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Front Line COVID-19 Critical Care Working Group

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— FOR IMMEDIATE RELEASE: APRIL 15, 2020 PROTOCOL ATTACHED —

Front Line COVID-19 Critical Care Working Group Urges Immediate Adoption of Early Intervention Protocol for Any ER or Hospitalized Patient Developing Breathing Difficulty

**A Treatment Strategy Directed at Suppressing Hyper-Inflammation
to Reduce the Need for Ventilators and Save Lives**

**Intravenous Methylprednisolone
Full Dose Low Molecular Weight Heparin
High Dose Intravenous Ascorbic Acid (Vitamin C)**

NEW YORK, NY: Leading critical care specialists at five academic or major hospitals who together have formed the **Front Line COVID-19 Critical Care Working Group**, have released a protocol for treating patients who arrive in hospitals with COVID-19.

Based on available research, the experience in China reflected by the Shanghai expert commission, and their decades-long professional experiences in Intensive Care Units around the country, the five experts strongly urge fellow physicians to immediately adopt a change in strategy by delivering powerful therapies earlier in the disease course, prior to admission to the ICU or the need for a mechanical ventilator.

Based on early experiences with this more aggressive approach, they predict that early adoption of the protocol will reduce ICU admissions, obviate the need for mechanical ventilators, and most importantly, save many lives.



NOTE: The opinions expressed in this release do not necessarily represent the official positions of any institutions with which the quoted physicians are affiliated.

“If you can administer intravenous corticosteroids and ascorbic acid starting in the Emergency Room and every 6 hours thereafter while in the hospital, the mortality rate of this disease and the need for mechanical ventilators will likely be *greatly* reduced,” says Dr. Pierre Kory, the Medical Director of the Trauma and Life Support Center and Chief of the Critical Care Service at the University of Wisconsin in Madison.

He explains that *it is the severe inflammation sparked by the Coronavirus, not the virus itself, that kills patients.* The hyper-inflammation triggered by COVID-19, also known as “cytokine storm” requires use of corticosteroids to prevent deterioration into a very severe form of Acute Respiratory Distress Syndrome (ARDS), a condition which causes the lungs to fail.

Further, the inflammation appears to cause high rates of blood clotting in multiple organs necessitating the use of blood thinners.

The typical treatment for ARDS is to put patients on a mechanical ventilator, but Dr. Paul E. Marik, of the Eastern Virginia Medical School, says that should be the very last resort. Of the 7 COVID-19 patients Dr. Marik has treated with this protocol in the ICU, all survived. One other COVID-19 patient died of a pre-existing heart condition and gastro-intestinal bleed.

Of the 24 seriously ill COVID-19 patients Dr. Joseph Varon has treated with this protocol in Houston’s United Memorial Medical Center, ALL survived.

The experts all emphasize that early intervention is critical in preventing the deterioration and death that has been described across the world once patients enter the ICU. After observing minimal improvements or recoveries in the first of New York’s Northwell Health Care system’s many dozens of patients, Northwell’s critical care specialists found that by changing their therapeutic strategy towards initiating the combination of high-dose ascorbic acid and corticosteroids earlier in the disease course, the need for mechanical ventilation has been greatly reduced.

Some doctors may question the introduction of corticosteroids in the treatment of a severe viral syndrome. However, the two largest studies involving more than 7,000 patients with SARS or H1N1 pneumonia demonstrated a significant reduction in mortality.

Dr. G. Umberto Meduri, Professor of Medicine at the University of Tennessee Health Science Center in Memphis, says corticosteroids are critical for controlling the inflammatory storm caused by this novel virus. Ten randomized studies have proven safety and efficacy in non-viral acute respiratory distress syndrome (ARDS). Corticosteroid treatment was associated with a seven-day reduction in duration of mechanical ventilation and a 30% reduction in mortality.

Positive results in treating COVID-19 are reported from China. Guidelines for China, Korea, and Italy include corticosteroid treatment. Dr. Meduri adds, “There is no justification based on available evidence and professional ethics to categorically deny the use of corticosteroid treatment in the severe life-threatening ‘cytokine storm’ associated with COVID-19.”

New York internist, Dr. Keith Berkowitz says, “Given the dire circumstances in New York State, with almost 122,000 confirmed cases of COVID-19 and 4,159 deaths, it is imperative that every hospital immediately adopt this safe, low-cost, and highly effective treatment protocol, but they must implement it BEFORE the ICU, not after they reach the ICU because, in this disease, the organ damage caused by the uncontrolled inflammation tends to be so severe that patients rarely recover at that point.”

