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CoVID-19 Testing PCR – A Critical Appraisal

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Postulate:

The standard testing for CoVID-19 utilizes a technology that its discoverer warned should never be used for diagnosis. This technique, known as PCR, has led to massively inaccurate and misleading conclusions. Public health authorities currently are basing societal mitigation policies and recommendations almost exclusively upon this technology by tracking putative numbers of "cases" instead of deaths and hospitalizations, and the result is an unprecedented negative impact upon society that is futile and unnecessary. It is futile in the naïve assumption that SARS CoV-2 can be contained in the population and unnecessary since deaths and hospitalizations and attendant consequences therefrom are back to pre-pandemic levels. It is imperative that tracking data upon which ongoing mitigation practices rest revert back to accurate figures for deaths and hospitalizations from CoVID-19.

Personal Disclosure:

I am a recently retired pediatrician after 33 years in private pediatric practice, 11 years as a faculty member of a major University Department of Pediatrics serving in a community Pediatric Residency training program, and have been practicing pediatric Integrative Medicine for 6 ½ years. During this Integrative Medicine time, my patients were predominantly those with autoimmune diseases, chronic Lyme disease, and autism spectrum disorders. I have no experience with diagnosing or treating CoVID-19 in patients. My training and experience have, however, provided me a vast experience sorting out often conflicting and equally credible appearing narratives about chronic diseases and the immune system. By virtue of the foundational role of the immune system in children with the kinds of complex, chronic health aforementioned conditions, I have studied the immune system and its role in recovery or otherwise from these chronic and disabling conditions intensively over the past seven years or so.

Being a resident of a retirement community myself and a member of a high-risk group for CoVID-19, along with a suddenly accelerated time frame for my planned retirement due to a shut-down from outside exposure in the retirement community, I have invested hundreds of hours into researching everything CoVID since March 16, 2020.

Background

CoVID-19 became a household word in the United States in March, 2020 when the pandemic became manifest. Needless to say, it has affected every person living, as well as all our institutions, businesses, activities, and the overall economy in ways that were unimaginable.

During the initial few weeks of the pandemic in our country, the scope and apparent seriousness of what was unfolding was unprecedented and with reports of over-running of hospitals and large numbers of deaths in select high-density urban populations (Wuhan, China, New York City, etc) the initial response that included widespread shutdowns and the other well-known mitigation measures were justified.

Following a massive shifting of resources, extreme mitigation in the form of shutting down businesses, physical distancing, mask wearing, and other measures, the anticipated and feared massive over-running of hospitals'

ability to manage the CoVID-19 case load became manageable, and after the first six weeks or so, in most of the smaller communities across the country, shutting down hospital and medical office usual procedures and medical care led to both unexpectedly low medical utilization overall, personnel layoffs, and widespread adverse impact upon normal usual healthcare, thus over time adding to "collateral damage" in the form of missed medical treatment for non-CoVID health conditions, etc. Even makeshift hospitals created from conversion of other facilities to hastily constructing new ones ended up not being needed for CoVID patients and not utilized.

Initially the primary driver of public health recommendations and policies were data for hospitalizations and deaths from CoVID-19. During this initial phase, before the ultimate magnitude of the problem could be determined, the difficult and painful measures of shutting-down businesses, schools, and restrictions of personal liberties for the greater good of public health and safety were justified as being of finite duration, expected to be a matter of up to six weeks or so in order to "flatten the curve" of the rapid acceleration of the virus and its effects – not to be followed indefinitely.

He warned against this technique ever being used for diagnosis …

As diagnostic testing became available, tracking with all three of these measures was followed. After the first six weeks or so, high density urban areas that were hit hard in the beginning did experience "flattening the curve" and most other communities were spared the once-feared massive over-run of their ability to deal with the caseload of sick CoVID-19 patients.

