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DISCLAIMER: Polaris does not intend to offer an opinion on the medical implications and developments of the coronavirus. Rather, Polaris has the benefit of working with a research analyst, Jamie White, who has a lengthy background in the medical field who has been able to interview a number of frontline physicians. To that end, Polaris does not claim to the veracity of the materials herein; Mr. White's guarded viewpoints are solely his and should not be used to make personal investment decisions; content from this memo and any literature disseminated should be used for informational purposes only and does not constitute advice.

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In the past week, the Polaris research team conducted interviews with medical and science experts, seeking to provide clients with real-time medical intelligence on the COVID-19 (SARS-CoV-2) pandemic. Below is a culmination of those research efforts.

Executive Summary

- COVID-19 (SARS-CoV-2) may have a life cycle of 18 months based on base infections rates >250,000.ⁱ
- The R_0 or R-Naught is the Basic Reproduction Number. R_0 indicates the average number of people who will be infected with a disease from one contagious person. Without control measures, COVID-19 has been estimated to have an R_0 of somewhere between 1.5 and 3.5, compared to influenza with an R_0 of 0.9 to 2.1.ⁱⁱ Based on an approximated R_0 of 2.5, the number of new COVID-19 infections is broadly calculated to double every 3.75 days.
- Some experts predict that the R_0 of COVID-19 will reach < 1 (metric of containment) in the US by June-July although this may be sooner if testing compliance in US gets to > 95%. Current estimates approximate 25% testing compliance in the US. (Interview with Mayo Clinic Physician, March 18, 2020)
- Current US strategy is mass isolation to flatten the curve. US government officials have indicated that such strategy may adjust once widescale testing is available, as seen in South Korea, which has low mortality and less restrictive isolation policies.
- US PCR testing capacity is limited to 10,000 samples a day. However, Rapid Testing for IgG (AYTU BioScience) and confirmatory testing via PCR (Roche-Thermo Fisher) have been FDA approved. Roche is currently mass producing PCR Tak-PACK kits, with expected ramp up in the near term.
- Chloroquine is being used in select hospitals across the nation as a primary treatment in patients classified as severe and critical.ⁱⁱⁱ Gilead's Remdesivir is beginning human trials for a potential anti-viral medication to be used in the hospital setting.
- The Imperial College of London is forecasting a bimodal distribution for COVID-19 with a potential reemergence of the pandemic sometime in Fall.^{iv}

BASICS OF THE VIRUS

What is COVID-19?

COVID-19, also referred to as SARS-CoV-2, is a new strain of coronavirus originating in central Wuhan, China. On December 31, 2019, Chinese authorities alerted the World Health Organization (WHO) to an outbreak of a novel strain of coronavirus causing severe illness, which was subsequently named SARS-CoV-2. The WHO epidemiologists believe the virus originated in bats, a known carrier of many viruses that cause SARS. Coronaviruses constitute the subfamily of viruses Orthocoronavirinae, in the family Coronaviridae, order Nidovirales, and realm Riboviria.^v Coronaviruses, in general, are a family of viruses that target and effect mammals' respiratory systems. They cause a range of illnesses from the common cold to critical interstitial pneumonitis. Based on specific characteristics, there are four main "ranks" (genera) of coronaviruses: alpha, beta, delta, and gamma. The majority of these only effect animals, with a subset of virus transmissible to humans, belonging to genera alpha and beta.^{vi}

COVID-19 is an enveloped virus with a single stranded RNA genome and helical nucleocapsid. The genome of the virus ranges in size from 27 to 34 kilobases, the largest of all known RNA viruses.^{vii} In comparison to previous Severe Acute Respiratory Syndrome (SARS) viruses, COVID-19's spike proteins bind to a person's cells with 10 times the affinity.^{viii} COVID-19 spike proteins contain a site that recognizes and becomes activated by an enzyme called furin. Furin is a host-cell enzyme in various organs, including the liver, lungs and small intestines. The fact this enzyme resides in large percentage of the human tissue means COVID-19 is particularly dangerous because it can attack many organs at once.^{ix} The COVID-19 virus replicates in the tissue that is responsible for oxygen diffusion into the blood. The interstitial tissue goes through an inflammatory process, severely limiting gas in the exchange in the lung.^x As a result, this interstitial pneumonia is very different than classic pneumonia or strains of influenza A or B.

