ALTERNATIVES TO THE COVID VACCINATION FOR AUTOIMMUNE PATIENTS

BY KEESHA EWERS, PHD, ARNP-C, AAP, IFM-C

COVID-19 Vaccines Statement

Updated on January 25, 2021 **Read time 1 minute**

In the interest of the public good, we welcome and support the release of COVID-19 vaccines. We continue to refer to the Centers for Disease Control (CDC) for guidance regarding who should receive a COVID-19 vaccine and promote monitoring of all vaccinated individuals. Additionally, we will continue to offer education and guidance to clinicians about COVID-19 and COVID-19 vaccines through upcoming webinars and courses. Continued diligence with regard to well-established public health measures including masking, physical distancing and hand washing is also advised.

The functional medicine approach, focusing on lifestyle and personalized nutrition, provides support both to those considered good candidates for the vaccine by the CDC (especially those who may have to wait for the vaccine) and those who are considered poor candidates. This approach strengthens the immune system, addresses complex chronic diseases that confer increased risk, decreases the potential severity of SARS CoV-2 infection, and improves overall health.

We are closely monitoring the research, development, and experience with COVID-19 vaccines. We will offer further education and guidance as we learn more over the ensuing months. In the meantime, The Institute for Functional Medicine supports and directs individuals and clinicians to the Centers for Disease Control and Prevention (CDC) for up-to-date information, recommendations and guidelines.

For more information

Amanda Wood, *Director of Communications*

amandawood@ifm.org

THE INSTITUTE FOR FUNCTIONAL MEDICINE®

Data from the Institute for Functional Medicine

RESOURCES AND REFERENCES: 2020-2021

- CENTERS FOR DISEASE CONTROL
- INSTITUTE FOR FUNCTIONAL MEDICINE
- SCIENTIFIC AMERICAN
- NATURE
- SCIENCE FOCUS
- PUB MED NCBI
- THE EVIDENCED BASED MEDICINE CONSULTANCY, LTD.
- THE WHITE HOUSE COVID RESPONSE TEAM
- THE FRONT LINE COVID-19 CRITICAL CARE ALLIANCE

WHITE HOUSE BRIEFING FEBRUARY 26, 2021

- “On top of rising numbers, there are new variants at play”, said Anthony Fauci, MD, the white house COVID-19 response team's chief medical adviser.
- Recently discovered strains in California and New York have been added to a growing list of potentially stronger, more contagious variants.
- The strain first identified in the U.K. Now accounts for 10% of COVID-19 cases in the United States.
- "It is increasing in its prevalence now, and by the end of March, it might be the overwhelming strain that is spreading," Fauci said.
- Vaccines ineffective against new strains…but companies working on “boosters”…

univadis
from Medscape

Login Sign up free

Specialties News Resources Education

Search news, drugs, diseases, ...

COVID-19 map

more on COVID-19 ongoing trials

United States of America

Updated Time	02/26/2021
Total detected cases	28 225 167
Total deceased cases	500 345
Daily detected cases	74 429
Daily deceased cases	2 137
Tests processed	351 578 714
Total hospitalized with symptoms	51 116
Patients under intensive therapy	10 466

Sources

Follow the latest COVID-19 figures in your area and around the globe. Figures are broken down by country and region and include cases and COVID-19 associated deaths.
Information is locally sourced and updated as new data become available.

COVID THIRD LEADING CAUSE OF DEATH IN THE U.S.

- 500,000 deaths in the United States has surpassed:
  - Number of people killed during the Civil War
  - Number of people killed in World Wars I and II combined
  - Number of people killed in all wars combined since 1945
- Taiwan lost 8 people to the novel Corona Virus and instituted no lock down.
- New Zealand instituted a lock down and lost only 26 people.

ROX Index to Predict Risk of Intubation

Predict risk of intubation at 2, 6 and 12 hours in hypoxemic respiratory failure.
Not yet validated for COVID-19

Si US

Calculator References/About

1. SpO_2 90 % >

2. FiO_2 90 % >

3. Respiratory Rate 32 > breaths/minute

Results

ROX Index

3.13

Risk of Intubation

Not low risk. ROX less than 4.88 is associated with a higher risk of failure of oxygen by high flow nasal cannula (HFNC) and need for intubation

Risk of intubation, based on ROX at 2, 6 and 12 hours after initiation of HFNC

Predictors of HFNC failure with need for intubation include ROX less than 2.85 at 2 hours, ROX less than 3.47 at 6 hours and ROX less than 3.85 at 12 hours

Created by QxMD

TAIWAN AND NEW ZEALAND

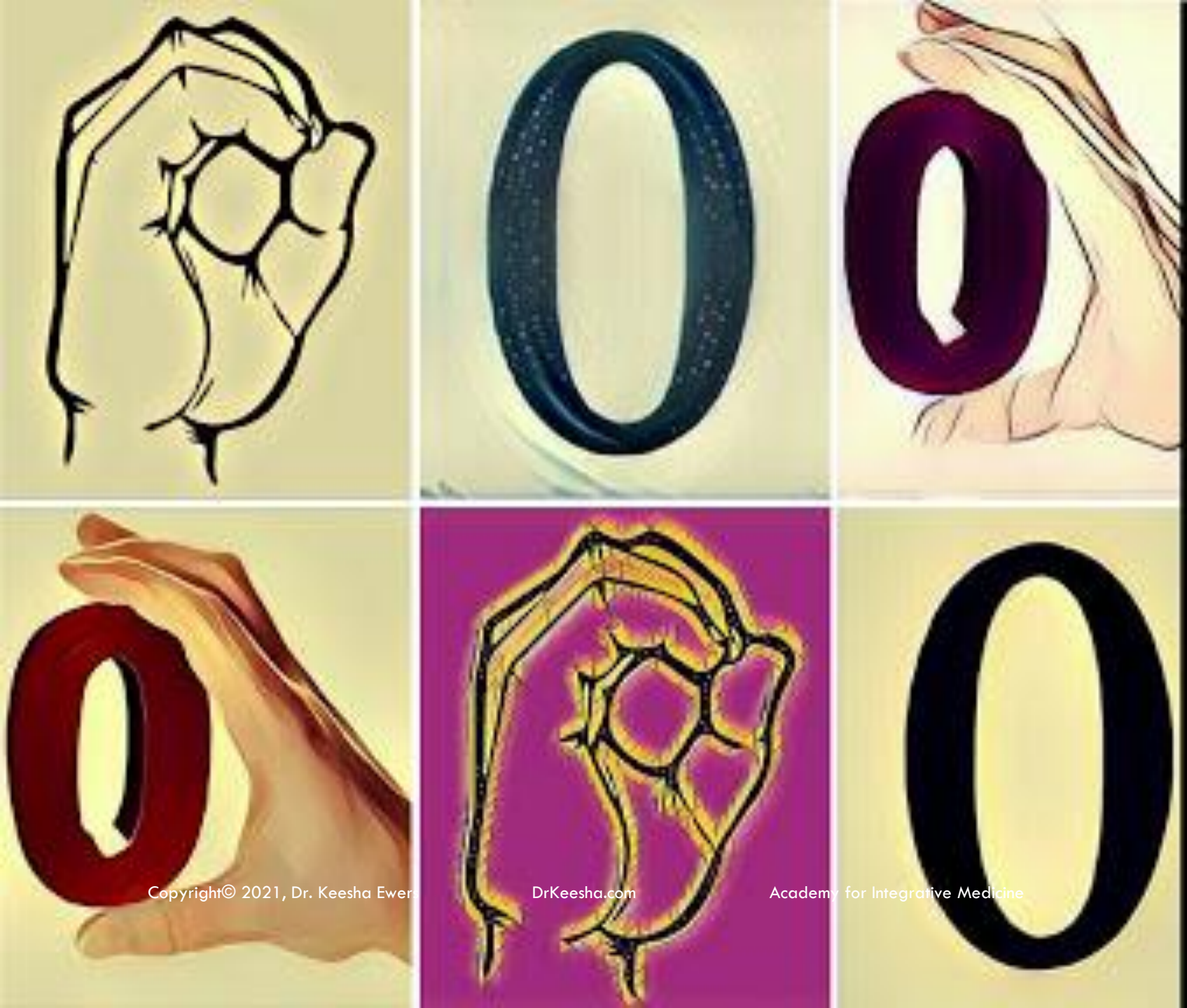
- Taiwan announced its first confirmed case of COVID-19 on January 21, 2020; a 50+ year old woman returning to Taiwan from her teaching job in Wuhan.
- New Zealand recorded its first case of COVID-19 on February 28, 2020; a 60+ year old woman who arrived on February 26th from Iran via Bali.

WHAT DID TAIWAN AND NEW ZEALAND DO RIGHT?

- Taiwan coordinated national response in the early stages of the pandemic through their CDC in conjunction with the central epidemic command center (CECC):
  - Screened all passengers entering Taiwan as they got off the planes and restricted travel into the country to only residents.
  - Banned gatherings >100 people indoors and >500 people outdoors by March.
  - **Everyone masked immediately and contacts of those exposed also quarantined for 14 days.**
- New Zealand had closed borders and locked the country down by closing schools, going fully online and restricting travel by March 26, 2020. Also masked and social distanced by summer and had 14-day quarantine policies for people exposed and their contacts.

THE ROLE OF VACCINATIONS IN CURTAILING COVID IN TAIWAN AND NEW ZEALAND?

 DrKeesha.com Academy for Integrative Medicine



ZERO

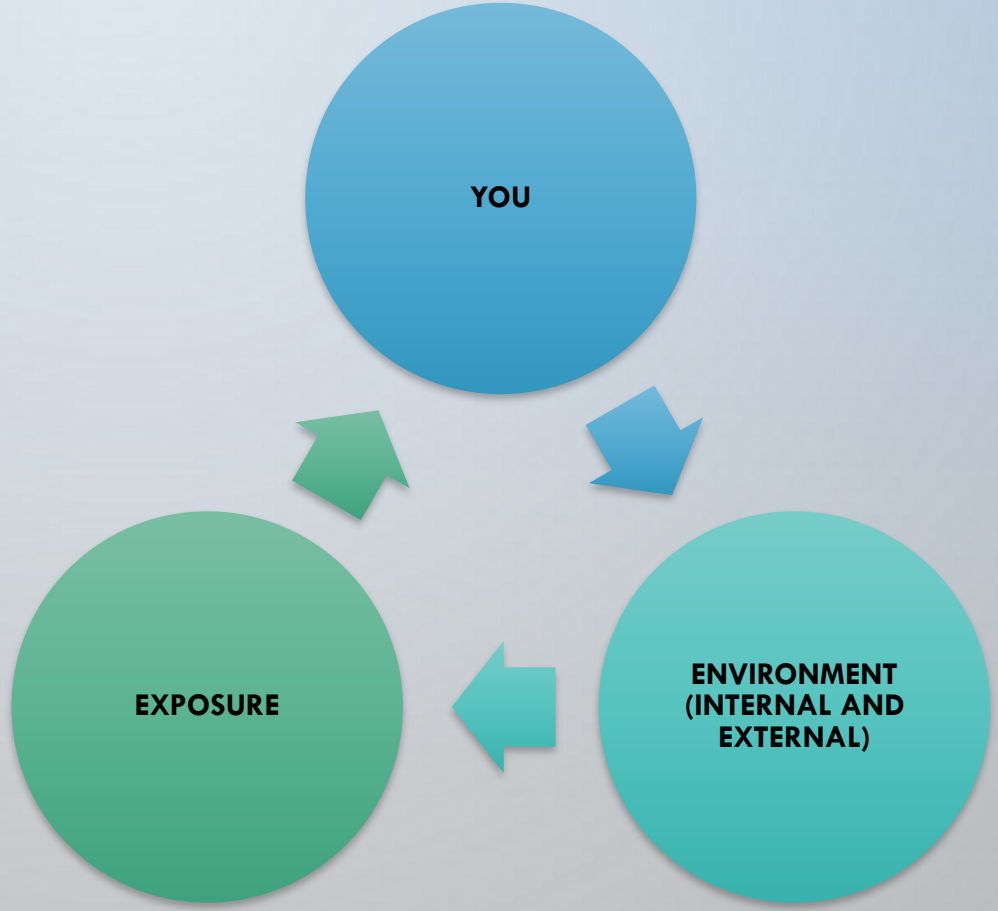
WHAT WE WILL COVER:

- You will understand the varieties of available tests and what they are testing for.
- You will learn about the varieties of vaccinations and what they are good for (& not good for).
- You will discover how to make informed decisions if you have autoimmune disease.
- You will learn about possible alternatives that can be used if you have autoimmune disease.
- You will understand the various aspects of your immune system and how to boost yours.

