



National EMS Network

Newsletter

The Coronavirus Pandemic and Eosinophilia-Myalgia Syndrome

by Stephen Naylor Ph.D. and Gerald J. Gleich M.D.

1. Introduction

The world changed in 2020. The Eosinophilia-Myalgia Syndrome (EMS) community is now subject to another health-threatening problem. You have to deal with the vagaries of a miniscule particle known as the “coronavirus”. The scientific name of the virus is SARS-CoV-2 and the disease itself is known as Covid-19. This type of terminology is similar to that adopted for the Human Immunodeficiency Virus (HIV) that causes the disease Acquired Immune Deficiency Syndrome (AIDS). The scientific literature and media report that SARS-CoV-2 originated in the city of Wuhan, Hubei Province, China. Although new scientific analyses indicate that it possibly came from Shenzhen, Guangdong Province, China. Conspiracy theories notwithstanding, it has been suggested that the virus originated from the local bat population and was transferred to humans via another animal species like the pangolin (a scaly anteater). Chinese health authorities noted, in either mid-November or early December 2019 (the exact dates are disputed), that there were a small number of unusual infections in Wuhan. An alert was subsequently sent to the World Health Organization (WHO) on December 31, 2019.

The Chinese authorities shut down the city of Wuhan, but not before people from the city would travel widely both within China and across the globe. In addition there was limited understanding of what was occurring in the city of Shenzhen. The first case reported in the USA occurred on January 19, 2020 when a 35-year-old man was diagnosed in Washington State with Covid-19. Approximately two months later, (March 12, 2020), ~ (approximately) 20,000 infected patients and over 1000 deaths worldwide had been reported, and Covid-19 was designated a pandemic by the WHO. This was recognition that infectious agents such as viruses do not discriminate based on geography, race, or political persuasion. The SARS-Cov-2 virus is a simple ball of lipids (fat) encasing genetic RNA material, accompanied by 29 different functional proteins. By May 15th, 2020, there were ~4.5 million people infected, and ~305,000 people had died across 185 countries. We are all observing, in real-time, the efficiency of this virus and the global damage and terror it can cause.

2. The Flu or Not the Flu, That is the Question?

All of you are familiar with the annual “Seasonal Flu” outbreak, which typically occurs from October-April in the USA. There are two types of human influenza/flu viruses, namely type A and B, along with associated subtypes (Note-the flu should not be confused with the common cold, caused primarily by members of the Rhinovirus family). Each year most of us get a “shot” which is a vaccine against the seasonal flu. The vaccine is not 100% effective because it is only a best estimate against the virus type/subtype that will be the infectious agent for the forthcoming year.

The deleterious effects of the seasonal flu virus on both individuals and populations vary from year to year. They are dependent on the infection efficiency, transmissibility, co-morbidity and mortality rates associated with the virus. We often regard this annual outbreak as a simple inconvenience, but mistakenly, not life-threatening. You should note however that in the 2018-2019 seasonal flu outbreak, an estimated ~35,000 people died and ~35 Million people were infected in the USA alone. The previous year, 2017-2018, was much worse in the USA where ~61,000 died, and ~45 million were infected. On a global basis, it is estimated that ~250,000-750,000 die annually and over 500 million are infected with this “benign” seasonal flu!

SARS-CoV-2 is a member of a different viral family, the Coronaviruses. There are hundreds of virus species in this family. Human coronaviruses were first identified in the 1960’s, and at present there are seven members of this sub-family known to infect humans. The most noteworthy includes the SARS-CoV-1 virus (origin-believed to be bats via civets to humans) that caused the outbreak of 2003 resulting in 8,422 infected individuals, with a fatality rate of 11%. In addition the MERS-CoV virus (origin believed to be from camels) caused an outbreak in 2012 that ultimately infected a total of 2,494 patients with a fatality rate of ~25%. There are no known vaccines available for either of these viruses.

The current virus that causes Covid-19 disease is a new threat that has not infected humans in the past. A significant consequence of this fact is that currently humans **do not possess any immunity** against the SARS-CoV-2

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**2020 BOARD OF DIRECTORS
ELECTION RESULTS**

NEMSN members have overwhelmingly elected three sitting Board members to another term of office. Lois Vierk, Nancy Grant and Michael Bird earned support from among the nearly two dozen NEMSN members who cast ballots. With these results, NEMSN has seven directors. There are two vacancies which the Board could fill if there are members who are interested. If you are inclined, please express your interest via an email to Nemsntalk@aol.com. The next official election of Board Directors will be held in early 2022. THANK YOU TO ALL WHO VOTED.

NEMSN BY-LAWS CHANGES ADOPTED

NEMSN members gave their support to various by-law updates and changes in balloting completed earlier this year. The changes garnered "yes" votes from 18 voting members. One member voted "no" and two others abstained. The changes address issues of NEMSN's purpose, membership, Board of Director terms of office and meetings. All were explained in previous newsletters. Results from your votes mark the first time in twenty years that our organization's by-laws have been revised. THANK YOU TO ALL WHO VOTED.