In comparison to SARS (severe acute respiratory syndrome) and MERS (Middle East respiratory syndrome) coronaviruses, which were both identified in the past 20 years, COVID-19 is likely more highly transmissible but not as deadly, according to a February 2020 Journal of the American Medical Association (JAMA) report.^{xi} Case Fatality Rate (CFR) is the rate of new deaths compared to new infections. SARS had a CFR of 9.6%; MERS had a CFR of 34.4 %.^{xii}

What makes this virus novel?

The WHO has determined COVID-19 is novel because the genetic mutation originating in the Wuhan Province has slight genomic variations to the seasonal coronavirus (common cold) and other known causes of SARS.^{xiii} For an infectious disease to be considered novel less than 45% of the global population must have immunity to the infectious agent. The goal of broad vaccination programs is to achieve at minimum 45% vaccinations of the population in order for the vaccine to provide herd immunity. The herd effect or herd immunity is formally defined as "the reduction of infection or disease in the unimmunized segment as a result of immunizing a proportion of the population."^{xiv}

How does the virus spread?

COVID-19 spreads through three primary mechanisms: direct contact, indirect contact and droplets. Direct contact is spread through direct physical contact with an infected person where the virus is passed through infected bodily fluid. Indirect contact is contact with objects outside of the body. Recent analysis suggests that the virus can remain viable on copper for up to 4 hours, on cardboard up to 24 hours and on plastic and stainless steel up to 72 hours.^{xv} Droplet spread is most commonly from a cough or sneeze, where the virus is aerosolized in microscopic droplets and is viable in air for up to 3 hours.^{xvi}

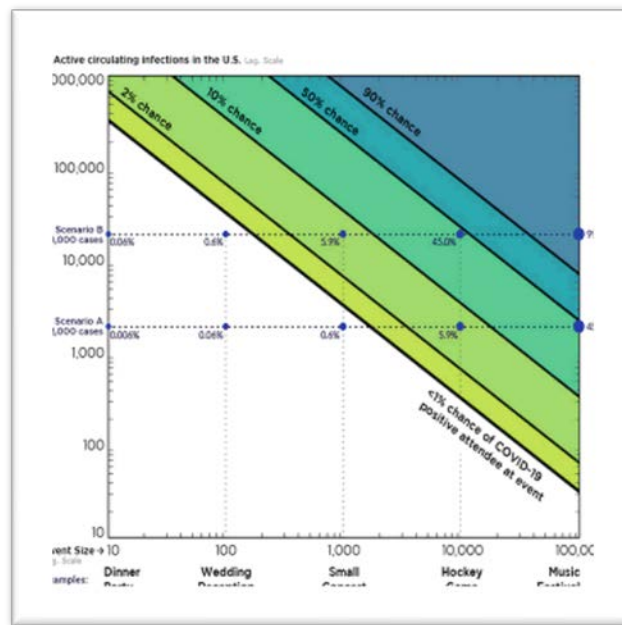
COVID-19 Doubling Time (R-Naught)

The R_0 or R-Naught is the Basic Reproduction Number. R_0 indicates the average number of people who will be infected with a disease from one contagious person. It specifically applies to a population of people who were previously free of infection and haven't been vaccinated. If a disease has an R_0 of 18, a person who has the disease will transmit it to an average of 18 other people, as long as no one has been vaccinated against it or is already immune to it in their community. An R_0 of less than 1 is considered containment.

Without control measures, COVID-19 has been estimated to have an R_0 of 1.5 to 3.5, compared to influenza with an R_0 of .9 to 2.1.^{xvii} Based on an approximated median R_0 of 2.5, the number of new COVID-19 infections is broadly calculated to double every 3.75 days. With proper control measures, this virus can be maintained at an R_0 of less than 1, which has been achieved in numerous countries.^{xviii}

What is the risk of infection?

