom Reed, D.P.M. (foot and ankle surgeon).

Anonymous reviewers contributed invaluable insights for this January 2023 update.

The editor, Jane M. Orient, M.D., is responsible for any errors.

Physician resources for patients seeking early treatment:

- Physician Resource List by State: <u>aapsonline.org/covidearlytreatment</u>
- Telemedicine Resources for COVID treatment: <u>www.c19protocols.com</u> (click "Facilities" from menu)

APPENDIX III: Sample Forms for Clinical Tracking in COVID

•	SAMPLE) VII ATIENT NAM									
Height:	Weigh	nt: <i>F</i>	\ge:	BP:	Pulse:_	RR: _	O2 ^c	%		
☐ YES	□ NO	1. Have yo	ou had a	fever >101, (or felt feveri	sh lately?				
☐ YES	□ NO	2. Have yo	ou had a	new or diffe	rent type co	ugh lately?				
☐ YES	□ NO	3. Have you had shortness of breath, difficulty breathing?								
☐ YES	□ NO	4. Any chills or repeated episodes of shaking with chills?								
☐ YES	□ NO	5. Any daytime sweats unrelated to exercise, or night sweats?								
☐ YES	□ NO	6. Any nausea, GI upset, vomiting or diarrhea?								
☐ YES	□ NO	7. Have you had recent loss of taste or smell?								
☐ YES	□ NO	8. Do you have new or different muscle/joint aches?								
☐ YES		•	9. Have you felt loss of energy, or severe fatigue lately?							
☐ YES		10. Have you had trouble with focus, memory or concentration?								
☐ YES		11. Have you had any other flu-like symptoms?								
☐ YES		12. Have you lost appetite and or lost weight?								
☐ YES		13. Any travel to COVID-19 areas in last 14 days?								
☐ YES		14. Any contact within last 14 days with someone who tested								
)-19? If so w						
☐ YES	□ NO			d positive fo						
☐ YES	□ NO	16. Have you been clinically <u>diagnosed</u> with COVID-19?								
		RISK FACT	ORS CHE	CKLIST: DO	<u>/OU HAVE A</u>	NY OF THES	SE CONDIT	IONS?		
☐ YES	□ NO	=		ease, history troke? (circle		=	ımias, high	ı blood		
☐ YES	□ NO	•		PD, asthma,	-		other?)			
☐ YES		Kidney dis			paintonary	1010313, C1,	other.,			
☐ YES		-	-	ic Syndrome	/Insulin Resi	stance?				
				ulin? Yes:		3.00.				
☐ YES	□ NO	•	•			_				
☐ YES	□ NO	Any kind of cancer, undergoing treatment? Any type of autoimmune disease?								
☐ YES	□NO	Do you regularly take corticosteroid medicines? © Vive! Life Center/Elizabeth Lee Vliet, M.D.								
	(SAMPLE)	COVII	O TR	EATMENT	FLOW	SHEET	INITIAL	SERVICE		

Name	DOB	SEX
Nume	000	JL /\

	Day	1	3	5	7	Comments
1.	Fever or chills. 100° F or higher.					
2.	Cough					
3.	Shortness of breath					
4.	Fatigue					
5.	Muscle or body aches					
6	Headache					
7.	New loss of taste or smell					
8.	Sore throat					
9.	Congestion or runny nose					
10	Nausea or vomiting					
11	Diarrhea					
12.	Pulse Rate/O2 sats					
13.	Side effects/New meds					

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