**OPPORTUNITIES ABOUND. HELP WANTED.
FILL IN YOUR "STAY-IN-PLACE" TIME.**

To be blunt, readers, NEMSN needs you. With the passing of long-time Board member Sandy Keating, NEMSN lost its pivotal newsletter production, layout and distribution talent. While we do not necessarily need an individual to step up and seek election or appointment to the Board, we do need a "volunteer" who brings far more expertise to newsletter production than your current Board members. We need someone who is technologically savvy, is familiar with layout and article preparation, can interact with a printing company and can manage NEMSN's mailing list. The newsletter is published once per year at minimum, and perhaps as many as 2-3 times. And, you can assume these duties and easily practice social distancing, pause for hand sanitizing and wear facial protection. Please tell us you are interested by emailing us at Nemsntalk@aol.com.

Update Your Email and Contact Information

We need your email address! We'd like to be able to keep in touch better with our members and there's also the option to receive our newsletters by email, if you prefer. We need any updates to your US mail address, too. Please email NEMSN at Nemsntalk@aol.com or phone 201-868-5791. You can send us a letter - NEMSN, P.O. Box 4171, Monitor Station, West New York, New Jersey 07093.

The Importance of Coronavirus Testing Explained

by Stephen Naylor Ph.D.

1. Introduction

We are all struggling with the two tidal waves of misinformation and information concerning the coronavirus pandemic. Each one of us is trying to understand this complex and evolving situation in order to make decisions that benefit and protect our families and us as individuals. Also in this hyper-connected world we are aware that a pandemic requires us to think about the consequences of individual decisions. How do they affect the local community, state and ultimately the country? This situation is clearly overwhelming and most people succumb to the lowest common denominator, namely self-preservation, and “what is best for me and my family?” There is nothing wrong in setting priorities, but it is important to remember that the SARS-CoV-2 virus (the cause of Covid-19) originally infected just a single person. Now approximately five months later, over 4.5 million people (May 15th, 2020) worldwide have the disease! If your neighboring town or state capitulates to the those individuals clamoring for their “liberty back” before safety measures are in place, YOU can quickly become a statistic in the Covid-19 infection numbers. One stark example of this possibility can be found in the Pacific port city of Guayaquil, Ecuador. In mid-February 2020, a seventy-one-year-old woman traveled from Madrid, Spain back to her hometown. She celebrated her popular return by attending numerous parties. Alas, she was subsequently diagnosed as the first Ecuadorean with Covid-19. Now, Guayaquil is a heartbreaking hotspot. Hundreds of dead bodies remain in family homes! The local authority services are unable to respond to the overwhelming demands of body removal, all as the result of a single individual. (<https://www.theguardian.com/news/audio/2020/apr/27/covid-19-spread-southamerica>).

So how do we as individuals, families and populations avoid such situations and make thoughtful decisions about our situation and the future? It is remarkably straightforward, TESTING, TESTING, and TESTING. The paradigm is simple in that testing generates data and information, which allows individual informed decision-making. At the population level, data from testing allows mathematical models to be constructed. This in turn facilitates predictive outcomes, which informs policy makers of priorities that need to be set. However it is important to understand that models are only as good as the quality and amount of data produced from testing. This is, in part, why the models you see each night on your television screens appear to change as a function of the number of tests done.

2. Testing

We are all familiar with the concept of medical or diagnostic testing. A visit to your physician often necessitates the taking of a blood sample. The blood is tested for the presence/absence of a specific cell type or molecule. These cell or molecular markers are then quantified and the numerical value is compared to the population “range” as to whether it is too low, too high or within normal range. Such measurements/tests determine if you have a disease, or in this case an infection.

a. **Rigor and Jargon** - The development of a test is not simple and is subject to numerous considerations. This is to ensure that the data and information from the test is accurate. Imagine the horror, trepidation and panic if an oncology test you had taken appeared to be positive, but in fact was an inaccurate or faulty test and you did not have cancer! In order to avoid such unacceptable errors a test is rigorously developed. The test must have defined and acceptable i) specificity (refers to the % of individuals with FALSE positive results); ii) sensitivity (% of individuals with FALSE negative results); accuracy (how close to the real value is the measured test result); iii) precision (a statistical measurement such that if you measured your blood sample 10 times how close together would be the 10 measured values); iv) limits of detection (LOD- what is the lowest level/amount that the test can measure); and v) time required for the test and analysis to be undertaken. All these parameters, with jargon filled terms, define the quality of the test and whether it can be practically used in the determination/diagnosis of a disease.

b. **Regulatory Framework** - The approval of both a platform/machine to undertake tests and the tests themselves for use in humans is a complex patchwork of regulations and involves a number of US Government Agencies. In the current crisis, the US Health & Human Services (via the Food and Drug Administration) has approved a number of diagnostic tests involving the SARS-Cov-2 virus under what is known as the Emergency Use Authorization (EUA) provision of the Federal Food Drug and Cosmetic Act. For a list of such EUA approvals see <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>. It should be noted that under such provisions not all tests are created equal. A number of tests were “approved” but were not validated. This means that the platform and reagents used for the test, as well as the test itself were not compared to the “gold standard” method of making the diagnosis. This means that issues like accuracy, reliability, reproducibility and other metrics were not fully determined and therefore some data could be suspect.

