Preparing for the COVID-19 Third Wave: The Case for Hyperbaric Oxygen Therapy

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The free market is not good at disaster recovery. Catastrophe is not profitable.
– Kim Stanley Robinson, Green Earth

Introduction

How a public department responds to a crisis is a measure of its effectiveness.
As for the novel coronavirus, which causes the disease known as COVID-19, the responsible department in New Mexico is the New Mexico Department of Health,1which is overseen by the governor. No easy job at this time, the governor must balance the potential effects of the disease, which is caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)2, both on mortality and on our economic activity. A study in March of this year implied that if this virus was as virulent as the Spanish flu pandemic of 1918-1920, the deaths could be as high as 2% of the world population, resulting in "flu-generated economic declines for GDP and consumption in the typical country of 6 and 8 percent, respectively."3 Today some economists believe that it will be even worse, exceeding Great Depression rates of mass unemployment and falling-off-the-cliff decline of gross domestic product.

What we know about today's global pandemic has been provided primarily by the federal Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), World Health Organization (WHO), and international news sources. No cure or vaccine is currently available against the virus. Indeed, many believe a vaccine will not be available till late 2021 when Phase 3 trials similar to those of mRNA-1273 by Moderna are completed. 4Some like Dr. Fauci and Bill Gates figure otherwise with earlier time frames though the Food and Drug Administration (FDA) will likely have the last say. Mass vaccinations that likely may happen could involve risks due to shortened observation time for negative systemic side effects (Moderna has had 80% systemic side effects.)

Acting on this information, the state government and health officials have focused on preventing too many persons with COVID-19 severe symptoms from impacting the ability of hospitals to provide mechanical ventilator treatment (e.g. breathing with a machine). A limiting factor, mechanical ventilators are used in about 20% of patients with COVID-19 symptoms of unusually serious respiratory distress. That is the reason for the state's emergency targeting, the "flattening the curve" of symptomatic cases, intended to prevent a rise in numbers hospitalized with severe symptoms. So far, it may have worked. However, that may even get worse because what we know about coronaviruses is that viral mutation happens and is usually deadlier in such pandemics in the fall. In many cases the mechanical treatments are not available at many of New Mexico's rural and tribal health clinics. Further according to the Albuquerque Journal reporting, we have had 680 people who have died with COVID-19. Many of those who died

also had preexisting diabetes, heart disease or lung disease (92%). All of those conditions have an existing treatment that is approved by the FDA for treatment with hyperbaric oxygen. This therapy has not been used in our state on COVID-19 patients. Why not? That is a good question. Perhaps it is our not challenging the FDA and the mainstream narrative on this disease, that all we need to focus on is hope for a vaccine or drug for an immediate cure. I believe after reading the data on this therapy called hyperbaric oxygen therapy, that the state's focus is shortsighted. will result in the Our governor and the Department of Health will not be effective with COVID-19 in the fall and deaths may skyrocket especially among our indigenous population. So, what I have provided here is an overview of the COVID-19 disease, current treatment approved for the symptoms of the disease that is most prevalent and what the hyperbaric oxygen treatment is that has been bypassed. I have also included a list of recommendations to pursue to provide this treatment as soon as possible to save New Mexican lives.

COVID-19 Hypoxia and the Cytokine Storm

Hypoxia is the main cause of death for COVID-19 patients. Patients cannot get enough oxygen at the tissue level, leading to pulmonary fibrosis and acute respiratory distress syndrome (ARDS). It is similar to a mountain climber's disease – high altitude pulmonary edema – where liquids build up in the lungs and thus prevents oxygen from circulating from the lungs to the blood. Without oxygen, this dangerous condition, hypoxia, according to WebMD website, leads to damage to brain, liver, and other organs. "Even though the general mortality rate is low (0.2-7%, country based), patients who develop ARDS have a significantly higher mortality rate, up to 61-90%."5

With COVID-19, a second major cause of death comes with what is known as the cytokine storm syndrome. This inflammatory response mechanism is still not clear but appears to occur when proteins are released during one's immune response to the disease. Then when the body seeks to clear the coronavirus and tries to protect it against future reinfection, a pulmonary fibrosis sets in.6 Unfortunately, for many, in those couple of weeks after the initial COVID-19 infection, their immune system's cytokines ramp up dangerously. That can contribute to the morbidity by attacking and killing the body's own cells. Data from around the world notes poor recovery prognosis, especially in patients with both an elevated level of IL-6 (an important cytokine found to be elevated early on in COVID-19 patients compared to those who survived), and ferritin which is a blood protein that contains iron.