ELEMENTS

- Viral Spread
- Testing
- Solutions

INDIVIDUALIZED VECTOR



COVID-19: PRIMER ON SARS-COV-2 TESTING

TESTS FOR SARS-COV2/COVID-19 AND POTENTIAL USERS

 DrKeesha.com Academy for Integrative Medicine

TESTING FOR COVID-19/SARS-COV-2

- The ability to accurately identify whether individuals are at risk for, infected with, or have an immune response to sars-cov-2 is essential to address the COVID-19 pandemic from both a personal and a public health perspective. Reliable testing is critical for:
  - Determining the state of an individual's immune response to exposure.
  - Assessing whether an individual is contagious and needs to be quarantined.
  - Deciding if an individual is immune and can return to society without undue risk.
  - Facilitating contact tracing to reduce viral spread.
  - Determining the prevalence and natural history of this novel disease.

Type of Test	Measure	Value	Beneficiary
Nucleic acid amplification test for viral RNA (nasopharyngeal swab, oropharyngeal swab, sputum, bronchoalveolar lavage fluid, saliva)	Presence of RNA from SARS-CoV-2 Current or recent infection and proxy measure of infectivity	+ Inform individual of infection status so they can anticipate course of illness	+ Individual
		+ Inform patient management	+ Healthcare or long-term care facility
		+ Facilitate contact tracing and inform actions needed to prevent transmission	+ Public health
Antibody detection (blood, serum, plasma)	Past exposure to SARS-CoV-2 Current tests are NOT a direct measure of immunity	+ Detect susceptible individuals (antibody negative) and those previously infected	+ Identify those potentially immune to SARS-CoV-2 (for tests that detect protective immunity)
		+ Identify individuals with neutralising antibodies – if specifically measured	+ Healthcare facilities: experimental therapies
		+ Facilitate contact tracing and surveillance actions needed to prevent transmission	+ Public health

TESTING INCLUDES TWO MAIN CATEGORIES

- Those that **detect the presence of the virus** and
- Those that **determine the host response to the virus by detecting antibodies specific to sars-cov-2**.
- Transmission of sars-cov-2 can occur from **direct contact or via airborne droplets**.
- There are **several possible responses** after an individual is exposed to the virus, as shown in the table in next slide.

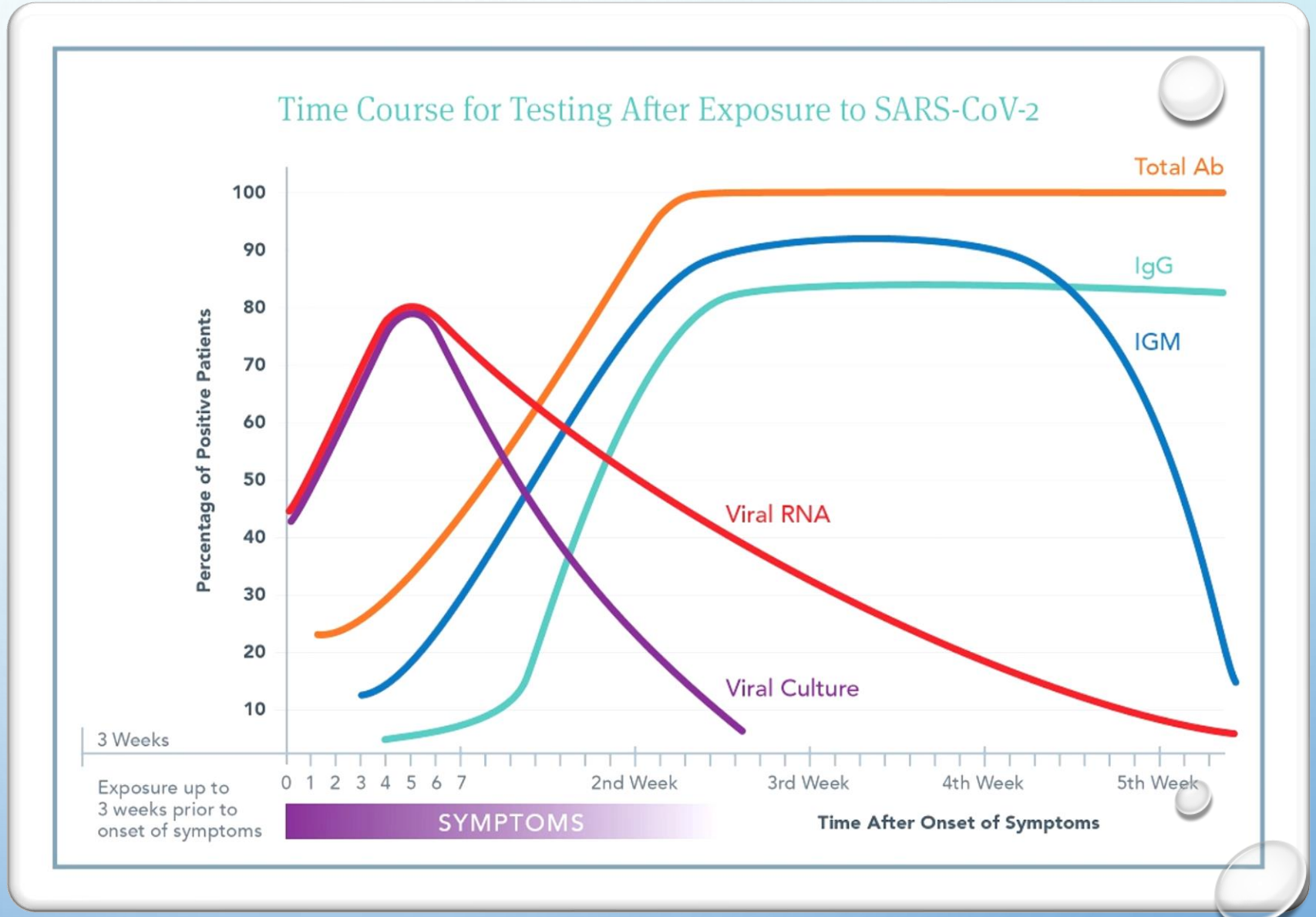
Possible Outcomes After Exposure to SARS-CoV-2		
Symptomatic	Viral RNA shedding	Production of antibodies
-	-	-
-	+	-
-	-	+
-	+	+
+	-	-
+	+	-
+	-	+
+	+	+

TIME COURSE

- Although there is a vast amount of individual variability in response to viral exposure, understanding the general time course of exposure, onset of symptoms, length of viral shedding, and production of antibodies is important for deciding which test to get and how to interpret the findings.

This figure is an aggregate view based on a number of different published studies. It outlines the likelihood that an individual will have a positive test result at a specific time after onset of symptoms.

Day 0 is time of symptom onset.



TIME OF EXPOSURE TO SYMPTOM DEVELOPMENT RANGES FROM 2-21 DAYS

- >90% of people who develop symptoms will do so within 14 days.
- Up to 10% of people may develop symptoms later than 14 days.
- Many people never develop symptoms but may still develop antibody responses.
- **The timing and level of antibody responses in asymptomatic people is presently unknown**.

VIRAL SHEDDING CAN BEGIN 3-21 DAYS AFTER EXPOSURE (PRECEDING SYMPTOMS)

- Viral RNA shedding can occur in nasopharynx, oropharynx, saliva, and sputum for up to 21 days after symptom resolution.
- Testing evaluates viral rna, not shedding of intact virus (infectivity).
- It appears that intact viral shedding is complete 14 days after symptoms begin, though viral rna shedding continues.

ANTIBODY PRODUCTION BEGINS SOON AFTER SYMPTOMS (5-14 DAYS)

- Timing of antibody development (IGM, IGG, & IGA) varies across individuals.
- Median antibody production is at 15 days after exposure.

Viral Testing Summary	
Samples	Sputum, if available, then nasopharyngeal, nasal, and lastly, oropharyngeal swabs. Saliva testing is now also available and works best when collected from a deep cough after arising. Take samples within seven days of symptom onset.
Methods	Ensure viral transport medium is not expired and follow proper collection techniques. Send for RT-PCR at FDA, EUA-approved CLIA lab.
Timing	Viral shedding can begin 3-21 days after exposure. Viral RNA shedding can occur for up to 21 days after symptom resolution. Testing evaluates viral RNA, not shedding of intact virus (i.e., infectivity). It appears that intact viral shedding is, in most cases, complete 14 days after symptom onset—note that this differs from the time course of viral RNA shedding, as measured by NAA.

Summary of Antibody Testing	
Samples	Whole blood, plasma, or serum.
Methods	Send to lab with EUA and validated ELISA or lateral flow membrane testing. Point-of-care testing is not currently FDA-approved (as of April 20, 2020).
Timing	Higher sensitivity begins seven days after symptom onset.
Type	Testing for both IgM and IgG antibodies measuring multiple viral proteins will increase both sensitivity and specificity.

Symptomatic	Viral RNA shedding	Production of antibodies	Interpretation	Action
-	-	-	Susceptible	Social isolation to prevent contracting virus; risk stratification to determine return to work (based upon public policy).
-	+	-	Infected	Quarantine, retest RNA and Ab in two weeks.
-	-	+	Past exposure, immunity likely, evaluate for return to work	If an individual had symptoms, then RNA and Ab test seven days after resolution of symptoms. Return to work if RNA negative and Ab positive. If individual never had symptoms, repeat RNA test and Ab test and consider return to work if RNA negative and Ab positive.
-	+	+	Infected with developing immunity	Quarantine, retest RNA and Ab in seven days, return to work if RNA negative and Ab positive (consider additional RNA negative test if exposure to high risk populations).
+	-	-	Assume infected	Quarantine, consider second RNA test to confirm.
+	+	-	Infected	Quarantine, retest RNA and Ab in two weeks.
+	-	+	Infected with developing immunity	Quarantine, consider second RNA test to confirm.
+	+	+	Infected, with developing immunity	Quarantine, retest RNA and Ab in two weeks.

YOUR IMMUNE SYSTEM

HOW IT WORKS AND WHAT CAN GO WRONG

KINDS OF IMMUNITY

- Innate immunity
- Adaptive (acquired) immunity
- Passive immunity
- Immunizations

THE INNATE IMMUNE SYSTEM

- We are born with innate immunity. These are our first defenders.
- Innate immune responses are stomach acid, mucosal membranes, skin, the cough reflex, the microbiome.
- They are also required to initiate specific adaptive **immune** responses.
- **Innate immune** responses rely on the body's ability to recognize conserved features of pathogens that are not present in the uninfected host.