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3. Coronavirus Testing

The SARS-Cov-2 virus causes Covid-19 disease. How does it do that? Think of viral infection as a four-stage process. Stage I is infection. The virus is transmitted to you via droplets from a proximal infected individual or a contaminated surface. The virus ultimately enters your body through your nose or mouth or possibly eyes, and seeks out cells in your lungs (or other parts of the body) to invade and takes over the cellular machinery. Stage II is the propagation of the virus in your body. It replicates within your cells, infecting additional cells in the process, causing cellular, tissue and organ damage. Stage III is the immune response of your body fighting back against the virus, but in this process additional damage to the host's body can occur. Stage IV is the final outcome, resulting in either recovery or death. As the infected host in Stages I-III you can "shed" virus and infect other people. In order to monitor all these complex inter-connected processes two different types of testing are now undertaken for the SARS-Cov-2 virus.

a. **Are you infected now?** - The test is simple for the patient, provided you have access to testing capabilities. A swab is inserted either up your nose or to the back of your throat to sample cells. If the virus is present then pieces of specific viral RNA will also be present. The swab is then analyzed using a process known as Reverse Transcriptase PCR. This analysis is designed to determine if the viral RNA is present and thus determine if you are infected or not.

b. **Have you ever been infected?** - This is a *different* test. Blood is drawn from the patient and the sample analyzed for specific antibodies. These antibodies are produced in Stage III (described above) when your adaptive immune system, involving B and T cells, fight against the viral infection. In the process, your body produces specific antibodies against SARS-Cov-2, which remain in your circulatory system. Detection of these antibodies informs you and the physician that you have been previously infected by the virus, but are no longer capable of transmitting the virus.

The information from these two tests is binary for the individual. Either you are currently or have been previously infected, or you are not infected nor previously been exposed to the virus. Based on these facts from the tests you and your family can then plan accordingly. However, besides this, all these data combined into population databases can be exceedingly powerful for policy makers to make public health and economic decisions. Understanding the number of people infected, how readily each individual infects another person, how many people have been infected and are now healthy, the rate of spread in a population, and the mortality rate are all derived from this process of testing!

4. Conclusions

There has been a crescendo of calls for more, improved, readily available testing in the USA. Public health officials and physicians have been at the forefront of this effort. As you now might understand this is not empty grandstanding. It is of vital necessity for the health and well-being of individuals, as well as states and nations, to understand what is happening as the virus sweeps through a country and the world.

The importance of early, efficient, easily accessible widespread testing is exemplified in comparing South Korea versus the USA. South Korea has been praised around the globe for its aggressive responsive testing regimen. In contrast the early efforts (January-March 2020) of the USA have been greeted with consternation and incredulity. The difference in opinions is open to discussion, however facts provide a sobering lesson. Only seven weeks ago South Korea and the USA had officially reported the same number of deaths caused by Covid-19. Today (May 15th, 2020) South Korea has a total of only 260 fatalities (with approximately 1-2 additional deaths per day). In stark contrast the USA fatality total is 87,218 (with approximately 2,500 additional deaths per day). Even allowing for national population differences (USA - 328.2 Million versus South Korea - 51.6 million, an approximately 6:1 ratio) this is still a sobering and staggering difference in such a short period of time. In addition the differential effect of the virus on the two national populations continues to worsen for the American public. The South Korean Government implemented aggressive and expansive testing coupled with contact tracing, followed by quarantining infected patients. This model is belatedly being discussed in the USA as state by state as the country begins to open up. This is all predicated on adequate testing capability, which is still questionable here in the USA. Only time will tell if the USA Government (Federal and State) understands the foundational importance of testing. But hopefully now you do!

(Please note the opinions expressed in this article are solely those of the author and do not necessarily reflect the views of NEMSN. Readers should consult with their personal physicians as to how to manage the prevention and treatment of Covid-19 flu.)

Influenza Patients in 1918 Helped by Osteopathic Manipulation Treatment

There are retrospective studies showing the benefit of Osteopathic Manipulation Treatment (OMT) for the outcomes of morbidity and mortality in patients treated during the Spanish influenza pandemic of 1918. From the medical literature we reference two articles from the National Institutes of Health (NIH) and the American Osteopathic Association (AOA), and we provide you with pertinent quotes along with links to the full articles.

 "Avian influenza: an osteopath component to treatment" (2007) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1939852/>

"Retrospective data gathered by the American Osteopathic Association shortly after the 1918–1919 influenza pandemic have suggested that osteopathic physicians (DOs), using their distinctive osteopathic manipulative treatment (OMT) methods, observed significantly lower morbidity and mortality among their patients as compared to those treated by allopathic physicians (MDs) with standard medical care available at the time. In light of the limited prevention and treatment options available, it seems logical that a preparedness plan for the treatment of avian influenza should include these OMT procedures, provided by DOs and other healthcare workers capable of being trained to perform these therapeutic interventions."

 "The Coming Influenza Pandemic: Lessons From the Past For the Future" (2005)
<https://jaoa.org/article.aspx?articleid=2099489>

"[T]he lessons learned within the osteopathic medical profession as a result of the 1917-1918 pandemic could prove useful once again if (or when) a new influenza pandemic occurs. As AOA editor in chief, Gilbert E. D'Alonzo, Jr, DO noted in his 2004 editorial, 'Influenza epidemic or pandemic? Time to roll up sleeves, vaccinate patients, and hone osteopathic manipulative skills,' influenza patients treated osteopathically during 1917-1918 had a 0.25% mortality rate, as compared to the national average of 6% (and 10% for pneumonia patients, compared with 33% to 75% for the national average)."