Testing that was adopted and became the basic form of diagnostic lab test was that based upon Polymerase Chain Reaction (PCR), a technology discovered by Kary Mullis, who was awarded the Nobel Prize in 1993 for this discovery. Although Mullis died in 2019 before the beginning of the CoVID-19 pandemic, he had much to say about PCR. *He warned against this technique ever being used for diagnosis due to the complexity of the process and because of a relatively high rate of false positive results if performed on asymptomatic individuals, as well as with false negative results. He pointed out, among other things, that PCR required selecting a particular number of "amplifications" or multiplications of the original tiny string of genetic material (DNA), and that the cutoff between "positive" and "negative" was arbitrary and could vary from place to place or over time.*

Now, *six months* into the pandemic, the most accurate measure of deaths, IFR (Infection Fatality Ratio) has declined to a range that is within the bounds of deaths attributed to seasonal influenza in moderate to severe years. Physicians for Informed Consent (PIC) published in June 2020 an article "CoVID-19 Assessing Infection Severity" data from the CDC published in May 2020 showing the following:

- Mortality of SARS-CoV-2 based on *symptomatic* cases was 0.4%. Since 35% of cases were estimated by the CDC at the time to be asymptomatic, the *overall* CFR (case fatality rate) was 0.26%
- Comparison with CFR reports from seasonal influenza and influenza pandemics range from 0.1% to 2.25%. The latter figure was for the 1918-1920 pandemic, but the CFR for seasonal influenza in 1957-1960 was 0.28%, higher than the 0.26% for CoVID-19 reported by the CDC in May 2020.

This decrease in IFR was predictable to a certain degree, as initial figures for mortality were simple calculations based upon the number of deaths from CoVID divided by the number of cases diagnosed, with the latter number determined from testing among sick individuals only, and including those believed clinically to have CoVID-19 despite a negative PCR test. Once widespread testing became adopted, the denominator – total number believed to be infected – became rapidly larger. Some evidence has suggested furthermore that the virus has become relatively attenuated and less severe in its clinical impact – a development that would not be unusual for a pandemic virus.

It has become clear that IFR rates are far lower than initial projections and fears, which were derived from initial modeling data that proved to be orders of magnitude higher than reality. Even as this reality was recognized, the basis for mitigation practices shifted from using IFR rates and hospitalization numbers as the primary determinant to sole reliance upon case number data. There is reason to believe this is the opposite of what should be done.

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This current case number fixation has created a world where on a daily basis, the number of reported cases is featured in headlines all over the country in newspapers, on internet posts, and shared on social media. In one example, in early September, in the Greensboro, North Carolina newspaper, it was reported that a particular school where testing was done to monitor asymptomatic children, one child tested positive with the standard PCR based test procedure – and the school was immediately closed. If the number of "cases" is inaccurate and wildly inflated – for which we will see below there is compelling evidence – then such school closings are unnecessary and counterproductive. The same problem applies to other mitigation practices that are based exclusively upon case numbers.

It has been documented by Dr Scot Atlas, among others, that the number of deaths from *mitigation for CoVID-19* has now significantly exceeded that from CoVID-19 itself. This is attributed to increased rates of depression, suicide, drug overdoses, etc. Further data have shown that excess total mortality rates comparing current with past years' total mortality are not significantly higher than usual past rates. This of course begs another question far too involved to discuss here – the possibility that part of the perception of the impact of CoVID-19 is based upon shifting usual numbers of deaths from influenza that are peculiarly lower than usual to a diagnosis of CoVID-19. This in turn begs another question about the possible impact upon numbers of CoVID-19 deaths being inflated artificially because of the additional reimbursements to hospitals for CoVID-19 codes for hospitalizations and deaths. But even assuming that putative deaths from CoVId-19 are not artificially inflated, deaths from mitigation for CoVID-19 has exceeded those from CoVID itself.

Four recent sources delve into the PCR testing phenomenon in detail and together make a compelling argument that the standard form of diagnostic testing for CoVID-19 – PCR – is, just as its discoverer Kary Mullis argued prior to his death in 2019, grossly inaccurate and *should not be used for diagnosis*. Needless to say, this is a shocking suggestion, but I believe the evidence strongly supports this conclusion. Now we will discuss briefly the basics about PCR testing and show why it is imperative that ongoing public health mitigation measures shift from using PCR case numbers to accurate, non-inflated data from hospitalizations and deaths caused by CoVID-19 – at least until an accurate testing process can be established for determining infectious case numbers.

Four primary sources from which the following points are made:

1. Polymerase Chain Reaction (PCR) Test by Charles Patrick Davis, MD, PhD and Medical Editor Melissa Conrad Stoppler, MD Reviewed 6/22/20.
2. Your Coronavirus Test is Positive. Maybe It Shouldn't Be. The New York Times. Apoorva Mandavilli. August 29, 2020.
3. Dr Ben Edwards explains Covid-19 Pandemic is OVER. Why now only the CASEdemic exists 9/3/20.
4. Predicting Infectious Severe Acute Respiratory Syndrome Coronavirus 2 From Diagnostic Samples, Jared Bullard, Kerry Dust, et al. *Clinical Infectious Diseases*. 22 May 2020.