ADAPTIVE IMMUNITY

- **Adaptive immunity** is created in **response** to exposure to a foreign substance.
- The **innate immune system** contains cells that detect potentially harmful antigens, and then inform the **adaptive immune response** about the presence of these antigens.
- An antigen-presenting cell (APC) is an **immune** cell that detects, engulfs, and informs the **adaptive immune response** about an infection.
- Once activated against a specific type of antigen, the **immunity** can remain throughout life.
- Depending on the health of all three immune responses, the span of developed **immunity** can be lifelong or short.

PASSIVE IMMUNITY

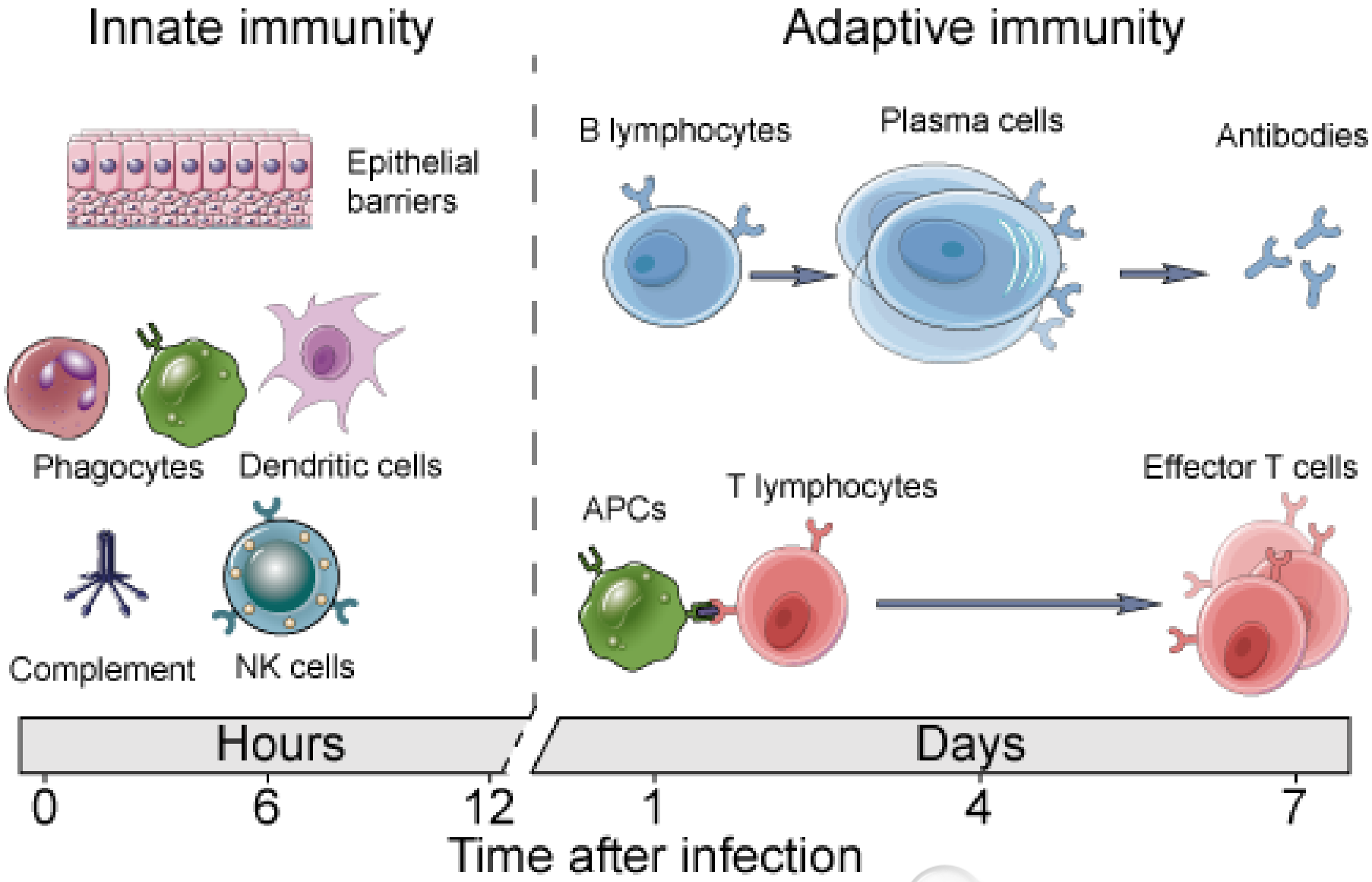
- Passive immunity is borrowed and won't last forever…such as the antibodies passed through a mother through breast milk or the placenta.

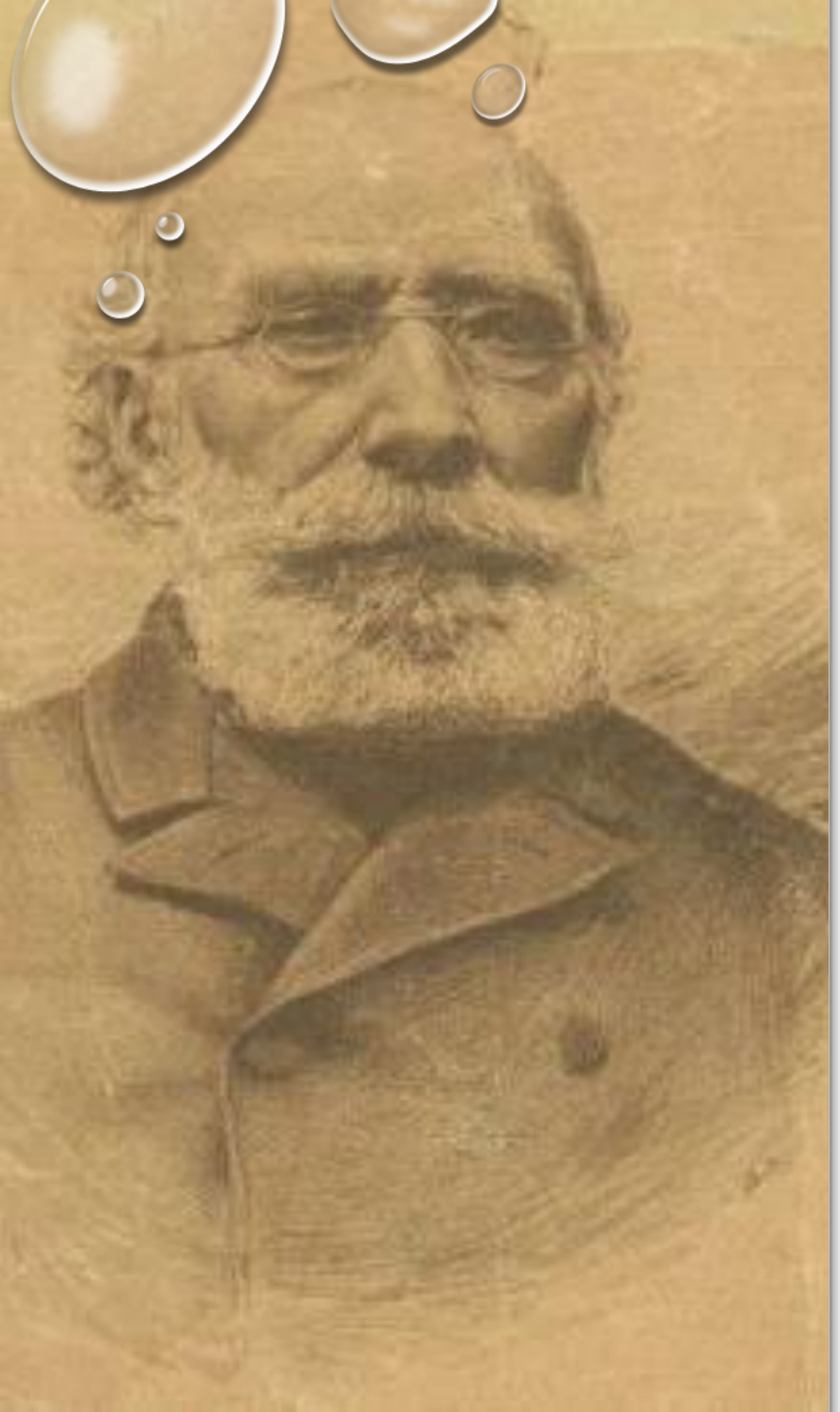
IMMUNIZATIONS

- Immunization introduces antigens or weakened pathogens to a person in such a way that, theoretically, the individual does not become sick but still produces antibodies.
- Because the body saves copies of the antibodies, it is hopefully protected if the threat should reappear later in life.

IMMUNE PROBLEMS

- **Immunodeficiencies:** Arise when one or more parts of the immune system do not function.
- **Autoimmunity:** The immune system mistakenly targets healthy cells, rather than foreign pathogens or faulty cells. In this scenario, they cannot distinguish self from non-self.
- **Hypersensitivity:** The immune system overreacts in a way that damages healthy tissue.

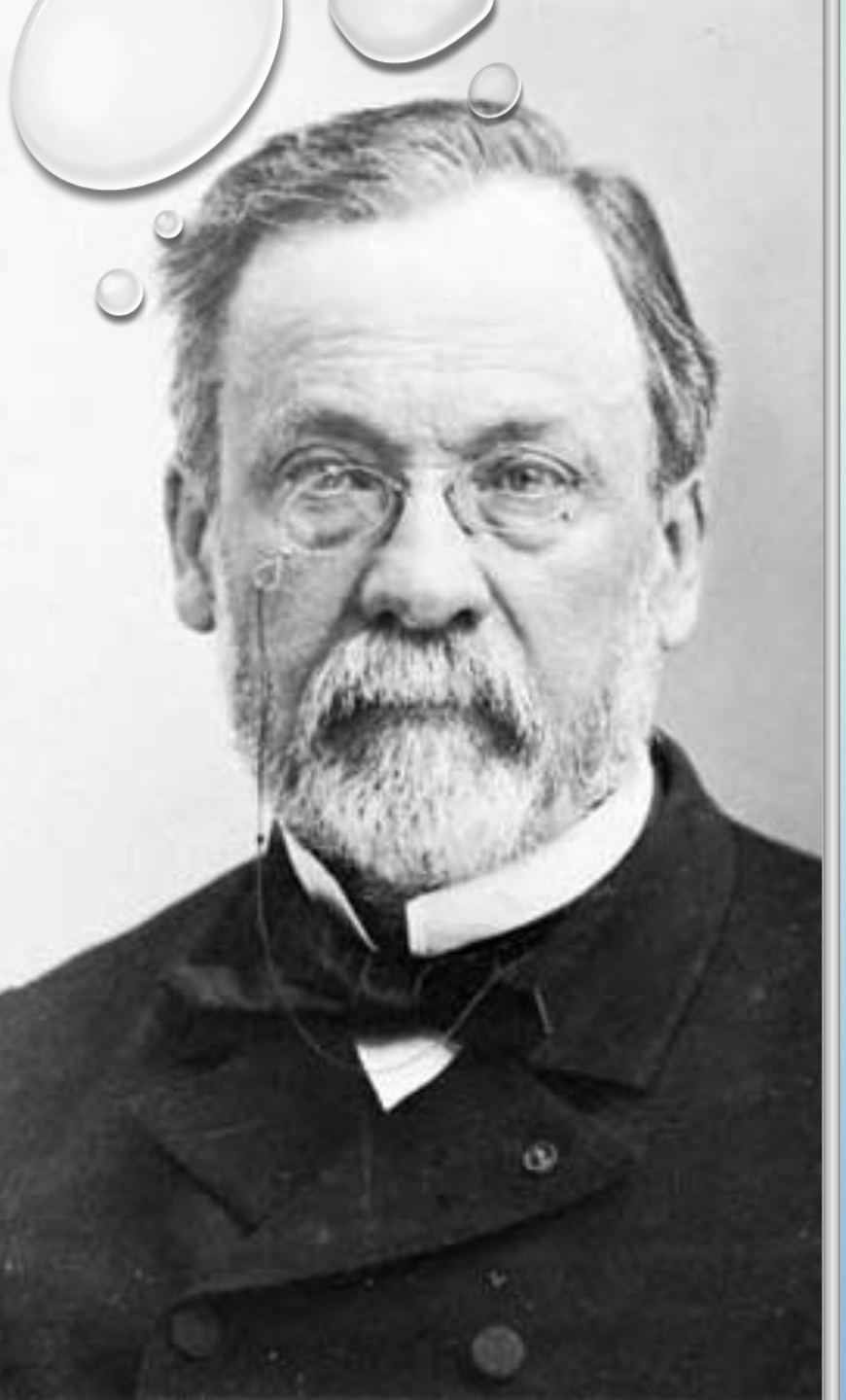




ANTOINE BÉCHAMP

- Denying that bacteria could invade a healthy animal and cause disease, Béchamp claimed instead that unfavorable host and environmental conditions destabilize the host's native microzymas, whereupon they decompose host tissue by producing pathogenic bacteria.