 To find a doctor trained in OMT, check out www.cranialacademy.org.

Therapeutic Drugs Versus Dietary Supplements and Eosinophilia-Myalgia Syndrome Onset

by Stephen Naylor Ph.D. & Gerald J. Gleich M.D.

1. Introduction

As you all know, over thirty years ago three women in the state of New Mexico manifested unique symptoms characterized by myalgia, elevated white blood cell (eosinophils) levels and assorted other symptoms. Ultimately, it was determined that the contaminated dietary supplement L-Tryptophan was the cause of this condition and Eosinophilia-Myalgia Syndrome (EMS) was alas "born". A number of epidemiological studies demonstrated a clear correlation between consumption of L-Tryptophan manufactured by the Japanese company Showa Denko K.K. and onset of EMS. In addition it was noteworthy that the end of the epidemic was facilitated when the FDA removed L-Tryptophan from the retail market in November 1989. But note that L-Tryptophan has been freely available again in the USA since 2005.

Careful and exhaustive epidemiological studies as well as sample lot analyses of contaminated L-Tryptophan revealed that seven individual contaminants were identified as being case-associated with the onset of EMS. In other words, one or more of these contaminants had some significant probability of being responsible for the manifestation of EMS. Recently in studies done with our colleague Dr. Klaus Klarskov (University of Sherbrook, Canada), we have detected over **six hundred** contaminants present in the original Showa Denko L-Tryptophan! Much of this history is now well documented. But have you ever considered the difference in regulatory processes governing therapeutic drugs versus dietary supplements and how that affects safety and efficacy of all these products?

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2. Therapeutic Drugs – Safety & Efficacy

Numerous laws regulate the development, production and manufacturing of therapeutic drugs. In the USA, the Federal Food, Drug and Cosmetic Act, including its amendments, defines these processes and is enforced by the Federal Drug Administration. Similar laws and regulatory agencies operate in other countries to afford protection to the patient/consumer. The current Drug Discovery and Development (DDD) paradigm that produces therapeutic drugs was conceived in the early 1960's and has remained relatively unchanged over the past sixty years. The process is extremely slow and costly, but designed to deliver products with defined safety/toxicity and efficacy profiles. In other words the drugs are safe to consume and work in the treatment of a specific disease. The DDD process is far from perfect and pharmaceutical companies, both large and small, face significant cumulative risk when bringing a drug candidate to market. The process starts with initial screening of chemical compound libraries (10^4 - 10^6 candidates), which is filtered down to an optimal single compound. This "lead" compound has only an approximately 8% chance of successfully traversing the clinical trials gauntlet. In addition, the **failure rate** of a drug candidate at each clinical trial phase, which involves evaluation in humans, is reported to be 46% (Phase I - tests safety), 66% (Phase II-tests efficacy) and 30% (Phase III – large numbers of patients to test idiosyncratic properties). The average time required from drug discovery to product launch is an eye-watering 12-15 years. In addition, the total capitalized cost of bringing a drug to market was recently estimated to be staggering \$2.87 Billion.

The DDD regulatory process is focused on safety and efficacy of the drug product. This process is designed to protect you, the patient/consumer. Even when a drug enters the market place it is still monitored for adverse effects. This is known as Phase IV, and is a surveillance stage where patients/consumers and physicians report safety issues. Not all approved drugs stand the test of market pressures due to the scrutiny of this pharmacovigilance and post-clinical trial market surveillance. When a drug manifests significant problems once on the market, it is removed either because of safety or effectiveness problems. For example, there have been 177 therapeutic drugs withdrawn from the worldwide marketplace predicated primarily on safety concerns. Nonetheless, given the emphasis of the regulatory process on the safety and efficacy of such products, the global market for pharmaceuticals is \$1.2 Trillion (\$485 Billion-the USA alone) in 2018.

3. Dietary Supplement Use & Regulation

A dietary supplement is defined as an oral product that supplements your daily dietary intake. Ingredients can include vitamins, minerals, amino acids, proteins that include enzymes, and extracts of tissues from animal organs or glands. Herbal supplements, also referred to as botanicals, are a subset of the dietary supplement product line and contain one or more herbs. These latter supplements are derived from plants, algae or fungi and are sold as teas, extracts, powders, capsules or tablets. Unlike therapeutic drugs there are NO mandatory federal/national requirements to determine safety and efficacy of dietary supplements.

In the USA, the FDA is now responsible for the regulatory oversight of dietary supplements as well as individual ingredients. Prior to 1994, dietary supplements were subject to regulatory requirements used in the food industry. Often the supplement was deemed to be "Generally Regarded As Safe" (GRAS). This descriptor had a long history of usage to describe food additives. After the 1989 L-tryptophan EMS epidemic, the US Congress acted. They passed the Nutrition Labeling and Education Act (NLEA) in 1990, followed by the Dietary Supplement Health and Education Act of 1994 (DSHEA). Under the terms of DSHEA, the FDA was designated as the regulatory agency with oversight of dietary supplements. After passage of the act, supplement companies themselves were responsible for showing that their products were safe, and that label claims such as efficacy were truthful. In addition manufacturers were required to produce supplements that did not contain impurities or contaminants. The DSHEA codified this **self-policing model**, and acceptable trace contaminant levels were, and still are, defined by the volunteer organization, the US Pharmacopeia, which is not a government agency.