COVID-19's Current USA Treatment of Hypoxia (Drugs, HFOT, ECMO, CPT)

Treatments of COVID-19 hypoxia has typically involved the use of anti-inflammatory drugs, such as corticosteroids or those used for rheumatoid arthritis and Still's disease, 7 a rare inflammatory arthritis. Some of the drugs have a long half-life in the body, and it is "possible to have significant side effects," according to Dr. M. Konig of Johns Hopkins University, a specialist in the arthritis field. The typical COVID-19 patient seen by Dr. Konig will in the first week or week and a half of the disease exhibits the symptoms (cough, shortness of breath or breathing difficulty, fever, chills, muscle pain, sore throat, and loss of taste or smell) but they are

not yet critically ill. Some new research suggests that a possible new drug treatment could use the terpenes from cannabis with CBD to provide better results than corticosteroids.8
In any case, the drugs administered might not succeed alone, and then the patient might be placed on oxygen through a mask and administered high flow oxygen therapy (HFOT). HFOT is another method of non-invasive respiratory support. A patient that is not improving following those steps typically then is placed on invasive mechanical ventilation. It is documented that mechanical ventilation with intubation can contribute to the possibility of additional fungal and bacterial infections and can damage the lungs. **The COVID-19 death rate on ventilators by studies exceed 70% — not a good patient outcome.** An advanced treatment measure for those who get so sick that even mechanical ventilators cannot keep them alive is a radical option called extracorporeal membrane oxygenation (ECMO). It is a form of lung and sometimes heart bypass that allows for the insertion of tubes into a patient's blood vessels, which is used to remove the venous blood, that is then run through an artificial lung which then pushes oxygen rich blood back into the body. Patient's survival rate is 50% or lower, and only 264 hospitals in the USA out of 6,000 are capable of performing this procedure.9

Still another approach to combating COVID-19 is passive antibody administration in a treatment known as convalescing plasma therapy (CPT) in which the antibodies in a recovered COVID-19 patient's whole blood or plasma is taken to treat another COVID-19 patient; if administered early the hope is in 10 to 14 days, the patient develops primary immunity against the virus. This work was already being done in Houston. The FDA has stated that more clinical trials are needed. This was despite the Journal of the American Medical Association (JAMA) in its March 27, 2020 issue, citing the success of 5 patients who showed symptoms of severe respiratory distress, severe pneumonia, and a high viral load. Of the 5 patients, three were discharged and two were in stable condition.10A number of clinical trials are now ongoing.
Compassionate Treatment by Hyperbaric Oxygen Therapy (HBOT)

During the 1918 Spanish flu pandemic, a therapy was indeed found that showed effectiveness against the influenza. "In 1918 Dr. Orval Cunningham of Kansas City was brought a dying friend of a fellow physician. The patient was moribund and blue. Before Cunningham could perform his planned animal experiments, he was asked to treat this dying patient. With just a one-hour treatment with compressed air at 1.68 atmospheres absolute, the patient experienced improvement. Combined with additional hyperbaric treatments over the next 3 days this patient's life was saved. Others followed."11Known as hyperbaric oxygen therapy (HBOT), it is "a process in which your entire body is exposed to oxygen under increased atmospheric pressure."12It typically involves a mono-place chamber suitable for one patient, or a multi-place chamber a room, capable of holding two hospital gurneys and/or seats for up to a dozen patients.13

Such HBOT chambers are pressurized for treatment usually from 1.4 to 2.0 atmospheres absolute ATA. (1.0 ATA is a gauge pressure that is true regardless of location, relative to the average atmosphere pressure at sea level of 14.7 pounds per square inch, or psi. So, 2.0 ATA is twice the atmospheric pressure at sea level.). The HBOT chamber, then with 100% hyperbaric

oxygen added, enables a flooding of the body and its tissues. It is carried out typically in doses lasting 60 to 120 minutes a day. Depending on every patient response, the treatment could be increased from once a day to two twice a day over a course of a number of days, usually five. Today, aside from injuries suffered by deep sea divers, HBOT is typically used for wound care, such as for flesh-eating bacteria, but also for poisonings, strokes, crush injuries, vascular diseases and complications from diabetes. HBOT treatment efficacy on COVID-19 is thought to be due to it altering the lipid structure (fats) of the virus and modifying the viral RNA. Doing so blocks virus replication and prevents it from binding to the ACE2 receptor. These results have similarly been seen in the treatment and viral suppression of AIDS HIV, and in the recovery of ASRS-CoV-1 patients during the SARS epidemic of 2002-2003.