"Germs seek their natural habitat – diseased tissue – rather than being the cause of diseased tissue." - Antoine Béchamp



LOUIS PASTEUR

- A transitional period of germ theory expansion began in the late 1850s with the work of Louis Pasteur.
- This work was later extended by Robert Koch in the 1880s.
- By the end of that decade, the miasma theory was struggling to compete with the germ theory of disease.
- Viruses were discovered in the 1890s and a "golden era" of bacteriology ensued, during which the germ theory quickly led to the identification of the actual organisms that may cause some diseases.

TERRAIN VS GERM THEORY AND IMMUNITY

- Both theories are important and work well together for good health.
- Because of poor soils and the prevalence of toxic chemicals and metals in our foods, air and water, today's bodies are generally weaker.
- Add to that the stress, insufficient diets and fast food, radiation and electromagnetic fields (emfs), it is important that we have medicines to help us combat invading microbes if our bodies do not have a strong enough immune system to deal with them naturally.
- Then top all of this off with an immune system that is already attacking you…autoimmunity.
- Taking precautions to protect yourself from catching prevalent microbes, like the coronavirus, is important (hand washing, staying out of crowds, and masking).

"It is more important to know what sort of person has a disease than to know what sort of disease a person has." - Hippocrates

COVID AND THE IMMUNE SYSTEM

- Most viruses are kept at bay from barriers that protect you from engaging in the genetic information in the viruses. These tight junctions are destroyed by the common chemicals in the environment and stress and many medications.
- This results in an uncontrolled relationship with the millions of viruses within you that then causes you to take in information you would not ordinarily have to deal with.
- Luckily, we are not just a barrier system. We also have an immune system that interacts with the virome that tells us what stressors they are experiencing and what their adaptive strategies are.

VIRUSES AS A GENOMIC TEMPLATE FOR LIFE

- We are constantly interacting with the fungi, virome, microbes in the environment and receiving information from them that helps us to thrive. We have over 280 feedback loops that keep us in a genomic regulatory step that keeps us knowing how to stay healthy in relationship with our environment.
- You are constantly giving and receiving information to all beings on this planet through the fungi, bacteria, viruses and other microbes you are exposed to and exchanging genetic material with.
- The human genome has signatures from the virome that accounts for 52% of the information we get.
- The virome is the genomic template for life.

THE VIROME

VIRUSES AND THE ROLE THEY PLAY IN HEALTH AND DISEASE

 DrKeesha.com Academy for Integrative Medicine

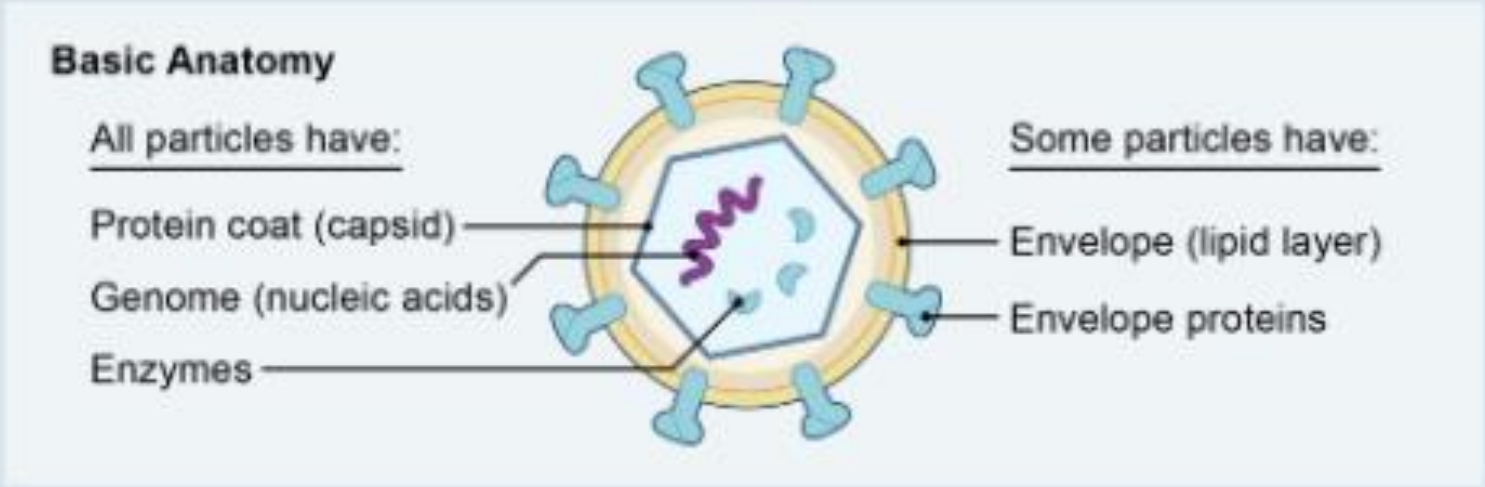
THE VIRAL CONSTELLATION

- 380 trillion viruses are living on and inside your body right now—10 times the number of bacteria.
- Some can cause illness, but many simply coexist with you.
- There are 19 different strains of redondovirus in the respiratory tract; some are related to periodontal disease or lung disease and others help fight respiratory illnesses.

OUR VIRAL CONNECTION

- We are not made up primarily of “human” cells that are occasionally invaded by microbes; our body is really a superorganism of cohabitating cells, bacteria, fungi and most numerous of all: **viruses**.
- The latest counts indicate that as much as half of all the biological matter in your body is not human. Our viromes accumulate from birth on…
- All areas of the body are populated by the virome…breast milk, skin, joints, gut, organs, the cerebrospinal fluid and the brain.
- We didn’t even know about the virome until 10 years ago.
- Now we know that many viruses actually hunt bacteria in the air, soil, water and in all sentient beings…including us.

Viruses are extremely tiny biological particles made up of strands of RNA or DNA inside a protein coat. They can only replicate with the help of a host cell that they infect. Viruses can be characterized by their shape **A**, their host cell **B** or their genetic code **C**.



VIRUSES ARE PART OF THE MORPHOGENETIC FIELD

- In the air you breathe there are 10,000,000 more viruses than there are stars in the sky, cells in the ocean and in the ground you stand on.
- We are in a massive field of viruses. We do not need protection from them. We need to be grateful to the virome that it's only 1 that arises periodically to create imbalances in us.
- We have seen variations of COVID over the course of the last few decades before. We will continue to see them. They are popping up like daisies right now as the vaccinations roll out.

THE SCIENCE AND THE VIROME

- The virome gives our adaptive immune system information for how to adapt, how to evolve and how to stay alive on our planet. It's transferring information from the other beings we share the planet with, from the planet itself, from plant material and from toxicants to our genome so it can do its epigenetic best to keep us going.
- Just like earth is not the center of the universe and the world is not flat, the human cell is not the center of human health. We do not have to battle away germs.
- The next technological breakthrough we are waiting for is to discover we have a place within nature… within the interdependent web of life.
- We have believed and behaved as though we are the top of a pyramid rather than part of a web.

VIRAL EVOLUTION

- In its entirety, the human virome is neither ‘good’ nor ‘bad’ – it is simply an ancient part of us.
- Viruses share a deep evolutionary relationship with animals and plants.
- Every cell in your body is part of an unbroken chain of life that has extended over 3.8 billion years. Viruses have been an important part of that evolutionary waltz from the very start.
- The more we learn about the virome, the more we come to see how some aspects are essential for a healthy life.
- So, expect a coming revolution in how we conceive of viruses.

RETELLING THE COVID STORY

- Adaptation and diversification is what our immune system is for. The virome is one of the tools that helps us stay alive on this planet. It's one of the aids to the immune system.
- The story about the vaccine is we need this technology to change our relationship with one virus. This is a multibillion-dollar industry who wants the story to be told in this way.
- We've seen this virus before as it's been around for at least 700 years.
- This adaptation within the corona has changed our relationship with nature and is showing us our vulnerabilities.
- The innate immune system is what kicks in the second a new antigen is introduced to the human body.
- The proteins on the outside of the virus give us information that we need to adapt and be in relationship with it.
- The vaccine changes the instructions for how to adapt to the virus.

COVID-19 VACCINES

COVID-19 MRNA VACCINE

- COVID-19 mrna vaccines give instructions for our cells to make a "spike protein."
- The spike protein is found on the surface of the virus that causes COVID-19.
- Covid-19 mrna vaccines are given in the upper arm muscle.
- Once the instructions (mrna) are inside the immune cells, the cells use them to make the protein piece. After the protein piece is made, the cell breaks down the instructions and gets rid of them.
- Next, the cell displays the protein piece on its surface. Our immune systems recognize that the protein doesn't belong there and begins building an immune response and making antibodies, like what happens in natural infection against COVID-19.
- Given in a series of 2 shots.
- This is new technology that has been studied but never with COVID and never released to a human population.