A dietary supplement is considered "new" if it contains an ingredient not recognized as a food substance, unless it was sold as a supplement before October 1994. If it is new, the manufacturer must provide the FDA with reasonable evidence that the new ingredient is safe before the supplement is marketed to the public. However, the FDA is NOT authorized nor required to review dietary supplements for safety and effectiveness before they are marketed. The FDA can take action against adulterated or misbranded dietary supplements only AFTER the product is sold to consumers. Once a dietary supplement is on the market, the FDA tracks side effects or safety concerns reported by consumers, supplement companies, and others. Thus the "oversight" of supplement safety and effectiveness before they are marketed. The FDA can take action against adulterated or misbranded dietary supplements only AFTER the product is sold to consumers. Once a dietary supplement is on the market, the FDA tracks side effects or safety concerns reported by consumers, supplement companies, and others. Thus the "oversight" of supplement safety and efficacy provided by the FDA is minimal. This is in stark contrast to therapeutic drugs. So why do individuals take supplements given the limited regulatory oversight and monitoring of safety and efficacy?

Most of us live in a time and place defined by individualism. With the advent of the Internet and World Wide Web, we are all experts in everything! This is a pronounced sentiment when applied to our individual health and wellness. This self-reliant attitude has been encouraged by most national governments having determined that self-care is an important component of primary healthcare. It also helps that such an approach is exceedingly cost effective in the context of annual health budgets! All these factors contributed to the fact that the global supplement market in 2018 was approximately \$140 Billion, and \$38.5 Billion in the USA alone. Consumer Reports recently published in early January 2020 a thought-provoking perspective on the use and “understanding” of supplements by the US public. It is estimated that 68% of the US population takes supplements at least once per week. However, as Consumer Reports noted, there are very few systematic studies or clinical trial data to demonstrate the efficacy of dietary supplements. Many of the reported subjective responses appear to be primarily due to placebo effects. Even more concerning is the safety of supplements. Almost 50% of Americans believe that supplements have been tested by the FDA for safety and 78% think they are safe, yet supplement usage leads to approximately 23,000 emergency room visits per year in the USA.

3. Differences Between Therapeutic Drugs and Supplements

Therapeutic drugs have a strict regulatory process to ensure safety and efficacy in patients/consumers. However, dietary supplements are lightly regulated and treated much more like special foods.

a. **Therapeutic drugs are deemed unsafe until proven safe** – There is a highly regulated process in place for a therapeutic drug to be approved, as described above. Once the FDA has approved the therapeutic drug, it can only be manufactured under stringent, monitored conditions. The packaging must include the “label” with complete information on the best dose, route of administration and regimen for taking the drug. In addition the label must also include the disease indications, known side effects, any unusual interactions with other drugs or foods, and contraindications. Finally any new therapeutic drug can only be prescribed by a licensed physician either for the approved disease indication(s) or any other disease condition via what is called off-label prescription usage.

b. **Dietary supplements are deemed safe until proven unsafe** - Under the 1994 DSHEA, dietary supplements were defined as a category of food. The DSHEA says, “that dietary supplements cannot contain anything that may have a significant or unreasonable risk of illness or injury” when the supplement is used as directed on the label, or with normal use if there are no directions on the label. However, manufacturers are not required to actually test supplements in clinical trials. The DSHEA allows the FDA to stop a company from selling a dietary supplement only after it has proven that the product poses a significant risk to the health of Americans. This means they are found unsafe only after they cause harm. This is the reverse of the way prescription and non-prescription drugs are handled. Also dietary supplements are usually self-prescribed, so there’s no controlled system for reporting bad reactions and side effects. Doctors and patients can report problems, but are not required to do so. If a supplement has unknown side effects or interactions with other drugs, foods, or supplements, the side effects and interactions are not likely to be discovered as quickly as those of new drugs on the market.

4. Summary

Therapeutic drugs, such as the statins, can cost billions of dollars to develop and bring to market. They are monitored and approved by regulatory agencies like the FDA, based on their safety and efficacy properties. This process is designed to provide the patient/consumer with viable products that ostensibly do no harm, and the quality assurance and quality control of such products is also highly regulated. However, since human biology is exceedingly complex, it is impossible to fully guarantee the safety and/or efficacy of any therapeutic drug. For example there is a number of approved therapeutic drugs that when taken by a small percentage of the population can develop into a disease known as “Drug Reaction with Eosinophilia and Systemic Symptoms” (DRESS). The list of pharmaceuticals that may cause this reaction includes almost sixty different drugs. This disease condition subsides when the patient stops taking the drug. Another example is “Drug-Induced Lupus Erythematosus” (DILE) where a small number of drugs can also cause eosinophilia in patients treated for lupus. It should be noted that in both cases this is not due to contaminants, but to a specific response(s) by the patient’s immune system.