The chart below^{xix} depicts the risk of acquiring COVID-19 based on gathering size. According to the chart, a gathering of 10,000 people results in a 45% chance of being infected with COVID-19. This is assuming 20,000 base rate of infections in a geographical location.^{xx}



What are the implications of infection?

It is worth noting that according to the aforementioned JAMA report, 81% of the COVID-19 cases are classified as mild; 14% are classified as severe, which is shortness of breath and chest x-ray finding; and 5% are classified as critical, which require some type of breathing assistance, due to respiratory failure or shock.^{xxi}

What is the patient demographic?

Recently China's Center for Disease Control and Prevention published the results of the largest study to date showing patient demographics, thereafter reported in JAMA.

Patient demographics of infection by age and mortality in China - 72,314 COVID-19 cases ^{xxii}

AGE

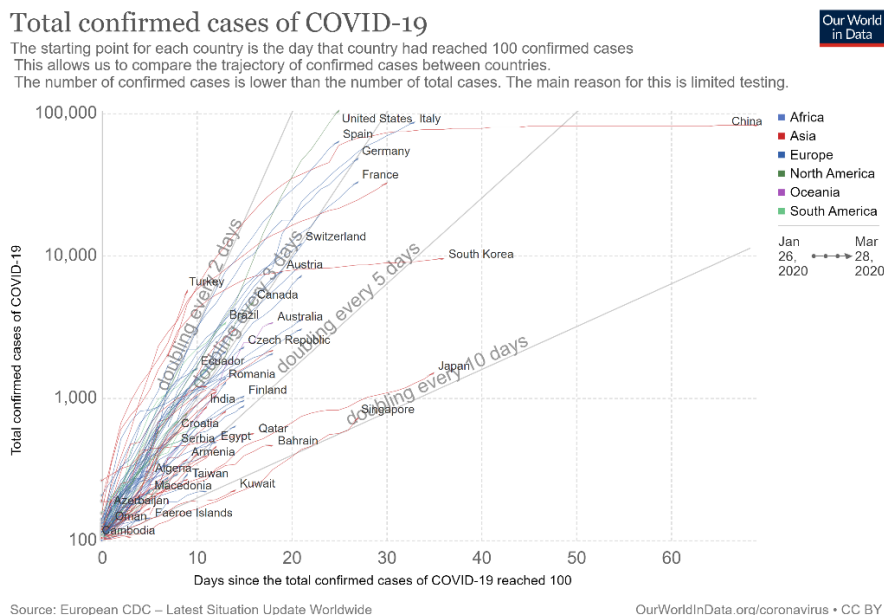
- 30 to 79 - 38,680 cases or 87%
- 20 to 29 - 3,619 cases or 8%
- 80 & older - 1,408 cases or 3%,
- 1 to 10- below 1%
- 10 to 19 - 1%

MORTALITY

- Of the confirmed cases, 1,023 patients—all in critical condition—died from the virus, resulting in a CFR of 2.3%.
- In patients older than 80, CFR was 14.8%
- For patients in their 70s, CFR was 8%.

TESTING FOR COVID-19

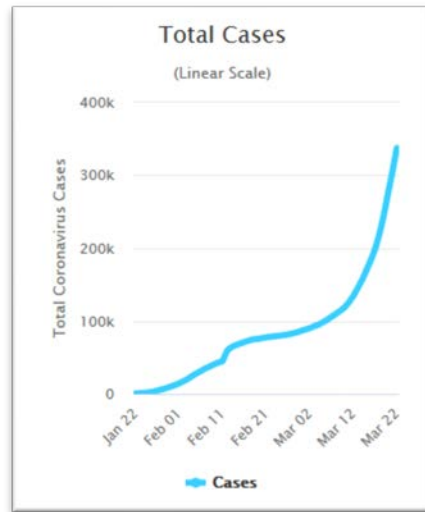
COVID-19 testing is done by a Polymerase Chain Reaction (PCR) test. PCR functions by mass producing a segment of the virus DNA/RNA from a sample. If the specific RNA/DNA is in the sample, copies of the segments are mass produced until they reach a critical mass, referred to as “molecular photo-copying”, resulting in a positive test. ^{xxiii} PCR tests are, in theory, fairly simple to create: scientists pick snippets of the virus’ gene and use a series of chemicals to look for that gene snippet in the sample. If they find the snippet, it means the patient has the virus. Although simple to create, PCR tests are complicated to execute, with a lab technician employing various processes to produce results, which typically are available in a few hours. PCR testing became the basis for the WHO’s test used in countries around the world, including South Korea. Countries around the world were able to adopt and scale that test. South Korea implemented broad spectrum testing immediately in early March 2020 (South Korea has tested more than 270,000 people, which amounts to more than 5200 tests per million inhabitants—more than any other country except tiny Bahrain)^{xxiv}, and as evidenced in the chart below, the country successfully flattened its infection rate curve to date. The graph^{xxv} shows infection curves of countries. Based on this graph, countries that have implemented widespread testing demonstrate effectiveness of this strategy.