We will begin with an explanation of a complex subject – the rationale and scientific basis for the PCR technique, as applied to the prevailing diagnostic test being used in the United States, as well as most of the world. It is essential to understand in order to draw valid conclusions about the significance or lack thereof, of the CoVID-19 PCR test.

Basics of PCR

PCR is a chemical reaction to identify tiny bits of DNA, the primary form of material in human genes which in turn comprise chromosomes. Due to the infinitesimally small size of the particles, they must be amplified, or made exponentially larger in order to work with them. This amplification process is what Kary Mullis discovered, and consists of multiplying sequentially by doubling the material present. So, 2 becomes 4, then becomes 8, then 16, and so forth.

As noted, PCR multiplies DNA. The genetic material that comprises the virus for CoVID-19, as well as most other viruses, is RNA, an even smaller particle. It must be converted to DNA in order to utilize the PCR process. This is accomplished by action of an enzyme called reverse transcriptase (RT) in the first of four steps involved in the process. RT thus allows a single strand of RNA to be translated into a complementary strand of DNA. The product of RT acting on RNA is called RT-PCR.

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Another term is "Real-time PCR" – a variation of PCR that allows analysis of the amplified, or "multiplied" DNA during the typical number of 40 cycles. Fluorescent dye is added in some techniques to facilitate interpretation and obtain test results more rapidly.

The ultimate end-point of a PCR test is a result that is being arbitrarily defined as "positive" or "negative." The extraordinary implications of this simple decision to frame results of the PCR testing as the basis for the entire "case numbers" tracking upon which virtually all public health measures are being based is almost incomprehensible. Dr. Michael Mina, assistant professor of epidemiology at the Harvard T. H. Chan School of Public Health is quoted in the New York Times article above as saying that this oversimplified interpretation of PCR as positive or negative is "irresponsible." This relates to the following discussion of the amplification process, sometimes also referred to as cycles. Dr. Mina is quoted in the Harvard Magazine (8/3/20) as saying that Current PCR testing detects virus "long after the infected person has stopped transmitting the virus." He further states "That means *the results are virtually useless for public health efforts to contain the raging epidemic*." (emphasis added)

PCR Amplification or Cycles

Most PCR tests are set to run at 40 cycles, a few at 37. North Carolina uses a cutoff of 37 cycles. This is important to remember as we develop the implications of this process. Tests with thresholds so high may detect not only live virus, but also simple genetic fragments, leftover from past infection that poses no risk for current exposure to others.

According to the NY Times article citing virologist Dr. Juliet Morrison, any test with a cycle threshold above 35 is too sensitive (in other words will read positive when the individual is not infectious). He recommends a more reasonable cutoff of 30 to 35 cycles. Dr. Mina would use a threshold of 30 or lower. A CDC calculation suggests that it would be extremely difficult to detect any live virus in a sample above 33 cycles. Another source suggested that if a threshold of over 40 cycles is used, *everyone tested* would be "positive."

An article published by The Infectious Diseases Society of America (IDSA) in their journal *Clinical Infectious Disease* (May 22, 2020) referenced in the 3rd source above, had the following to say:

> *Reverse-transcription polymerase chain reaction (RT-PCR) has become the primary method to diagnose viral diseases, including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).*

We took SARS-CoV-2 RT-PCR-confirmed positive samples and determined their ability to infect Vero Cell lines. Ninety RT-PCR SARS-CoV-2-positive samples were incubated on Vero cells. Twenty-six samples (28.9%) demonstrated viral growth. There was no growth in samples with a CT > 24 or STT > 8 days.

SARS-CoV-2 Vero cell infectivity was only observed for RT-PCR Ct < 24 and STT < 8 days. Infectivity of patients with Ct > 24 and duration of symptoms > 8 days may be low.

It is important to know that IDSA is considered among many infectious disease specialists to be the highest authority from which they draw their information and from which they make their clinical decisions.