In direct contrast the dietary supplement product pathway to market is mostly self-regulated by the very companies that are likely to profit from sales to consumers. Regulatory agencies like the FDA are limited in their oversight capability, but continue attempts to police dietary supplements (see <https://www.fda.gov/food/dietary-supplements/whats-new-dietary-supplements>). They can only intervene after a crisis of effect or confidence occurs with consumers. There is an ongoing debate about the quality of supplement ingredients and their efficacy in meeting the health benefit claims made by supplement providers. But by far the most pressing concern is the safety of such products. In part this is a problem associated with limited quality assurance and control oversight, as well as a lack of any controlled toxicological and clinical trial steps in the process. This industry has often claimed that a naturally occurring compound can only be good for you as well as being safe to consume. But surely this simplistic sound bite needs to be challenged,

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virus. This is the primary reason why there has been such a massive global response to this infectious disease. The scientific and clinical communities are trying to rapidly learn as much as possible in order to understand the infection efficiency, transmissibility, co-morbidity and mortality rates of this new virus. What do we know so far? At present (May 15th, 2020), 1,460,159 Americans have been infected, and 87,218 have died (representing a 5.9% fatality rate). On a worldwide basis, 4,483,864 people have been infected and 303,825 have died (6.7% fatality rate). The SARS-CoV-2 virus appears to be more transmissible than the seasonal flu viruses. The estimates suggest that one infected person will infect 2.5-3.5 other people (seasonal flu estimates suggest one person infects ~1.5 other people). Fatality rate estimates range from 0.1-4.0% (seasonal flu -0.1%), but this is still unclear and may change as testing dramatically increases, and the accuracy of diagnosing individuals infected with SARS-CoV-2 is improved. It should be noted that a small pilot study (with significant limitations) in NY State suggests infection rates of up to 20% of the population. A common co-morbidity between SARS-CoV-2 and seasonal flu is the onset of Acute Respiratory Distress Syndrome-like symptoms, attributable to the striking ability of the virus to infect the lung and decrease its function. The incubation period for SARS-CoV-2 after infection is 2-14 days (average-5 days). In contrast, seasonal flu incubates for 1-4 days (average-2 days). Symptoms for both Covid-19 and seasonal flu are very similar, and include fever, dry cough, fatigue, lack of appetite and shortness of breath. Note that the CDC recently announced new symptoms for Covid-19 that include chills, muscle pain, headaches, sore throat and loss of taste /smell. All these data clearly indicate that SARS-CoV-2 is a virus that causes a flu-like disease, with pronounced similarities to the seasonal flu.

This perplexing virus however, also appears to possess other infective properties that make it different from both the seasonal flu as well as from the SARS-Cov-1 coronavirus of 2003. A series of unusual symptoms associated with SARS-Cov-2 infection have been reported. They include i) Covid Toe - a skin rash on toes similar to chilblains, and rash on the sole of the foot; ii) conjunctivitis (commonly referred to as pink eye); iii) skin necrosis- a red or purple mottled pattern due to a lack of blood supply; iv) dizziness/headaches; v) tingling or burning sensation, probably due to your immune response. In addition, numerous reports have now appeared in the literature indicating that many patients suffer from abnormal clotting of the blood. This can lead to problems throughout the body depending on the location of the clot and can produce conditions such as an ischemic stroke. Finally in both the UK and USA, a condition similar to Kawasaki disease (over-active immune response) has manifested in babies and young children, and tragically a baby recently died due to this SARS-Cov-2 related co-morbidity. Recently the CDC announced that this condition should be diagnosed as "Multisystem Inflammatory Syndrome in Children" (MIS-C).

3. Prevention and Treatment of SARS-CoV-2

EMS patients have additional factors to consider in this Covid-19 pandemic. Such individuals typically possess compromised immune systems as well as other damaged organ problems caused by the original elevated eosinophil levels. All EMS patients need to take additional precautions against SARS-CoV-2 and should consider the following:

i. **Prevention** - The SARS-CoV-2 virus can be spread directly from human-to- human through the air via water droplets or aerosol transmission. Recent data have indicated that an infected individual coughing or sneezing out viral particles can spread the infectious agent over 12-27 feet. This is a much greater distance than the 6 feet physical distancing recommended by the Centers for Disease Control and Prevention (CDC). Also studies have demonstrated that the virus can stay airborne for up to 8 minutes in certain circumstances. In addition the virus can also be transmitted by physical contact with a contaminated surface. Studies suggest that the virus can survive several days (1-7 days) depending on the type of surface material, such as cardboard, plastic or metal.

In order to minimize physical exposure to the virus individuals should follow guidelines suggested by many states to "shelter-in-place" or "stay-at-home". If you must venture outside to purchase groceries or medications or to exercise, then you should consider the following. The virus must enter your body to actually infect you. This transmission is primarily thorough your mouth, nose or eyes by direct contact with virus containing water droplets or an aerosol. A secondary route is when your hands touch a contaminated surface and then you touch your face. So when you venture outside, wear a facemask and wrap-around glasses to cover your mouth/nose and eyes, respectively. This should significantly reduce airborne infection as well as prevent you touching your mouth, nose and eyes with contaminated hands. In addition, wear disposable gloves. This latter action does NOT prevent picking up the virus from contaminated surfaces, but you must immediately and safely discard the gloves on arriving back at your home before touching your door handles. Once in the home, immediately wash your hands for 20-plus seconds, and insure washing between fingers and your thumbs. You should take a shower to remove any residual virus from your body. Finally in terms of home delivered food and other packages; i) if possible avoid restaurant prepared foods and make your own meals, ii) wipe down cardboard or Styrofoam box surfaces with hand wipes.

ii. **Therapeutic Options** - EMS patients need to consider the role of elevated eosinophils, organ damage caused by eosinophilia, and compromised immune system function.