Hyperbaric Oxygen Therapy Positive Treatment Results and Clinical Trials for COVID-19
The experience with HBOT varies, but this summary is notable. ***"The use of HBOT for the treatment of COVID-19 is supported by various international clinical trials and recognized by the World Health Organization as a non-drug treatment for COVID-19. Clinical trials categorically show that HBOT halts viral progression and COVID-19 pneumonia, rejuvenates hypoxic organs, and accelerate the body's natural healing process. The ability of hyperbaric oxygen to penetrate inflammatory pulmonary secretions allows adequate oxygen to reach the blood while inhibiting the inflammatory process."14.***

Chinese doctors in Wuhan also have used it as a treatment saving many patients. "During the current pandemic, various hospitals from China to USA have been using hyperbaric oxygen therapy (HBOT) to treat dozens of critically ill COVID-19 patients with pneumonia and severe breathlessness plus multiple high-risk factors including obesity, diabetes, heart disease and hypertension. The outcome: Following a short cycle of HBOT, patients have consistently made a swift and full recovery."15 By contrast, the Russian Academy of Sciences had noted that lung ventilation fails in 70% of COVID-19 cases and TASS Russian news reported on June 5, 2020 that Moscow's Research Institute of Emergency Care (Sklifosovsky Institute) began to use HBOT to treat COVID-19 cases.

New Mexico and Hyperbaric Oxygen Therapy Availability and Use.
On June 16, 2020, this author made a public record request of the state Department of Health for a hyperbaric oxygen therapy chambers location list for the State of New Mexico and if they had any records of the use of them in treatment for COVID-19. In the reply, health department officials said no documents exist responsive to the request.16
Calling hospitals and facilities, I found the state has three hospitals, with HBOT chambers and treatment. ***Out of the total of four though, only two are accredited clinical hyperbaric medicine facilities, Christus St. Vincent in Santa Fe and the Sherman and Sally Dugan Center at the San Juan Regional Medical Center in Farmington. The third facility is at the Mountain View Regional Medical Center in Las Cruces. One other facility called Taos Hyperbaric offers HBOT chamber and is privately owned.*** None offer COVID-19 HBOT either clinically or for compassionate use.

Status of Clinical Trials for HBOT and COVID-19 and Availability

The website www.clinicaltrials.govis an access site for global studies and trials for COVID-19. Currently, it says it has some 2,965 active studies as of 8/10/2020. As for HBOT, this site has but nine.17Trials are currently recruiting in that database some 840 patients and have December 2020 to December 2021 for completion dates for their studies. That could be due the relatively small numbers of chambers available. China, for example, has one chamber per 270,000 persons, and many are multi-place, and indications are that availability is being increased. In the United States, excluding private and military chambers, we have according to the Underseas and Hyperbaric Medical Society (UHMS), only a few hundred locations are clinical. With a U.S. population of more than 326 million, only one clinical chamber per one million people. It was said without references however that up to 1,300 hospitals in the USA offer HBOT but this I have not been able to confirm. Clearly, fewer clinical trials with HBOT are being conducted in response to COVID-19. Why not? Well, a medical doctor at one of our national HBOT facilities said as I mentioned that Albuquerque has no clinical HBOT chambers, that it is not a surprise since there is little money in treating people with something that makes them well.

Medicare and Hyperbaric Oxygen Therapy (HBO)

Medicare Part B (medical insurance) might cover HBO therapy, but only if the therapy is administered in a clinically approved FDA medical chamber and the patient shows one of 15 conditions that qualify. Further there is the issue of protocols and acceptance for treatment with a virus pathogen and cleaning at any clinical setting and training. Costs are 20% of the Medicare approved amount, and the Part B deductible could apply. COVID-19 ARDS is not a condition that is currently qualified for HBO treatment under Medicare. As a senior if I could get HBOT, my own Presbyterian insurance supplement under Medicare base deductible responsibility would be $2,500 and I would still be responsible for premium charges of over $1,200. Considering many seniors have little to no savings, the treat of bankruptcy and loss of shelter can be the outcome of treatment if it were available for patients with COVID-19 ARDS.

Our Fall Future

With vaccines on the near horizon still in testing phases and many showing systemic side effects, and having knowledge that coronavirus mutations are usually occur in the fall and that are more deadly, New Mexico elected officials and leaders in the state's healthcare community must be planning ahead.

At the very least, we in New Mexico (and nationally) should have a crash plan for making HBOT systems available by the fall of this year – yes, just a few weeks from now — in much greater numbers than the few that exist statewide today. I then feel that with HBOT, COVID-19 patients needing extra oxygen to breathe will see significant health improvements as well as a decrease in complications, inflammation in the blood, need for invasive care, death, and cost of care.