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Once one understands the basic flaws inherent in using PCR for diagnosis, it must be pointed out that in addition to the problems discussed above, with varying numbers of cycles or amplifications being used in different states or even in different health systems in one state, it would be quite easy and simple to manipulate the number of positive results with this form of testing by simply changing the number of cycles to a higher number to produce the appearance of worsening or to a lower one to produce lower infection numbers. Remember that some experts say that if over 40 amplifications be used, 100% of people tested would be positive. Because the diagnostic test that is the foundation of testing for CoVID-19 is a PCR test, an individual who gets tested in a facility or area that is using a test setting the cutoff at 37 cycles for example and has a positive result might fly to another area where repeat testing using a 30 cycle test would likely be negative. So, the same individual who "had CoVID-19" in location one does not have it after flying to the second location. This reveals the absurdity of the PCR based test.

Evidence that the CoVID-19 Pandemic is fundamentally over

Dr. Edwards goes through a number of slides showing how deaths and hospitalizations from CoVID-19 across the United States, as well as across other countries generally have declined to pre-pandemic levels. And yet, in the face of the documentation of deaths and other collateral damage from the *response to CoVID-19* exceeding those from the virus itself, these grossly misleading and inflated case numbers are the basis for most policy guidelines.

When one understands the clear and well documented fallacy of utilizing PCR based testing for diagnosis, it is inconceivable that policy makers continue to rely upon this technology, whose discoverer warned should not be done. Continuing to do this suggests an ulterior motivation to do so. Increasing numbers of people are awakening to the reality of this fallacious practice, as demonstrated by a recent mass demonstration in Berlin, Germany at which over one million individuals from all over Europe protested the continuation of extreme mitigation practices in these circumstances. Environmental attorney Robert F. Kennedy, Jr. was the keynote speaker at this event and has a number of outstanding articles available to the public on the website for Children's Health Defense.

For those who are skeptical that such a misleading practice might continue for non-medical or unscientific reasons, one only needs to consider that the market for a Coronavirus vaccine promises to be world-wide …

A good example of this inappropriate application of unnecessary mitigation is described in an Op-Ed by Daniel Horowitz on September 8, 2020. Horowitz cites a report by Dr. Andrew Bostom, a cardiovascular and epidemiology researcher, who posted a spreadsheet on Twitter of all the cases in 17 state university systems up to September 4, 2020. There were more than 11,000 students testing positive for CoVID-19 and deemed to

represent "cases" – but *zero* hospitalizations. And yet schools and colleges are closing down left and right in response to such reports of clusters of "cases."

For those who are skeptical that such a misleading practice might continue for non-medical or unscientific reasons, one only needs to consider that the market for a Coronavirus vaccine promises to be world-wide, numbering in the billions, and probably for more than one dose, as well as needed for yearly administration. The same thing applies to a potential new drug for early treatment. It is relevant that a widely touted *early* combination treatment for CoVID-19 with zinc, azithromycin, and hydroxychloroquine has been widely discussed and promoted by front-line physicians who have reported remarkable success in reducing mortality rates and hospitalizations by 50 to 90 percent among sick CoVID-19 patients in many thousands of patients in over six countries and in the "hot zone" CoVID-19 area in New York City has been suppressed. This in the face of a number of controlled studies showing that such a combination *when used early* is safe, effective, and inexpensive. Studies cited by those imposing restrictions on this treatment were either designed to fail (treatment reserved for late in the clinical course or in one case using toxic doses of hydroxychloroquine) or contained fraudulent data and was retracted shortly after publication. The latter example was published in Lancet, one of the world's leading academic journals. Opposition even to allowing physicians to prescribe these two drugs widely used for decades for other indications, for CoVID-19 has been mostly political and has been exercised by governors, other non-physicians including pharmacy boards, etc.

It is past time to move away from reliance upon a flawed, highly misleading test for diagnosis upon which to base public policy recommendations and mandates. Public health policy guidelines and mandates based upon flawed data should be abandoned and centered around accurate data for hospitalizations and deaths from CoVID-19, carefully accounting for financially motivated up-coding in the process.

Once a more reliable diagnostic test that can produce results quickly is available, this can help to monitor societal penetration of the virus but should not be the basis for mitigation efforts when deaths and hospitalizations from CoVID-19 do not justify them.

****The views and opinions expressed in this article are those of the authors and do not necessarily reflect the views of Children's Health Defense.*