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a. Immune System: “The essential is invisible to the eyes,” writes Antoine de Saint-Exupéry in his novella *Le Petit Prince*). Your immune system is a complex host defense system consisting of a myriad of components and processes. Without it, we all would die. A compromised immune system results in greater susceptibility to infectious pathogens such as SARS-CoV-2. The innate immune system contains white blood cells such as the eosinophil and the neutrophil. Eosinophils target and kill parasitic infections, whereas neutrophils neutralize invading bacteria and viruses. Our adaptive immune system consists of B-cells and T-cells responsible for the production of antibodies and subsequent removal of most foreign particles, including a splinter or a virus. A normal, responsive immune system serves to efficiently protect you against agents such as SARS-CoV-2.

Individuals with compromised immune systems can more easily be infected and struggle to overcome the infectious agent. Thus, it is important to take steps to strengthen your immune system. Many EMS epidemic patients have already incorporated such steps into their daily, healthy lifestyle practices. These include: do not smoke; do consume a diet high in fruits, vegetables and nuts; get regular exercise; manage weight and alcohol consumption; get adequate sleep; and try to manage stress. See - <https://www.health.harvard.edu/staying-healthy/how-to-boost-your-immune-system> for more details. In addition follow the advice of your physician and consider the adoption of diet and/or medication which work against oxidative stress and systemic inflammation.

b. Drug and Antibody Therapies: This is an active area of research, discovery and development, and somewhat clouded by misinformation. According to clinicaltrials.gov there are currently 524 ongoing trials for SARS-CoV-2 diagnoses and treatments. In addition there are ~160 drug therapies and 102 vaccines being evaluated at the present time. HOWEVER, TO BE CLEAR THERE IS ONLY ONE DRUG, REMDESIVIR (GILEAD), APPROVED BY THE FDA FOR THE TREATMENT OF COVID-19 AT THIS TIME. (This drug reduces the amount of time a patient needs to spend in the hospital.) The process that a candidate drug must go through to be approved is both rigorous and very time-consuming. There are regulatory shortcuts that can be implemented in certain circumstances such as a pandemic. However, these systematic steps have been put in place to protect the public and insure that drugs are both safe and efficacious for the disease treatment approved.

A drug that has received massive misplaced media attention is Hydroxychloroquine (HCQ). This drug was approved in 1955 for the treatment of malaria and has also been approved for the treatment of lupus and rheumatoid arthritis. It has a number of adverse side effects including sudden cardiac death. Some promising cellular studies in the early 2000's suggested HCQ might be useful against coronaviruses. More recently, a few small, poorly designed human studies appeared to indicate that HCQ might prevent infection and alleviate symptoms of SARS-CoV-2. These very preliminary studies prompted the President of the United States to unwisely trumpet the potential of this drug in the treatment of Covid-19. Indeed, the FDA has issued an order that physicians can write a prescription for off-label use of HCQ against SARS-CoV-2 in an emergency. However, the dilemma is that comprehensive data is not yet available on the safety and efficacy of HCQ in Covid-19 treatment. The small number of recent, well-designed studies has provided contradictory results. Also human trials in both Sweden and Brazil were stopped due to adverse heart complications in clinical trial patients! In addition, the US Veterans Administration just announced the results of a trial of 368 patients. This and other studies have all found NO advantage to the use of HCQ for treating Covid-19. Indeed, in the Veterans Administration study, more patients died compared to the control group. While there are still now ~80 ongoing clinical trials of HCQ (with or without Azithromycin) involving thousands of patients, this drug has fallen out of favor. However, until the data and conclusions from such trials are available, patients should avoid self-medicating with HCQ and seek advice from their physician.

As noted above, another more promising approach is the repurposing of the Gilead pro-drug, Remdesivir, against SARS-CoV-2. This drug was evaluated and used in the 2014 Ebola outbreak that occurred in the USA. A recent study of 61 Covid-19 infected patients showed that 68% of participants receiving the drug manifested improved clinical outcomes. The FDA recently approved its use in Covid-19 patients. Another promising avenue of enquiry is the use of blood plasma from patients who have “recovered” from a SARS-CoV-2 infection. These patients produced antibodies (from their adaptive immune system) against the virus while infected. In a study from April 6, 2020, ten severely ill patients infected with SARS-Cov-2 were given a single dose of 200 mL of plasma from recovered individuals. The “clinical symptoms were significantly improved” in patients receiving the plasma/antibodies and “no adverse side effects were observed”. The authors caution that much more work is needed to optimize dosing and to insure efficacy and safety in a larger population of patients. But these initial data afford hope without the hype.

c. Vaccine: This is the gold standard treatment of viral infections. Almost all of us have been subject to vaccination including measles when younger. Vaccines contain the actual infectious agent that causes the disease. The difficulty is to ensure that the vaccine does not harm the recipient, but elicits an immune response to produce antibodies against the pathogen. In order to achieve this goal, the patient can receive a dead or weakened, less virulent infectious pathogen. More recently, new approaches using specific regions of DNA or RNA from the pathogen have been used in order to further minimize the potential of the vaccine causing infection in the patient. The considerable advantages of vaccines are that they actually prevent the infectious agent pathology, without the danger of the patient becoming sick. In addition,

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the vaccine confers some immunity that can last months to years for the patient. Currently, there are 106 ongoing clinical trials worldwide for a vaccine against SARS-CoV-2. The development of a vaccine typically can take several years. But, given the exigent circumstances, there are claims that in this case it may only take 9-18 months. There have been some overly optimistic statements that a vaccine might be available by the end of the year!