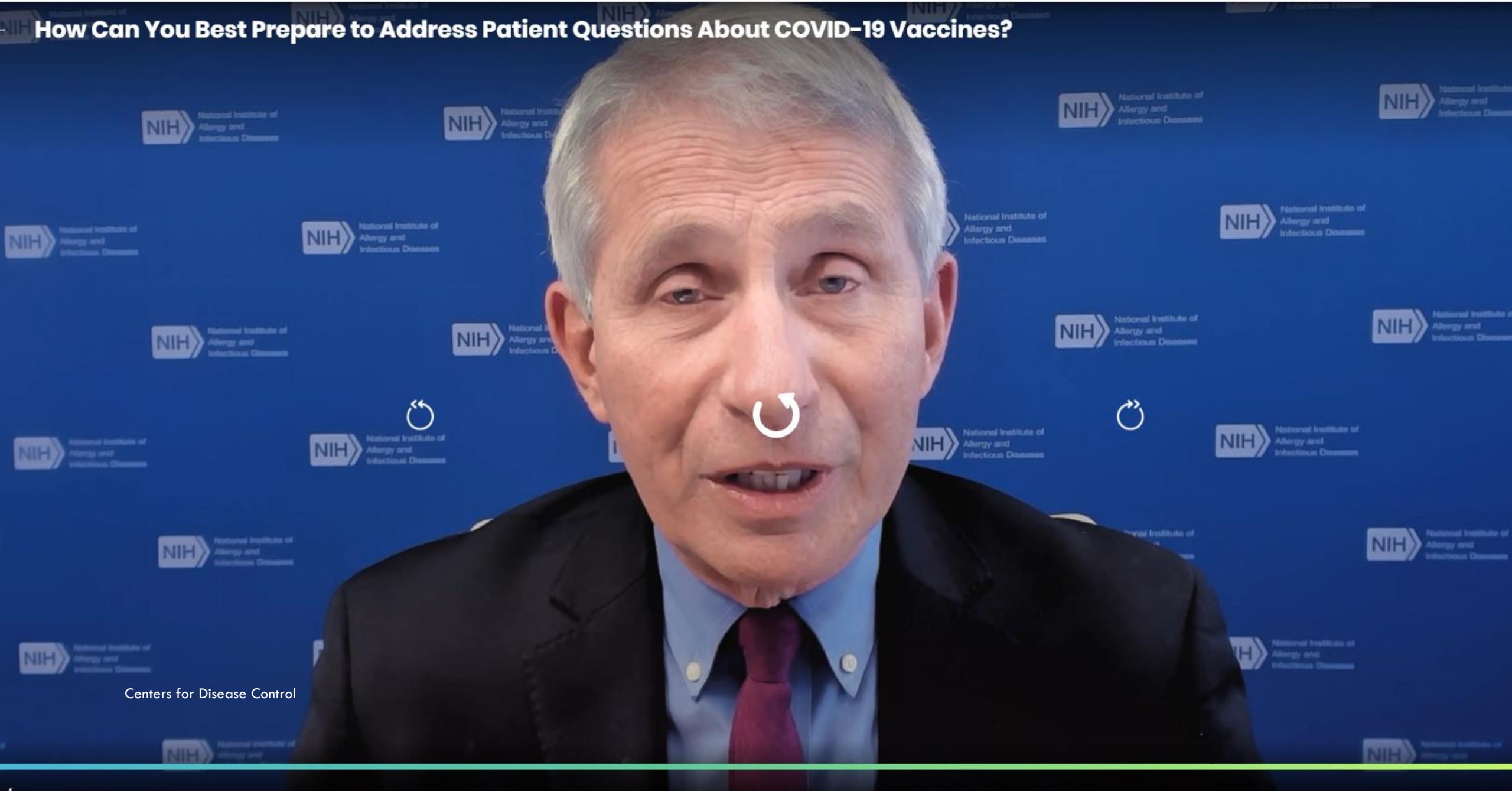
Centers for Disease Control

COVID-19 VIRAL VECTOR VACCINE

- Viral vector vaccines use a modified version of a different virus (the vector) to deliver important instructions to our cells.
- For COVID-19 viral vector vaccines, the vector will enter a cell in our body and then use the cell's machinery to produce a spike protein.
- The cell displays the spike protein on its surface, and our immune system recognizes it doesn't belong there.
- This triggers our immune system to begin producing antibodies and activating other immune cells to fight off what it thinks is an infection.
- At the end of the process, our bodies have learned how to protect us against future infection with the virus that causes covid-19.
- Given in a series of 2 shots.

Centers for Disease Control

pocnplus.com/watch/how-can-you-best-prepare-to-address-patient-questions-about-covid-19-vaccines



Preliminary recommendations for COVID-19 vaccination in patients with cancer were published in January 2021 by the National Comprehensive Cancer Network (NCCN) on the NCCN Web site.[1]

Note: COVID-19 vaccines should be prioritized over other needed vaccines. It is recommended that there be an interval of 14 days between administration of COVID-19 vaccines and administration of other approved vaccines.

Patients Receiving Hematopoietic Cell Transplantation or Cellular Therapy

It is recommended that COVID-19 vaccination take place ≥3 months after hematopoietic cell transplantation (allogeneic or autologous) or cellular therapy (eg, chimeric antigen receptor [CAR] T cell therapy).

Patients With Hematologic Malignancies

For patients receiving intensive cytotoxic chemotherapy, COVID-19 vaccination should be delayed until the absolute neutrophil count has recovered.

For patients with marrow failure from disease or therapy who are expected to have limited or no recovery, as well as for patients on long-term maintenance therapy, COVID-19 vaccination should be performed when the vaccine becomes available.

Patients With Solid-Tumor Malignancies

For patients receiving cytotoxic chemotherapy, targeted therapy, checkpoint inhibitor therapy or other immunotherapy, or radiation therapy, COVID-19 vaccination should be performed when the vaccine becomes available.

For patients undergoing major surgical procedures, COVID-19 vaccination should be postponed until at least a few days after surgery.

Patients' Caregivers and Contacts

Caregivers, household members, and close contacts aged 16 years or older should be vaccinated whenever they are eligible to receive the vaccine.

For more information, please go to Coronavirus 19 (COVID-19)

COVID-19 and Autoimmune Diseases

Yu Liu; Amr H. Sawalha; Qianjin Lu

DISCLOSURES | Curr Opin Rheumatol. 2021;33(2):155-162.

Abstract and Introduction

Abstract

Purpose of Review: The aim of this study was to evaluate the relationship between infection with SARS-CoV-2 and autoimmunity.

Recent Findings: Coronavirus disease 2019 (COVID-19) is an infectious disease caused by severe acute respiratory syndrome (SARS) associated coronavirus 2 (SARS-CoV-2). Although most of the infected individuals are asymptomatic, a proportion of patients with COVID-19 develop severe disease with multiple organ injuries. Evidence suggests that some medications used to treat autoimmune rheumatologic diseases might have therapeutic effect in patients with severe COVID-19 infections, drawing attention to the relationship between COVID-19 and autoimmune diseases. COVID-19 shares similarities with autoimmune diseases in clinical manifestations, immune responses and pathogenic mechanisms. Robust immune reactions participate in the pathogenesis of both disease conditions. Autoantibodies as a hallmark of autoimmune diseases can also be detected in COVID-19 patients. Moreover, some patients have been reported to develop autoimmune diseases, such as Guillain--Barré syndrome or systemic lupus erythematosus, after COVID-19 infection. It is speculated that SARS-CoV-2 can disturb self-tolerance and trigger autoimmune responses through cross-reactivity with host cells. The infection risk and prognosis of COVID-19 in patients with autoimmune diseases remains controversial, but patient adherence to medication regimens to prevent

ACR TASK FORCE: MARCH 2021

- 9 rheumatologists and 2 infectious disease MDs and 8 weeks looking at research…
- The task force confined its research to the COVID-19 vaccines being offered by Pfizer and Moderna.
- *Because little research has directly addressed the question concerning covid-19 vaccination for patients with rheumatic diseases, the task force extrapolated from data on other vaccinations in people with rheumatic disease and on the covid-19 vaccinations in other populations*.
- "It is really individual case reports or small cohorts where there may be a somewhat higher incidence of flare, but it's usually not very large in its magnitude nor duration," Curtis said.
- The task force also considered the possibility that vaccinations could lead to a new autoimmune disorder, such as Guillain-Barré syndrome or bell palsy. The risk is real, the task force decided, but not significant enough to influence their recommendations.

ACR TASK FORCE: MARCH 2021

- Do not get vaccinated if active autoimmune flare.
- Do not get vaccinated if receiving Retuximab.
- Other recommendations per following table…

IFM WEBINAR FOR PROVIDERS: FEBRUARY 2021

- 196 people had died post-vaccine since January 18th, 2021.
- Testosterone decreases efficacy.
- Estrogen increases efficacy.

Table 3: Guidance Related to the Use and Timing of Vaccination and Immunomodulatory Therapies in Relation to COVID-19 Vaccination Administration in RMD Patients*

Medication	Timing Considerations for Immunomodulatory Therapy and Vaccination*	Level of Task Force Consensus
Hydroxychloroquine; IVIG; glucocorticoids, prednisone-equivalent dose <20mg/day	No modifications to either immunomodulatory therapy or vaccination timing	Strong-Moderate
Sulfasalazine; Leflunomide; Mycophenolate; Azathioprine; Cyclophosphamide (oral); TNFi; IL-6R; IL-1; IL-17; IL-12/23; IL-23; Belimumab; oral calcineurin inhibitors; Glucocorticoids, prednisone-equivalent dose ≥ 20mg/day**	No modifications to either immunomodulatory therapy or vaccination timing	Moderate
Methotrexate	Hold MTX 1 week after each vaccine dose, for those with well-controlled disease; no modifications to vaccination timing	Moderate
JAKi	Hold JAKi for 1 week after each vaccine dose; no modification to vaccination timing	Moderate
Abatacept SQ	Hold SQ abatacept both one week prior to and one week after the first COVID-19 vaccine dose (only); no interruption around the second vaccine dose	Moderate
Abatacept IV	Time vaccine administration so that the first vaccination will occur four weeks after abatacept infusion (i.e., the entire dosing interval), and postpone the subsequent abatacept infusion by one week (i.e., a 5-week gap in total); no medication adjustment for the second vaccine dose	Moderate
Cyclophosphamide IV	Time CYC administration so that it will occur approximately 1 week after each vaccine dose, when feasible	Moderate
Rituximab	Assuming that patient's COVID-19 risk is low or is able to be mitigated by preventive health measures (e.g., self-isolation), schedule vaccination so that the vaccine series is initiated approximately 4 weeks prior to next scheduled rituximab cycle; after vaccination, delay RTX 2-4 weeks after 2nd vaccine dose, if disease activity allows	Moderate

RMD = rheumatic and musculoskeletal disease; IVIG = intravenous immunoglobulin; TNFi = tumor necrosis factor inhibitor; IL = interleukin; JAKi = janus kinase inhibitor; CYC = cyclophosphamide; RTX = rituximab; IV = intravenous; SQ = subcutaneous

**guidance to 'hold' a therapy was made based on the assumption that the patient had well-enough controlled disease to allow for a temporary interruption; if not, decision-making should be determined on a case-by-case basis, considering the circumstances involved*

***consensus was not reached for vaccination timing in patients receiving prednisone-equivalent doses ≥ 20mg/day; see full guidance document, when published, for additional details*

POTENTIAL ALTERNATIVES TO VACCINATIONS

FOR THE PATIENT WITH AUTOIMMUNE DISEASE

 DrKeesha.com Academy for Integrative Medicine

FIRST WORK ON YOUR INNER TERRAIN

- Boosting the inner innate immune system:
  - Sleep 8-10 hours a night.
  - Exercise in a way that matches your adrenals and hormones and do it daily.
  - Eat 10-12 cups of a rainbow of veggies a day (juice half of them…no fruit in your juicer!), clean protein, and good fats.
  - Hydrate with water and cut out alcohol, sugar and caffeine.
  - Eliminate inflammatory causing foods (requires you test, don't guess).
  - Make sure you have enough stomach acid.
  - Follow the epigenetic plan your individual system requests from you.
  - Supplement with nutritional supplements matched to your body's requests and the current research for prevention.
  - Heal your barriers…including your energetic ones…
    - Healing Trauma Through the Chakra System and The Stress Busting Tool Kit.
    - Breathe…

SECOND WORK ON SOCIAL INNATE IMMUNITY

- Boosting the social innate immune system:
  - Mask, mask, mask…and good handwashing.
  - Socialize in pods that have carefully sheltered in space with themselves.
  - Isolate when you suspect exposure and tell those whom you have been in contact with also.
  - Be patient…
    - Learn a new skill.
    - Engage in radical self-care.
    - Utilize technology to socialize.
    - Read, read, read.
    - Dream about what you want to do when we come into harmony with this virus.

SCIENCE BEHIND MASKING

- Unnecessary outdoors if socially distanced (Danish Study).
- Necessary indoors when around people you do not live with (Military Recruits Study).
- Viral spread via air droplets increases with:
  - Density – # of people in the room.
  - Duration – # of hours spent in the room.
  - Dimensions – # of square feet and ceiling height of the room.
  - Draft – amount of fresh air entry/speed of air flow.
- Standard masks don't protect against the above…just N-95s.