PANDEMIC GLOBALLY

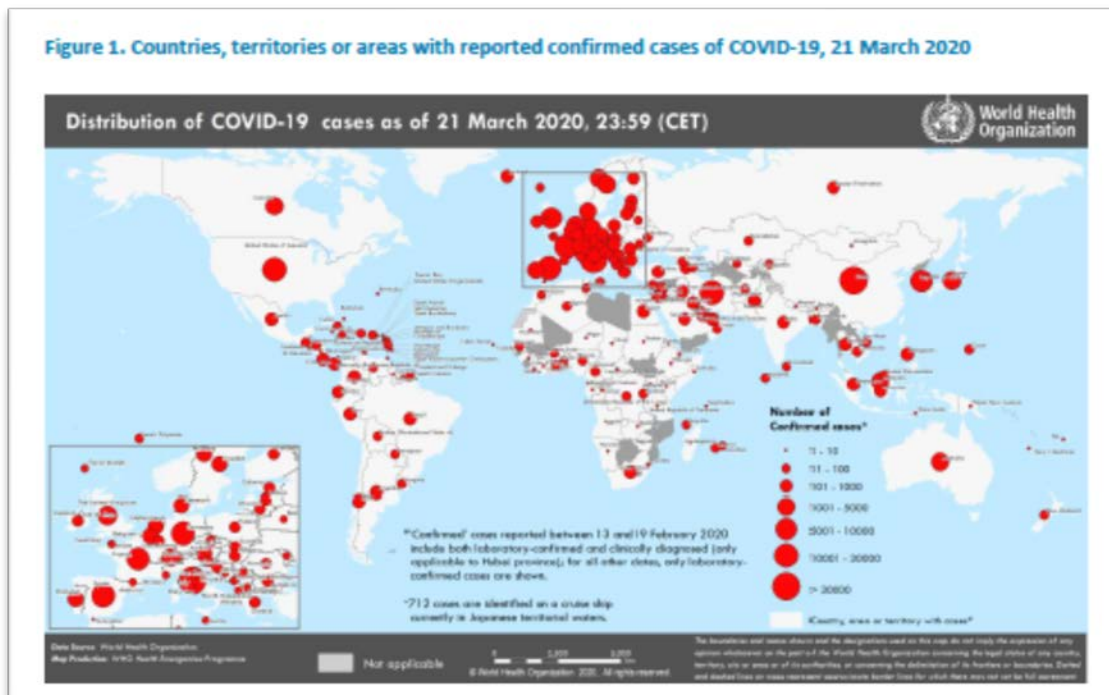
What is the current state of the pandemic globally?

As of March 23, 2020, there are 332,930 confirmed cases; 14,509 deaths;^{xxvi} and more than 100,000 recoveries. Based on available public data, rough calculations suggest doubling time of this infection is approximately every six days; the infection timeframe rose from three and half days in early March, seemingly indicating that isolation efforts are working. The graph^{xxvii} below provides an updated representation of current cases (through March 23, 2020).



The WHO publishes a daily situation report on the global COVID-19 pandemic. Europe has the highest reported number of new cases, and currently has the highest CFR of around 7% compared to the rest of the world, which has a CFR of between 1.5 to 3%. High risk patients are expected to have a CFR of 15%. Of particular concern are areas of Northern Italy and areas of Spain.