Some recommendations to make this happen.

- Standardization of minimum requirements for any HBOT system developed, to be certified by the FDA rapidly with this COVID-19 pandemic as an approved medical therapy device for use.

- Quick training for technicians with support personnel classes. HBOT syllabuses needs immediate development for the nation using WHO and NIH best practices for COVID-19 safety of medical personnel and technicians. Train the trainers for the technicians and support personnel could be drawn from the U.S. Air Force (Lackland Air Force Base, in San Antonio TX. has two chambers, one six patient multi place and one mono place. 210-671-3722) The HBOT technicians for medical board licensing for HBOT currently require a 40-hour HBOT specific course, then 270 hours of work in a supervised clinical setting, then the technicians must complete and pass a national certification licensing test.

- A call on our state's congressional delegation to allow HBOT to be an approved therapy for COVID-19 and for removal of the Medicare Part B deductible for COVID-19 HBOT and the 20% co-pay for the Medicare-approved amount. In China, HBOT is clinically approved for 12 emergency conditions, according to data from 2013, along with 48 non-emergency conditions including (ARDS) associated with many COVID-19 patients.18

- Federal and or state legislation to require insurance companies in the United States to approve HBOT for treatment without co pays or deductibles. The federal government would pay the normal co pays and deductibles for anyone who has early symptoms and tests positive for COVID-19, both of which would qualify an individual for treatment. Immediate analysis of hospitals nationally and their carrying capacity ability to provide non-invasive lung ventilation under pressure for patients on the cusp of needing mechanical ventilation. The number of accredited clinical facilities, with monoplace and multiplace chambers in the USA, according to the undersea and hyperbaric medical society database (UHMS.org) is 186. This is not counting other public and private facilities whose actual numbers are not in an easily accessible database. Immediately, conduct a full analysis of the ability of all HBOT chambers nationally to have protection against infection transmission in their chamber use for COVID-19 treatments.

- Implement a regional plan for manufacturing multi-person high pressure oxygen chamber systems, and set a goal similar to the Chinese experience after construction, to ship, install, and commission within 15 days in those areas in the United States experiencing the most serious COVID-19 outbreaks.

- Investigate repurposing airplanes for use as pressure chambers and the use of airports as hospitals.19 These have good advantages including " The Boeing 737 and some others use electrical air compressors; the patients can be located away from city centers; they are once repurposed can serve as flying hospitals and sent to locations with outbreaks quickly; the planes themselves require no major modifications; the pandemic has significantly reduced

airplane and airport use. Repurposing allows for airports not to go bankrupt."This repurposing should be undertaken immediately in conjunction with engineers from the Air Force and U.S. government laboratory physicists and technicians hired and tasked from such locations like MIT, the Jet Propulsion Laboratory, NASA, and the Sandia and Los Alamos national laboratories.

- Guarantee access to care. More than 33 million Americans have filed for unemployment in the coronavirus outbreak. In the process, many are losing access to health care. All hospital providers must increase access to care and testing. Testing must be available to all citizens, and including those in immigrant status and asylum seekers.

- Provide guaranteed access and pricing for any vaccines developed and tested. This work normally takes years. New Mexico laboratories need to be used as much as possible, which would mean placing weapons research and development on indefinite hold. New Mexico needs to ask its federal delegation to remove patent restrictions for generic vaccine development and make sure the vaccine is safe before it is being given to the public. This includes making sure the vaccines are free of heavy metals, DNA fragments, nanoparticles, chemical toxins, and tumorigenic particles.

- Task the state Department of Health to review all the COVID-19 testing kits and reject the use of ones that do not give correct positives. Allow for testing of antibodies during blood drawn for any purpose in New Mexico. Bailouts during COVID-19 need restrictions. The state legislature should have met in emergency session to review the impact of the CARES Act on New Mexico. Legislature and the state's congressional delegation must join together to pass an emergency resolution to prohibit this money to be used for corporate stock buys or to increase executive compensation while immediate needs such as production and deployment of HBOT chambers are being ignored.

- Provide for this information to be made for the State of New Mexico in a documentary video mode in multiple languages including sign language and distributed in communities statewide. Place a priority chamber acquisition and use the chambers to the state's hardest hit communities.21

It is my belief that going with the existing narrative that a cure, either that a vaccine or drug will soon be available will result in the state not protecting its population. Our State of New Mexico will be forced to both continue to close economic activity and inaction will allow many New Mexicans to unnecessarily die of the hypoxia and cytokine storm of COVID-19. We have to be ready for the fall.