IVERMECTIN

WHAT IS IVERMECTIN?

- Ivermectin is an anti-parasitic medication whose discovery won the Nobel prize in 2015.
- It has proven to also be highly potent as an anti-viral and anti-inflammatory medication.
- In the past 4 months, numerous, controlled clinical trials from multiple centers and countries worldwide are reporting consistent, large improvements in COVID-19 patient outcomes when treated with Ivermectin.
- A comprehensive scientific review of these referenced trials can be found on the open science foundation pre-print server here: https://osf.Io/wx3zn/ .

PROPERTIES OF IVERMECTIN

- Ivermectin inhibits the replication of many viruses, including SARS-CoV-2, influenza, and others;
- Ivermectin has potent anti-inflammatory properties with multiple mechanisms of inhibition;
- Ivermectin diminishes viral load and protects against organ damage in animal models;
- Ivermectin prevents transmission of COVID-19 when taken either pre- or post-exposure;
- Ivermectin hastens recovery and decreases hospitalization and mortality in patients with COVID-19;
- Ivermectin leads to far lower case-fatality rates in regions with widespread use.

COVID AND IVERMECTIN

- In COVID-19 specifically, studies show that one of its several anti-viral properties is that it strongly binds to the spike protein, keeping the virus from entering the cell.
- These effects, along with its multiple abilities to control inflammation, both explain the markedly positive trial results already reported, and poise ivermectin to again achieve similar historic impacts via the eradication of COVID-19.

COVID AND IVERMECTIN

- Acts through competitive binding of Ivermectin with the host receptor-binding region of SARS-CoV-2 spike protein, limiting binding to the ACE-2 receptor;
- binding to the SARS-CoV-2 RNA-dependent RNA polymerase (RdRp), thereby inhibiting viral replication (Swargiary, 2020);
- binding/interference with multiple essential structural and non-structural proteins required by the virus in order to replicate.

SIDE EFFECT FOR IVERMECTIN

- Since 1975 it has been included on the WHO's "List of Essential Medicines with now over 4 billion doses administered.
- Numerous studies report low rates of adverse events, with the majority mild, transient, and largely attributed to the body's inflammatory response to the death of parasites and include itching, rash, swollen lymph nodes, joint paints, fever and headache.
- According to the pharmaceutical reference standard Lexicomp, the only medications contraindicated for use with Ivermectin are the concurrent administration of anti-tuberculosis and cholera vaccines while the anticoagulant warfarin would require dose monitoring.
- Another special caution is that immunosuppressed or organ transplant patients who are on calcineurin inhibitors such as tacrolimus or cyclosporine or the immunosuppressant sirolimus should have close monitoring of drug levels when on Ivermectin given that interactions exist which can affect these levels.
- A longer list of drug interactions can be found on the database of www.drugs.com/ivermectin.html, with nearly all interactions leading to a possibility of either increased or decreased blood levels of Ivermectin.
- Ivermectin has been used safely in pregnant women, children, and infants.

EVIDENCE SUPPORTING EFFICACY OF IVERMECTIN

(Rct's = randomized controlled trials, oct's = observational controlled trials). Every clinical trial shows a benefit, with rct's and oct's reporting the same. Direction and magnitude; nearly all are statistically significant.

- **8 controlled trials** studying the prevention of covid-19.
  - **3 rct's** with large statistically significant **reductions in transmission rates**, a total of **774 patients.**
  - **5 oct's** with large statistically significant **reductions in transmission rates**, a total of **2,052 patients.**
- **19 controlled trials** in the treatment of both early and hospitalized COVID-19 patients.
  - **5 rct's** with large, significant **reductions in time to recovery or hospital length of stay**, a total of **774 patients.**
  - **1 RCT** with a large, statistically significant **reduction in rate of deterioration/hospitalization**, total of **363 patients.**
  - **2 rct's** with significant **decreases in viral load, days of anosmia, cough, or time to recovery**, a total of **85 patients.**
  - **3 rct's** with large, significant **reductions in mortality**, a total of **695 patients.**
  - **3 oct's** with large, statistically significant **reductions in mortality**, a total of **1,688 patients.**

NUMBER OF STUDIES AND PATIENTS IN TRIALS NOW

- **27 controlled trials**, including a total of 6,612 patients have been completed using well-matched control groups.
- **16 trials**, including over 2,500 patients, are prospective, randomized, controlled studies.
- **11 of the 27 trials have been published in peer-reviewed journals, 3,900 patients, remainder are in pre-print.**
- A meta-analysis recently performed by an independent research consortium calculated the chances that Ivermectin is ineffective in COVID-19 to be **1 in 67 million**.

FRONT LINE COVID-19 CRITICAL CARE ALLIANCE

- The FLCCC Alliance, based on the totality of the existing evidence, supports an A-I recommendation (NIH rating scheme; strong level, high quality evidence) for the use of Ivermectin in both the prophylaxis and treatment of all phases of COVID-19.
- Furthermore, we encourage all regulatory agencies to review our manuscript detailing these studies above as well as the multiple population-wide “natural experiments” that occurred in numerous cities and regions after the initiation of Ivermectin distribution programs.
- The widespread use of Ivermectin resulted in a significant reduction in cases and mortality rates that approached pre-pandemic levels in these areas.
- As evidenced by what occurred in these regions, Ivermectin is clearly an essential and vital treatment component in achieving control of the pandemic. (reiterated January 15, 2021)

Ivermectin is effective for COVID-19: real-time meta analysis of 42 studies

Covid Analysis, Nov 26, 2020 (Version 37, Feb 27, 2021)

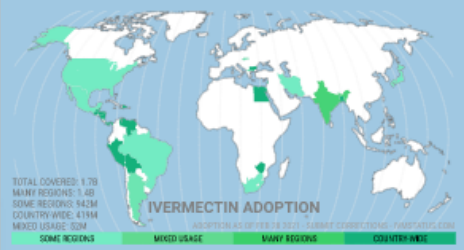
@CovidAnalysis Share Tweet PDF Studies

- 100% of the 42 studies to date report positive effects. Random effects meta-analysis for early treatment and pooled effects shows a reduction of 83%, RR 0.17 [0.11-0.28]. Prophylactic use shows a reduction of 89%, RR 0.11 [0.05-0.23]. Mortality results show 75% lower mortality, RR 0.25 [0.14-0.44] for all treatment delays, and 86% lower, RR 0.14 [0.03-0.62] for early treatment.
- 100% of the 21 Randomized Controlled Trials (RCTs) report positive effects, with an estimated reduction of 70%, RR 0.30 [0.19-0.49].
- The probability that an ineffective treatment generated results as positive as the 42 studies to date is estimated to be 1 in 4 trillion (p = 0.00000000000023). All data to reproduce this paper and the sources are in the appendix.

Early treatment	83% improvement	RR 0.17 [0.11-0.28]
Late treatment	51% improvement	RR 0.49 [0.37-0.66]
Prophylaxis	89% improvement	RR 0.11 [0.05-0.23]

Total	42 studies	331 authors	14,906 patients
RCT	21 studies	180 authors	2,869 patients

Indication	Studies	Patients	Effect size	WHO status
Scabies *[Kory]*	6	613	0.65 [0.54-0.78] 35% improvement	Approved
COVID-19 (RCT)	21	2,869	0.30 [0.19-0.49] 70% improvement	Not approved yet
COVID-19 (all)	42	14,906	0.25 [0.19-0.34] 75% improvement	



Show results for:

- All studies
- With exclusions
- Mortality results
- Viral clearance
- COVID-19 cases
- Peer reviewed
- RCT mortality
- All RCTs

frontiers

Review of the Emerging Evidence Demonstrating the Efficacy of Ivermectin in the Prophylaxis and Treatment of COVID-19

Pierre Kory, MD[1]*, G. Umberto Meduri, MD[2]†, Jose Iglesias, DO[3], Joseph Varon, MD[4], Keith Berkowitz, MD[5], Howard Kornfeld, MD[6], Eivind Vinjevoll, MD[7], Scott Mitchell, MBChB[8], Fred Wagshul, MD[9], Paul E. Marik, MD[10]

1 Front-Line Covid-19 Critical Care Alliance.
2 Memphis VA Medical Center - Univ. of Tennessee Health Science Center, Memphis, TN.
3 Hackensack School of Medicine, Seton Hall, NJ.
4 University of Texas Health Science Center, Houston, TX.
5 Center for Balanced Health, New York
6 Recovery Without Walls
7 Volda Hospital, Volda, Norway
8 Princess Elizabeth Hospital, Guernsey, UK
9 Lung Center of America, Dayton, Ohio
10 Eastern Virginia Medical School

* **Correspondence:**
Corresponding Author: Pierre Kory, MD, MPA
pkory@flccc.net
1 These authors have contributed equally to this work
† Dr. Meduri's contribution is the result of work supported with the resources and use of facilities at the Memphis VA Medical Center. The contents of this commentary do not represent the views of the U.S. Department of Veterans Affairs or the United States Government

Keywords

Ivermectin, COVID-19, infectious disease, pulmonary infection, respiratory failure

Abstract

In March 2020, an expert panel called the Front Line COVID-19 Critical Care Alliance (FLCCC) was created and led by Professor Paul E. Marik, with the goal of continuously reviewing the rapidly emerging basic science, translational, and clinical data in order to gain insight into and to develop a treatment protocol for COVID-19. At the same time, ...

See more

Preprint DOI

10.31219/osf.io/wx3zn

I-MASK+ PROPHYLAXIS AND EARLY OUTPATIENT TREATMENT PROTOCOL FOR COVID-19

PROPHYLAXIS PROTOCOL

Ivermectin[1]	***Prophylaxis for high risk individuals*** 0.2 mg/kg* per dose – one dose today, 2nd dose in 48 hours, then one dose every 2 weeks[2] ***Post COVID-19 exposure prophylaxis***[3] 0.2 mg/kg* per dose – one dose today, 2nd dose in 48 hours[2]
Vitamin D3	1,000–3,000 IU/day
Vitamin C	1,000 mg twice a day
Quercetin	250 mg/day
Zinc	50 mg/day
Melatonin	6 mg before bedtime (causes drowsiness)

I-MASK+ PROPHYLAXIS AND EARLY OUTPATIENT TREATMENT PROTOCOL FOR COVID-19

EARLY OUTPATIENT PROTOCOL[4]

Ivermectin[1]	0.2 mg/kg* per dose – one dose daily, minimum of 2 days, continue daily until recovered (max 5 days)[2]
Vitamin D3	4,000 IU/day
Vitamin C	2,000 mg 2-3 times daily
Quercetin	250 mg twice a day
Zinc	100 mg/day
Melatonin	10 mg before bedtime (causes drowsiness)
Aspirin	325 mg/day (unless contraindicated)
Pulse Oximeter	Monitoring of oxygen saturation is recommended (for instructions please see page 2 of this file)

I-MASK+ PROPHYLAXIS AND EARLY OUTPATIENT TREATMENT PROTOCOL FOR COVID-19

* ≈ 0.09 mg/lb per dose — please see conversion table on page 2 to calculate the appropriate ivermectin dose (take it with or after meals).

1 The safety of ivermectin in pregnancy has not been established. A discussion of benefits vs. risks with your provider is required prior to use, particularly in the 1st trimester.