The graph below is a map showing infection concentrations^{xxviii}:



PANDEMIC IN THE US

A critical care physician with the Mayo Clinic predicts roughly 300,000 infections will have spread in the US by June-July, with approximately 3,000 deaths. (Interview with Mayo Clinic Physician, March 18, 2020)

Until the ramp up of PCR Tests, U.S. testing is limited.

The US has limited PCR kits (capacity to conduct 7,000 to 10,000 tests daily^{xxix}), with testing reserved for high risk patients. Below are the current medical guidelines for testing. A patient must exhibit two or more of the following symptoms: fever (might be subjective), chills, rigors, myalgia, headache, diarrhea, sore throat, rhinorrhea and must meet criteria for high risk.

- CDC's definition of high risk:
 - Close contact with a confirmed case of SARS-CoV disease
 - Close contact with a person with mild-moderate or severe respiratory illness for whom a chain of transmission can be linked to a confirmed case of SARS-CoV disease in the 10 days before onset of symptoms
 - Immuno-compromised patients – Cancer and those of chemotherapy; HIV/AIDS and other conditions causing impairment to the immune system

The following are guidelines for hospitalization vs. quarantine at home

- Mild infection criteria – self isolation until 48 hours no symptoms
 - Fever >100.4 with non-lung findings only upper respiratory – self-isolation
- Moderate infection criteria - respiratory illness - quarantined and monitored in a hospital setting
 - Temperature of >100.4° F (>38° C)-and
 - One or more clinical findings of lower respiratory illness (e.g., cough, shortness of breath, difficulty breathing)
- Severe respiratory illness – placed in droplet precautions ICU or CCU
 - Meets clinical criteria of mild-to-moderate respiratory illness, and
 - One or more of the following findings:
 - Radiographic evidence of pneumonia, or
 - Acute respiratory distress syndrome, or

Although the U.S. has limited PCR tests, and equally limited lab capacity to process tests^{xxx} often resulting in week long delays, there is hope on the horizon. Multiple companies are currently ramping up production of PCR Tests. Quest Diagnostics is expected to produce an additional 26,000 confirmatory PRC tests a day starting March 25, 2020.^{xxxi} Thermo-Fisher (TF) from Waltham, MA received FDA approval for their Tak-Pack COVID kit, and is currently slated to produce an additional 26,000 daily tests by April 3rd. They have partnered with Roche and the company publicly stated that they will supply 5 million kits to US labs by April 1.^{xxxii}

In the interim, AYTU BioScience will provide 100,000 IgG rapid tests with the first shipment do in Denver the week of March 29th.^{xxxiii} The rapid IgG test will be sent to frontline healthcare workers to be incorporated into their triage process. Rapid IgG tests are a screening tool to identify a potential infection and are approximately 80% sensitive. If a person has a positive IgG screen, their sample will be sent to a laboratory for a confirmatory PCR test, which is both specific and sensitive. Although the positive rapid IgG test isn't definitive of COVID-19, it provides quick (within 15 minutes) preliminary information that can help guide isolation protocols and recommendations while patients await PCR tests that have a longer lead time.

The ramp-up in testing is of utmost importance, according to the critical care physician with the Mayo Clinic. In an interview with Polaris, he stated: "Until we get widespread testing online we will continue to see exponential growth in COVID-19." With clarity as to the new testing kit supply

chain timelines, some medical professionals speculate that the U.S. will reach 95% compliance in testing by June.

U.S. Medical Infrastructure

Data suggests that **widespread isolated testing centers** are the best strategy for containment. This week Polaris analysts spoke to an emergency physician in charge of disaster management and pandemic response for a network of hospitals covering Southern Virginia. The physician stated that their current mandate is to create orderly triage to minimize patient flow through the hospitals. They are accomplishing this through stand-alone triage centers away from the hospital to prevent hospital spread, since most people seeking medical attention will not require hospitalization. Most large medical networks are using this strategy. The physician anticipates smaller remote medical facilities will not have the staff or resources to accomplish this and will most likely hit critical mass much earlier.