Dr. Howard Kornfeld, who has been a Board-Certified Emergency Physician for 35 years, adds, “This protocol will not only save patients’ lives, it will also lessen the danger to the doctors and nurses who treat them by decreasing the need for mechanical ventilators.”

The physicians agreed that while randomized controlled trials, in normal circumstances, might be considered, that the protocol described here must be instituted now and should be studied with observational and epidemiological strategies.

Dr. José Iglesias from the Department of Critical Care, Community Medical Center, Toms River, New Jersey, advocates for early intravenous ascorbic acid (IVAA) as well as corticosteroids in COVID-19 hypoxemic pneumonia and comments, based on his recently published randomized controlled trial of 137 patients (*Chest*, in press) that “IVAA in sepsis, which shares cytokine storm with COVID-19, significantly reduced the time to the resolution of shock.”

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<https://covid19criticalcare.com>



Early Intervention Protocol for COVID-19 Can Save Lives

This video describes the work of five critical care specialists who are treating coronavirus patients at academic centers and other major hospitals across the United States.

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REFERENCES:

Vitamin C May Reduce the Duration of Mechanical Ventilation in Critically Ill Patients: a Meta- Regression Analysis. *Journal of Intensive Care*, 2020.

The Shanghai Consensus on Comprehensive Treatment of Coronavirus Disease: <https://covid19data.com/2020/03/04/expert-consensus-on-comprehensive-treatment-of-coronavirus-disease-in-shanghai-2019/>

Children's Hospital of Chicago — Vitamin C/ Vitamin B1/hydrocortisone, 43 patients – mortality decreased from 28 to 9 percent in 30 days. "American Journal of Respiratory and Critical Care Medicine," 2020.

CITRIS – ALI trial — showed a 30% absolute mortality reduction study found no difference in primary outcomes among patients with sepsis treated with vitamin C versus placebo. But there was a difference in a secondary outcome - overall mortality.

East Virginia Medical Center – Dr. Marik - Vitamin C/Vitamin B1/hydrocortisone, 47 patients – decrease in mortality from 4. to 8.5 percent. "Chest," American College of Chest Physicians, 2017

Iglesias J, Vassallo AV, Patel VV, Sullivan JB, Cavanaugh J, Elbaga Y, Outcomes of Metabolic Resuscitation Using Ascorbic Acid, Thiamine, and Glucocorticoids in the Early Treatment of Sepsis, CHEST (2020), doi: <https://doi.org/10.1016/j.chest.2020.02.049>

Long Y, Xu Y, Wang B, et al. Clinical recommendations from an observational study on MERS: glucocorticoids was benefit in treating SARS patients. Int. J. Clin. Exp. Med. 2016;9(5):8865-8873.

Front Line COVID-19 Critical Care Working Group

COVID-19 TREATMENT PROTOCOL

In all COVID-19 hospitalized patients, the therapeutic focus must be placed on early intervention utilizing powerful, evidence-based therapies to counteract:

The overwhelming and damaging inflammatory response

The systemic and severe hyper-coagulable state causing organ damage

By initiating the protocol within 6 hours of presenting with tachypnea or any oxygen requirement \geq 4L/min, the need for mechanical ventilators and ICU beds will decrease dramatically.

THERAPEUTIC PROTOCOL TO CONTROL INFLAMMATION AND EXCESS CLOTTING

1. Intravenous Methylprednisolone
 - a. Mild Hypoxia (<4L): 40mg daily until off oxygen
 - b. Moderate-Severe Illness: 80 mg bolus then 20mg q6h IV push for 7 days
 - c. Alternate: 80mg daily for 7 days
 - d. Day 8: switch to oral prednisone, taper over 6 days
2. Full Dose Low Molecular Weight Heparin
 - a. Mild Illness: 40-60mg daily
 - b. Moderate-Severe Illness: 1 mg/kg every 12 hours
 - c. Continue until discharged
3. High Dose Intravenous Ascorbic Acid (Vitamin C)
 - a. 3 grams/100ml every 6 hours
 - b. Continue for a total of 7 days or until discharged
4. Oral Hydroxychloroquine (initiate early after symptom onset)
 - a. 400 mg every 12 hours for one day
 - b. switch to 200 mg every 12 hours for a total of 4 days

TREATMENT OF LOW OXYGEN LEVELS

- a. If patient has low oxygen saturation on nasal cannula, initiate heated high flow nasal cannula
 - Do not hesitate to increase flow limits as needed
- b. **Avoid early intubation based solely on oxygen requirements, allow “permissive hypoxemia” as tolerated**
 - Intubate only if patient demonstrates excessive work of breathing
- c. Utilize “prone positioning” to improve oxygen saturation