2 The dosing may be updated as further scientific studies emerge.

3 To use if a household member is COVID-19 positive, or you have prolonged exposure to a COVID-19 positive patient without wearing a mask

4 For late phase — hospitalized patients — see the FLCCC's MATH+ Hospital Treatment Protocol for COVID-19 on www.flccc.net

---

Please regard our **disclaimer** and further information on page 2 of this document.

www.flccc.net


FUNCTIONAL
NUTRIENTS
Buffered-C
A Dietary Supplement
90 CAPSULES
FUNCTIONAL
NUTRIENTS
Zinc Plus
Dietary Supplement
90 Vegetarian Capsules
FUNCTIONAL
NUTRIENTS
Quercetin Plus
Dietary Supplement
FUNCTIONAL
NUTRIENTS
D3 + K2 Liquid
FUNCTIONAL
NUTRIENTS
Melatonin
A Dietary Supplement
100 TABLETS

IVERMECTIN

Summary of the Clinical Trials Evidence for Ivermectin in COVID-19

Ivermectin, an anti-parasitic medicine whose discovery won the Nobel Prize in 2015, has proven, highly potent, anti-viral and anti-inflammatory properties in laboratory studies. In the past 4 months, numerous, controlled clinical trials from multiple centers and countries worldwide are reporting consistent, large improvements in COVID-19 patient outcomes when treated with ivermectin.

Our comprehensive scientific review of these referenced trials on ivermectin can be found on

www.flccc.net/flccc-ivermectin-in-the-prophylaxis-and-treatment-of-covid-19/

For a quick overview, a **One-page Summary** of our review on ivermectin can be found on

www.flccc.net/one-page-summary-of-the-clinical-trials-evidence-for-ivermectin-in-covid-19/

Body weight conversion (kg/lb) for ivermectin dose in prophylaxis and treatment of COVID-19

Body weight **Conversion (1 kg ≈ 2.2 lbs)** (doses calculated per upper end of weight range)		**Dose** **0.2 mg/kg ≈ 0.09 mg/lb** (Each tablet = 3 mg; doses rounded to nearest half tablet above)	
70–90 lb	32–40 kg	8 mg	(3 tablets = 9 mg)
91–110 lb	41–50 kg	10 mg	(3.5 tablets)
111–130 lb	51–59 kg	12 mg	(4 tablets)
131–150 lb	60–68 kg	13.5 mg	(4.5 tablets)
151–170 lb	69–77 kg	15 mg	(5 tablets)
171–190 lb	78–86 kg	16 mg	(5.5 tablets)
191–210 lb	87–95 kg	18 mg	(6 tablets)
211–230 lb	96–104 kg	20 mg	(7 tablets = 21 mg)
231–250 lb	105–113 kg	22 mg	(7.5 tablets=22.5 mg)
251–270 lb	114–122 kg	24 mg	(8 tablets)
271–290 lb	123–131 kg	26 mg	(9 tablets = 27 mg)
291–310 lb	132–140 kg	28 mg	(9.5 tablets=28.5 mg)

DISCLAIMER

*The **I-Mask+ Prophylaxis & Early Outpatient Treatment Protocol for COVID-19** and the **MATH+ Hospital Treatment Protocol for COVID-19** are solely for educational purposes regarding potentially beneficial therapies for COVID-19. Never disregard professional medical advice because of something you have read on our website and releases. It is not intended to be a substitute for professional medical advice, diagnosis, or treatment in regards to any patient. Treatment for an individual patient should rely on the judgement of your physician or other qualified health provider. Always seek their advice with any questions you may have regarding your health or medical condition.*

A summary of the published data supporting the rationale for Ivermectin use in our I-MASK+ protocol can be downloaded from www.flccc.net/i-mask-prophylaxis-treatment-protocol/

For updates, references, and information on the FLCCC Alliance, the I-Mask+ Prophylaxis & Early Outpatient Treatment Protocol for COVID-19 and the MATH+ Hospital Treatment Protocol for COVID-19, please visit our website www.flccc.net

www.flccc.net

PULSE OXIMETRY

- Use the index or middle finger; avoid toes or earlobes.
- Only use values associated with a strong pulse signal.
- Observe readings for 30-60 seconds to identify the most common value.
- Remove nail polish from the finger being measured.
- Warm up cold extremities prior to measuring.
- A value <94% should prompt hospital admission.

IVERMECTIN RESEARCH & REFERENCES

- KORY P, MEDURI GU, IGLESIAS J, ET AL. REVIEW OF THE EMERGING EVIDENCE DEMONSTRATING THE EFFICACY OF IVERMECTIN IN THE PROPHYLAXIS AND TREATMENT OF COVID-19. 18 DEC 2020.HTTPS://COVID19CRITICALCARE.COM/WP-CONTENT/UPLOADS/2020/11/FLCCCIVERMECTIN-IN-THE-PROPHYLAXIS-AND-TREATMENT-OF-COVID-19.PDF.
- CONTERNO LO, TURCHI MD, CORRÊA I, MONTEIRO DE BARROS ALMEIDA RA. ANTHELMINTIC DRUGS FOR TREATING ASCARIASIS. COCHRANE DATABASE OF SYSTEMATIC REVIEWS 2020, ISSUE 4. ART. NO.: CD010599. DOI: 10.1002/14651858.CD010599.PUB2. ACCESSED 28 DECEMBER 2020.
- BARROW NJ, CAMPOS RK, POWELL ST, ET AL. A SCREEN OF FDA-APPROVED DRUGS FOR INHIBITORS OF ZIKA VIRUS INFECTION. CELL HOST & MICROBE. 2016;20(2):259-270.
- KIRCIK, LH, DEL ROSSO, JQ, LAYTON AM, SCHAUBER J. OVER 25 YEARS OF CLINICAL EXPERIENCE WITH IVERMECTIN: AN OVERVIEW OF SAFETY FOR AN INCREASING NUMBER OF INDICATIONS. J DRUGS DERM 2016; 15:325-332.
- WORLD HEALTH ORGANIZATION. 21ST MODEL LIST OF ESSENTIAL MEDICINES. GENEVA, SWITZERLAND. 2019. HTTPS://WWW.WHO.INT/PUBLICATIONS/I/ITEM/WHOMVPEMPIAU2019.06. ACCESSED 29 DECEMBER 2020.
- HIGGINS JPT, THOMAS J, CHANDLER J, CUMPSTON M, LI T, PAGE MJ, WELCH VA (EDITORS). COCHRANE HANDBOOK FOR SYSTEMATIC REVIEWS OF INTERVENTIONS VERSION 6.0 [UPDATED JULY 2019]. COCHRANE, 2019. AVAILABLE FROM WWW.TRAINING.COCHRANE.ORG/HANDBOOK.
- STERNE JA, HERNÁN MA, REEVES BS, SAVOVÍC J, BERKMAN ND, VISWANATHAN V, ET AL. ROBINS-I: A TOOL FOR ASSESSING RISK OF BIAS IN NON-RANDOMISED STUDIES OF INTERVENTIONS. BMJ 2016;355:I4919.
- REVIEW MANAGER 5 (REVMAN 5) [COMPUTER PROGRAM]. VERSION 5.4. COPENHAGEN: NORDIC COCHRANE CENTRE, THE COCHRANE COLLABORATION, 2020

IVERMECTIN RESEARCH & REFERENCES

- HIGGINS JP, THOMPSON SG, DEEKS JJ, ALTMAN DG. MEASURING INCONSISTENCY IN METAANALYSES. BMJ 2003;327(7414):557-60.
- THE GRADE WORKING GROUP. GRADE [WEBSITE] 2020 [AVAILABLE FROM: WWW.GRADEWORKINGGROUP.ORG.
- ALAM MT, MURSHED R, GOMES PF, MASUD ZM, SABER S, CHAKLADER MA, KHANAM F, HOSSAIN M, MOMEN ABIM, YASMIN N, ALAM RF, SULTANA A, ROBIN RC. IVERMECTIN AS PRE-EXPOSURE PROPHYLAXIS FOR COVID-19 AMONG HEALTHCARE PROVIDERS IN A SELECTED TERTIARY HOSPITAL IN DHAKA – AN OBSERVATIONAL STUDY. EJMED [INTERNET]. 15DEC.2020 AVAILABLE FROM: HTTPS://EJMED.ORG/INDEX.PHP/EJMED/ARTICLE/VIEW/599. (ACCESSED 29DEC.2020)
- CARVALLO HE, HIRCSH R, ALKIS P AND CONTRERAS V. STUDY OF THE EFFICACY AND SAFETY OF TOPICAL IVERMECTIN + IOTACARRAGEENAN IN THE PROPHYLAXIS AGAINST COVID-19 IN HEALTH 18 PERSONNEL. J. BIOMED. RES. [INTERNET] 19OCT.2020. ISSN:2633-8653. CLINICALTRIALS.GOV REGISTRATION NUMBER: NCT04425850. (ACCESSED 29DEC.2020)
- ELGAZZAR A, ELTAWEEL A, YOUSSEF SA, HANY B, HAFEZ M AND MOUSSA H. EFFICACY AND SAFETY OF IVERMECTIN FOR TREATMENT AND PROPHYLAXIS OF COVID-19 PANDEMIC. RES. SQUARE [INTERNET] 28DEC.2020. AVAILABLE FROM: HTTPS://WWW.RESEARCHSQUARE.COM/ARTICLE/RS-100956/V3 (ACCESSED 29 DEC.2020)
- HOUMAN W. USE OF IVERMECTIN AS A PROPHYLACTIC OPTION IN ASYMPTOMATIC FAMILY CLOSE CONTACT FOR PATIENT WITH COVID-19. CLINICAL TRIALS.GOV [INTERNET] 2020 JUN REGISTRATION NUMBER NCT04422561. (ACCESSED 29DEC.2020)
- MAHMUD R. CLINICAL TRIAL OF IVERMECTIN PLUS DOXYCYCLINE FOR THE TREATMENT OF CONFIRMED COVID-19 INFECTION. CLINICALTRIALS.GOV [INTERNET] 2020 OCT REGISTRATION NUMBER: NCT04523831. (ACCESSED 20DEC.2020)
- CHOWDHURY, ATMM, SHAHBAZ, M, KARIM, MR, ISLAM, J, GUO, D, AND HE, SA RANDOMIZED TRIAL OF IVERMECTIN-DOXYCYCLINE AND HYDROXYCHLOROQUINE-AZITHROMYCIN THERAPY ON COVID19 PATIENTS. RES. SQUARE [INTERNET] 14JUL.2020. AVAILABLE FROM: HTTPS://WWW.RESEARCHSQUARE.COM/ARTICLE/RS-38896/V1. (ACCESSED 29DEC.2020.)
- PODDER CS, CHOWDHURY N, MOHIM IS AND HAQUE W. (2020). OUTCOME OF IVERMECTIN TREATED MILD TO MODERATE COVID-19 CASES: A SINGLE-CENTRE, OPEN-LABEL, RANDOMISED CONTROLLED STUDY. IMC JOURNAL OF MEDICAL SCIENCE. 14. AVAILABLE FROM: HTTPS://WWW.RESEARCHGATE.NET/PUBLICATION/344240147_OUTCOME_OF_IVERMECTIN_TRE ATED_MILD_TO_MODERATE_COVID-19_CASES_A_SINGLE-CENTRE_OPENLABEL_RANDOMISED_CONTROLLED_STUDY. (ACCESSED 30DEC.2020)
- NIAEE MS, GHEIBI N, NAMDAR P, ALLAMI A, ZOLGHADR L, JAVADI A, ET AL. IVERMECTIN AS AN ADJUNCT TREATMENT FOR HOSPITALIZED ADULT COVID-19 PATIENTS: A RANDOMIZED MULTICENTRE CLINICAL TRIAL. RES. SQUARE [INTERNET] 24NOV.2020. AVAILABLE FROM: HTTPS://WWW.RESEARCHSQUARE.COM/ARTICLE/RS-109670/V1 (ACCESSED 29DEC.2020.)
- HASHIM HA, MAULOOD MF, RASHEED AM, FATAK DF, KABAH KK, ABDULAMI AS, ET AL. CONTROLLED RANDOMIZED CLINICAL TRIAL ON USING IVERMECTIN WITH DOXYCYCLINE FOR TREATING COVID-19 PATIENTS IN BAGHDAD, IRAQ. MEDRXIV [INTERNET] 2020.10.26.20219345. AVAILABLE FROM: HTTPS://DOI.ORG/10.1101/2020.10.26.20219345 (ACCESSED 29DEC.2020)