The stand-alone triage center serves two functions: 1) limit hospital employee infection rate, and 2) maintain reserves of Personal Protective Equipment (PPE). The U.S. is facing a shortage of PPE equipment since most is supplied from China; this will impact the rate of spread since PPE is being reused.^{xxxiv}

Currently the US strategy is to flatten the R_0 curve so that the ICUs and CCUs are not operating beyond capacity. The US currently has 64,000 ventilators unevenly distributed throughout the country. The strategy of self-isolation expects to flatten the infection rate curve, ensuring there are enough ventilators on hand to not overwhelm hospital resources. As with the H1N1, the areas likely to face the highest mortality rates are those with large aging populations and with limited access to larger hospital networks. This has recently been seen in farming areas of Nebraska and Oklahoma, which are consistently ravaged by influenza.

Despite the late response in US testing, the country has created a robust national testing database that is now tracking all testing sites in real-time. This is of major importance for when the US achieves high testing compliance. The national tracking database will provide the CDC will real-time intelligence allowing for mobilization of medical response teams, FEMA Command and Control, and National Guard Mobile Medical Units. The intent is to avoid hospital surges that would shock facilities' medical infrastructure. "If we can control the curve, we can significantly reduce the national mortality of COVID-19," stated the critical care physician with the Mayo Clinic.

The Future of the Virus

All of the physicians with whom Polaris spoke reiterated a similar path of the virus. Both believe COVID-19 will run an 18-month bimodal course with possible reemergence sometime in late Fall.

Treatments

COVID-19's genome has recently been sequenced at the National Institute for Health (NIH). This is extremely *important* since having the sequenced genome can lead to rapid sensitive and specific detection and treatment. Globally coordinated efforts and easing of regulations may lead to expedited treatment protocols. RNA viruses (like COVID-19) are not as complex to target with treatments as other more virulent infectious diseases.^{xxxv} Many pharmaceutical companies are racing to develop treatments and vaccines, which have already begun human clinical trials.

- Chloroquine is being used by select hospitals in the treatment guidelines for people classified as severe - critical with pneumonia secondary to COVID.^{xxxvi} "We consider the use of hydroxychloroquine on a case-by-case basis for hospitalized patients who are at risk of disease progression," says Dr. Daniel Kuritzkes, chief of the division of infectious diseases at Brigham and Women's Hospital and professor at Harvard Medical School.^{xxxvii}
- Chloroquine interferes with the virus ability to replicate in two ways. First, the drug enters compartments called endosomes within the cell membrane. Endosomes tend to be slightly

acidic, but the chemical structure of the drug boosts their pH, making the compartments more basic and decreases its ability to function within our cells. Second, chloroquine blocks COVID-19's ability to attach itself to the host's cell therefore blocking the virus mechanism for replication. The drug specifically prevents COVID-19 from plugging into a receptor called angiotensin-converting enzyme 2, or ACE2.^{xxxviii}

- Gilead is ramping up production of Remdesivir.^{xxxix} Rem attacks many functions of the virus. Rem was developed initially to prevent the spread of the Ebola virus.
- Vaccine development is underway but realistically won't be approved until 2021. One company, Glaxo Smith Kline, has multiple testing sites that have just entered approved clinical trials.^{xl}
- Although not a pharmacological treatment, physicians have had some success with patient positioning. The critical care physician with the Mayo Clinic stated that guidance on SARS ventilatory and sepsis management seems to be having positive outcomes. "If the patient is placed prone and the legs elevated it creates a positive pressure environment in the lungs and their data shows this technique is providing positive outcomes for roughly 10% of critical patients."

THOUGHTS AS WE MOVE FORWARD

The approach to this isolation campaign should be viewed in units of months not weeks until proper testing and efficacious peer reviewed treatment measurably contains the virus. To contain the virus, doctors posit the need for globally accessible testing and treatment; all efforts are seemingly dedicated to this objective. Many highly regarded medical experts expect COVID-19 to run an 18-month course; preparations and strategies are considered within this timeframe.

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