4. Summary

We are all in uncharted waters of uncertainty. Much of this is due to our lack of innate and adaptive immunity against SARS-CoV-2. To combat the pandemic our local, state, federal and global governments/agencies have made dramatic and impactful changes to our daily lives. In addition, we are all trying to ascertain what to do! Should we wear masks or not? Should we take HCQ to prevent or treat Covid-19? Should we stay home or mix freely with friends and coworkers? This continues to be an evolving situation, and all of us should filter information from a variety of sources in order to best judge what is optimal for one and all. As we learn more about SARS-CoV-2, history will determine if what we have been told to do was an over-reaction or a conservative response by prudent governments/agencies and each one of us. Time will tell.

At the present time, given what we know, what can EMS patients do? This is particularly pertinent as the USA begins to try and open up again. A history of elevated eosinophils will not directly cause an individual to be more susceptible to SARS-CoV-2 infection. However, the consequences of chronic elevated eosinophil levels may have caused organ damage, impaired immune response and systemic inflammation, thus leading to enhanced infection susceptibility. Given the compromised immune systems and damaged organs of many patients (both due to EMS itself and also to the treatments for the disease), plus the lack of a vaccine, prevention is the best option currently available. Individuals should stringently practice physical distancing and adhere to shelter-in-place guidelines. Follow the medical advice only of your physician as it pertains to potential therapeutic treatments. This is particularly important at the present time given that the President of the USA just appeared to suggest that you administer a known toxin, namely disinfectant, to yourself for treating Covid-19!

(Please note the opinions expressed in this article are solely those of the authors and do not necessarily reflect the views of NEMS. Readers should consult with their personal physicians as to how to manage the prevention and treatment of Covid-19 flu.)

Dedication

We would like to dedicate this article to all original EMS epidemic patients from the 1989-1990 outbreak. Your quiet fortitude, good humor and constant willingness to fight and not give up have been remarkable. Wendy Rosenblatt was one such individual who manifested the epitome of this dignified fighting spirit. Wendy died a year ago due to complications from EMS. One of us (SN) got to know Wendy through numerous conversations in the last two years of her life. Like most of you, she fought her myriad of complications from EMS with humor, love of family, and a never-give-up attitude. As Covid-19 sweeps the globe, current frightened and panicked SARS-CoV-2 infected patients can learn much from all of you.

Useful Covid-19 Links

1. World Health Organization (WHO) - Details on worldwide pandemic.
https://www.who.int/health-topics/coronavirus#tab=tab_1
2. Centers for Disease Control and Prevention (CDC) - USA perspective.
<https://www.cdc.gov/coronavirus/2019-ncov/index.html>
3. Mayo Clinic - medical details.
<https://www.mayoclinic.org/diseases-conditions/coronavirus/symptoms-causes/syc-20479963>
4. WebMD - symptoms.
<https://www.webmd.com/lung/covid-19-symptoms>
5. National Institutes of Health PubMed (NIH) - Scientific literature access, search engine.
<https://pubmed.ncbi.nlm.nih.gov/>
6. Johns Hopkins University - Global and Regional Coronavirus Tracker-live.
<https://coronavirus.jhu.edu/map.html>

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since obviously the supplement industry is not suggesting that, for example, we take strychnine (found in the plant *Strychnos nux-vomica* indigenous to Southeast Asia and Australia) as part of our daily health regimen!

We would suggest that since these supplements are unregulated, they are in a sense part of the “Wild West” for chemical and clinical experimentation in human disease. In addition these supplements are “regulated” by an industry that is now policing its own products in order to maximize revenues. Given all these concerns as well as consideration of the EMS epidemic and subsequent FDA recall of the dietary supplement L-Tryptophan, we should all be prudent and inform our friends and family that the cautionary reminder of “caveat emptor”, let the buyer beware, is most appropriate!

(Please note the opinions expressed in this article are solely those of the author and do not necessarily reflect the views of NEMSN.)

MANY THANKS TO ALL OF OUR CONTRIBUTORS

In these trying times, your generosity has shown through. In just four months, NEMSN has received over \$2,700 in response to our requests for assistance. This brings our bank account to nearly \$5,500, a level at which we have not been in many years. Your generosity is permitting us to produce newsletters more frequently, maintain our webpage, reach out to EMS survivors and others showing EMS-like symptoms and interact with medical advisors.

Could we use additional contributions? Yes for certain. But, we also very much understand that these are trying economic times for many. So, if you are able, please send along a donation to NEMSN c/o Michael Bird, 315 West Kirkwood Avenue, Apt. 403, Bloomington Indiana 47404.

Since the first of January 2020, contributions to NEMSN have been made by the following:

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