IVERMECTIN RESEARCH & REFERENCES

- AHMED S, KARIM MM, ROSS AG, HOSSAIN MS, CLEMENS JD, SUMIYA MK, ET AL. A FIVE DAY COURSE OF IVERMECTIN FOR THE TREATMENT OF COVID-19 MAY REDUCE THE DURATION OF ILLNESS. INT. J. INFECT. DISEASE [INTERNET] 2DEC.2020. AVAILABLE FROM: HTTPS://WWW.IJIDONLINE.COM/ARTICLE/S1201-9712(20)32506-6/FULLTEXT (ACCESSED 29DEC.2020)
- CHACHAR AZK, KHAN KA, ASIF M, TANVEER K, KHAQAN A AND BASRI R. EFFECTIVENESS OF IVERMECTIN IN SARS-COV-2/COVID-19 PATIENTS, INT. J. SCIENCES [INTERNET] NOV.2020:31- 19 35 AVAILABLE FROM: HTTPS://WWW.IJSCIENCES.COM/PUB/ARTICLE/2378 (ACCESSED 29DEC.2020)
- CEPELOWICZ RAJTER J, SHERMAN MS, FATTEH N, VOGEL F, SACKS J AND RAJTER JJ. USE OF IVERMECTIN IS ASSOCIATED WITH LOWER MORTALITY IN HOSPITALIZED PATIENTS WITH CORONAVIRUS DISEASE 2019. J. CHEST [INTERNET] 27OCT.2020. AVAILABLE FROM: HTTPS://JOURNAL.CHESTNET.ORG/ACTION/SHOWPDF?PII=S0012-3692%2820%2934898-4 . (ACCESSED 29DEC.2020)
- KHAN SI, KHAN SI, DEBNATH CR, NATH PN, AL MAHTAB M, NABEKA H, ET AL. [IVERMECTIN TREATMENT MAY IMPROVE THE PROGNOSIS OF PATIENTS WITH COVID-19.] ARCHIVOS DE BRONCONEUMOLOGÍA, 2020. VOLUME 56, ISSUE 12, PAGES 828-830,ISSN 0300- 2896.SPAIN. AVAILABLE FROM: HTTPS://DOI.ORG/10.1016/J.ARBRES.2020.08.007.
- GORIAL FI, MASHHADANI S, SAYALY HM, DAKHIL BD, ALMASHHADANI MM, ALJABORY AM, ET AL. EFFECTIVENESS OF IVERMECTIN AS ADD-ON THERAPY IN COVID-19 MANAGEMENT (PILOT TRIAL).MEDRXIV. 2020.07.07.20145979; AVAILABLE FROM: HTTPS://DOI.ORG/10.1101/2020.07.07.20145979 (ACCESSED 29DEC.2020).
- SPOORTHI V, SASANK S. UTILITY OF IVERMECTIN AND DOXYCYCLINE COMBINATION FOR THE TREATMENT OF SARS-COV-2. INTERNATIONAL ARCHIVES OF INTEGRATED MEDICINE. [INTERNET] 2020:7(10). AVAILABLE FROM: HTTPS://WWW.IAIMJOURNAL.COM/VOLUME-7-ISSUE-10-OCTOBER-2020/
- “I CAN’T KEEP DOING THIS.” DOCTOR PLEADS FOR REVIEW OF DATA DURING COVID-19 SENATE HEARING. 8 DECEMBER 2020. HTTPS://WWW.YOUTUBE.COM/WATCH?V=TQ8SXOBY-4W (ACCESSED 27 DECEMBER 2020).

On Jan 29, 2021, at 2:55 PM, Dr. Keesha Ewers - Fern Life Center <keesha@fernlifecenter.com> wrote:

Thank you Gary!

I just had the experience of a pharmacy calling and refusing to fill this for a patient after calling it in yesterday.

Have you heard or experienced this? I wasn't aware that was within their scope of practice.

Thank you for all of your work on this and getting back to me.

Warmly,

Keesha

Gary Goldman <garygoldmanmd@gmail.com>

Hi Keesha.

No - I haven't had that experience.

I would reference to the pharmacy that once a medication has been approved by the FDA that prescribers by law may prescribe it for any indication they see fit.

Also discuss that the NIH changed their recommendation from August 2020 which stated 'don't use outside of a clinical trial, to their January 14 update saying they "neither recommend nor not recommend. "

Who the hell does that pharmacist think he or she is?!?

Gary

Sent from my iPhone

OFF-LABEL USAGE

- The NIH COVID-19 treatment panel states that, “providers can access and prescribe investigational drugs or agents that are approved or licensed for other indications through various mechanisms, including emergency use authorizations (euas), emergency investigational new drug (EIND) applications, compassionate use or expanded access programs with drug manufacturers, and/or off-label use.”
- It is important to note that there have been multiple published, peer-reviewed controlled clinical trials throughout the world that point to the efficacy of ivermectin in the prevention and treatment of COVID-19.
- The panel also stipulates that the treatment recommendations in their guidelines are not mandates; but rather that “the choice of what to do or not to do for an individual patient is ultimately decided by the patient and their provider.”
- Providers may prescribe what they wish as long as they believe themselves to be well-informed and basing their decision on sound medical evidence.

PHARMACY REFUSAL TO FILL IVERMECTIN ILLEGAL

Note that if a pharmacist refuses to fill the ivermectin prescription by claiming that “it is not recommended or approved for COVID-19” they should be made aware of the following:

NIH treatment guidelines are not mandates and thus do not and cannot restrict any provider’s decision to prescribe a medication that the NIH Guidelines panel does not recommend. As stated in the Introduction to the NIH guideline for COVID-19:

- “It is important to stress that the rated treatment recommendations in these Guidelines should not be considered mandates. The choice of what to do or not to do for an individual patient is ultimately decided by the patient and their provider.”
- “Off-label” prescribing of a medicine that has received FDA-approval for another indication is both legal and common. Further, it is estimated that one in five prescriptions written today are for such off-label use.
- Thus, if a pharmacist refuses to fill a prescription without an accepted indication for refusal as above, this can be considered “**practicing medicine.**”
- Given that **pharmacists have no legal right to practice medicine**, in such a case, a complaint to the state medical licensing board would be appropriate. Further, the permit holder/store owner, the pharmacist in charge, the pharmacist who refuses to fill a prescription, and the wholesaler are all licensed by their state’s Board of Pharmacy. A complaint for unprofessional conduct can be filed against each with the appropriate Board of Pharmacy.

https://nabp.pharmacy/about/contact/

Contact

Address
1600 Feehanville Drive
Mount Prospect, IL 60056

Phone
847/391-4406

Social Media

Customer Support

We are happy to provide assistance or more information about our programs and services.

Hours:	Monday to Friday, 9 AM CST to 5 PM CST

IMASK PROTOCOL BUNDLE

- Purchase price is **$200.00** which includes:
  - **My office calling in the RX for you to the AMERICAN pharmacy in the United States ONLY that you have already called and verified will fill it for you.**
  - The bundle of **nutritional supplements and shipping to the United States ONLY** that go with Ivermectin for increased effectiveness.
  - The **bonuses** we have put together for you to boost your innate immunity.

BONUSES

WHEN YOU PURCHASE THE IMASK PROTOCOL

AIM

Dr. Keesha
FREEDOM TO FEEL FABULOUS

PRANAYAMA
PRACTICE

Do morning and evening before meditation

1	**Bhastrika (Bellows Breathing)**	Begin with 10 rounds, advancing weekly by tens to 50.
2	**Bahi Pranayama (Breath Retention)**	Begin with 1 round between each set of 10 Bhastrikas.
3	**Kapal Bhati (Cleaning Breath)**	Begin with 50 rounds, advancing by 50 to 500.
4	**Anuloma-Viloma (Alternate Nostril Breathing)**	Begin with 10 rounds, advancing by 10 to 50.
5	**Agnisara (Breath of Fire)**	Begin with 10 rounds, advancing to 20.
6	**Bhramari (Bumble Bee Breathing)**	Begin with 7, advancing by 7 to 21.
7	**Utjayi (Loud or Ocean Breath)**	Begin with 7, advancing by 7 to 21.

TO PURCHASE THE IMASK PROTOCOL BUNDLE

Step #1- Go to this link:

- **HTTPS://UT271.INFUSIONSOFT.COM/APP/ORDERFORMS/I-MASK-PROTOCOL-BUNDLE**
- Fill out the information asked for:
  - Your name (as it must appear on your RX), gender, date of birth
  - Your weight in pounds
  - Check the box that says you called to confirm your pharmacy will fill the RX
  - The pharmacy phone number

Dr. Keesha

FREEDOM TO FEEL FABULOUS

Step #1-payment and details

REQUIRED INFORMATION

Gender

Date of Birth

Weight (in lbs)

Your pharmacy phone # to call the Ivermectin in to from our office

Your Name As It Appears in the RX

I confirm that I have called the pharmacy to make sure Ivermectin is available when we call in the RX:

- Yes
- No

To properly process your order, please provide your Gender and Date of Birth on the fields above.

PAYMENT INFO

Credit Card Number | Month | Year | CVC

Shipping Options

$0.00 Standard Shipping

ORDER SUMMARY

I-Mask+ Protocol Bundle	1 Update	$200.00
Subtotal		$200.00
Have a promo code?	Due Today	$200.00

BILLING INFORMATION

First Name

All payments are secured by 256-bit encryption

https://ut271.infusionsoft.com/app/orderForms/I-Mask-Protocol-Bundle

STEP #2- FOLLOW THE INSTRUCTIONS IN THE EMAIL YOU RECEIVE

- Make sure you go to your spam, junk or trash folder if you don't see an email from **DrKeesha.com**.
- You will receive a link to a special page on our store that is **only for you**. You cannot find it by just going to the store.
- This link will add the bundle items **directly** into your cart.
- The **imask21 coupon code** will allow you to get the supplements with **free shipping** and will show $0.00.

Your order

Product	Subtotal
IMask+ Protocol - Webinar Purchasers × 1 D3 + K2 Liquid × 1 Quercetin Plus × 1 Zinc Plus × 1 Melatonin × 1 Buffered C Capsules × 1	$200.00
Subtotal	**$200.00**
Coupon: imask21	**-$200.00** [Remove]
Shipping	○ Shipping & Handling: $9.75 ◉ Free shipping
Tax	**$0.00**
Total	**$0.00**

Step #2- Clicking email link adds supplement bundle directly to your cart and gives you fre shipping

Checkout

RETURN TO SHOP

Returning customer? Click here to login

Have a coupon? Click here to enter your code

Coupon code already applied!

Billing details

First name *

Keesha

Last name *

Ewers

Ship to a different address?

Order notes (optional)

Notes about your order, e.g. special notes for delivery.

Step #3: Instructions

- Download instructional sheet for supplements which will show up as a link on your receipt.
- It also includes the instructions for social immunity.

CONTACT US

INFO@DRKEESHA.COM