# How the Unscientific Interpretation of RT-PCR & Rapid Antigen Test Results is Causing Misleading Spikes in Cases & Deaths

# Written By **Yohan Tengra** & **Ambar Koiri**

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# To, Professor (Dr) Balram Bhargava, Director-General at the Indian Council of Medical Research.

#### **Abstract**

The RT-PCR & RAT tests are currently the main testing method used to diagnose COVID-19. The principle is to collect respiratory cells and to use the RT-PCR (Reverse Transcription - Polymerase Chain Reaction) or RAT (Rapid Antigen Test) technique to detect fragments of the RNA of the virus. The false positive rate is high, between 30%-97%, which can mainly be explained by an incorrect execution of the technique and incorrect interpretation. Previously, these tests were routinely used to diagnose viral upper respiratory tract infections in adults and children, but generally, the test was performed in hospitalized symptomatic patients by an experienced medical team. Currently, all over the world, the public health strategy during this COVID-19 pandemic is based on an early detection of suspicious cases, an early diagnosis of symptomatic patients, and isolation of patients with COVID-19 in order to restrict the outbreak. However, identification of symptoms is currently being skipped, which leads to non-infectious asymptomatic individuals being restricted in various ways. The aim of this article is to help healthcare providers to interpret this test correctly in adults and children, & to aid the ICMR in revising its testing guidelines.

Note - \*References to backup all the data presented below will be put in blue brackets at the end of every statement and numbered accordingly. You can find the related number at the bottom of the document that will have the relevant link next to it\*

## **Introduction**

We are writing this document on behalf of **Awaken India Movement**, to bring out the facts about the RT-PCR test & Rapid Antigen Test results, their interpretation, & the real meaning of positive cases.

We bring to your attention important information regarding the testing that is currently being used by all State Governments in India to diagnose people with Covid-19.

#### **How the RT-PCR Test Works**

We will begin by briefly explaining how the RT-PCR test works. It takes genetic material from the throat sample that is collected on the swab, runs it through an enzyme called Reverse Transcriptase to convert the RNA from the virus into DNA, & then multiplies the DNA exponentially to find if fragments of the Sars-Cov-2 virus are present in the person or not. Since complete live viruses are necessary for transmission & not their fragments, the RT-PCR test is not designed to tell us whether someone has an active Sars-Cov-2 infection or not. When the genetic material is being amplified, it is being done via cycles, which makes the quantity double after every cycle. For e.g. If 35 cycles of the RT-PCR are run, the first cycle will multiply the material from 1 to 2, the next one will take it from 2 to 4, & so on, until 35 cycles are completed. To put this into perspective, if the RT-PCR starts with a quantity of 2 virus fragments, at the end of 35 cycles it will create 3500 crore fragments! [1]

Karry Mullis, an American Biochemist who got the Nobel Prize for his invention of the RT-PCR technique, said the following about the RT-PCR test: "With RT-PCR, if you do it well, you can find almost anything in anybody. It doesn't tell you that you're sick, & it doesn't tell you that the thing you ended up with really was going to hurt you. I'm skeptical that any RT-PCR test is ever true." [2]

According to data from one of the test kits approved by the ICMR called: "TaqMan 2019-nCoV Control Kit v1" by the company ThermoFisher Scientific, it clearly states: "For Research Use Only. Not for use in diagnostic procedures." [3] The same can be found on the websites of many of the test kits approved by the ICMR.

According to Public Health England: "RT-PCR detects presence of viral genetic material in a sample, but it is not able to distinguish whether infectious virus is present." [4]

Another expert on the RT-PCR & American Biochemist, David Rasnick PhD, said the following: "RT-PCR is a great scientific research tool; it's a horrible tool for clinical medicine. It will generate a huge number of false

positives. When people ask me about getting tested, I say DON'T DO IT. No healthy person should be tested. It means nothing, but it can destroy your life & make you absolutely miserable." [5]

#### The Real Gold Standard Test for Viruses & Bacteria

Now that we have a basic understanding of how the RT-PCR works, let's talk about the Gold Standard for testing infectious diseases. This is known as bacteria or virus culture, where viruses are injected in laboratory cell lines to see if they cause cell damage & death, thus releasing a whole new set of viruses that can go on to infect other cells. [6] This has always been the gold standard in other viruses & bacteria as well, like Ebola, Whooping Cough, etc. In a sick person with symptoms, if scientists are able to culture a virus or bacteria, it means he possesses sufficient quantities of it in his body which shows that he is infected. In the case of Sars-Cov-2 as well, this is the gold standard that the RT-PCR & other quick diagnostic tests like the Rapid Antigen Tests should be compared to. A paper published by Indian scientists in 2020 titled "COVID diagnostics: Do we have sufficient armamentarium for the present and the unforeseen?", published in the Indian Journal of Medical Specialties, the authors admit that viral culture is the gold standard for Sars-Cov-2. [7]

#### What does a RT-PCR False Positive Test Result Mean?

Does a RT-PCR positive mean TRUE POSITIVE if the gene fragments targeted in the RT-PCR are unique to the virus and the RT-PCR is VERY ROBUST?

There is speculation as to whether the RT-PCR can indeed find the virus from a person's sample or maybe the RT-PCR is not specific enough and might give positive when other viruses are present. Some RT-PCR manufacturers tell us there is "cross contamination" and "non-specific" interference with a list of viruses in their instruction manuals.

**POSSIBILITY ONE:** the RT-PCR test is positive, but this was due to cross-contamination or non-specific interactions. Then the test would be a FALSE POSITIVE because the SARS Cov2 virus is not present in the sample. This means the RT-PCR positive is a FALSE POSITIVE rather than a TRUE POSITIVE. But this is not the only possibility. We want to focus on our argument that depends on viral culture.

**POSSIBILITY TWO**: Even if the RT-PCR test only detects TRUE POSITIVES in the sense that the SARS Cov2 virus, or better, the target gene fragment, is present in the sample, it remains to be seen whether the person can infect others or even if the virus is still infecting the very person carrying the virus. [8]

#### Studies comparing RT-PCR to the Gold Standard

In a study titled "Correlation between 3790 qPcr positive samples & positive cell cultures including 1941 Sars-Cov-2" published in the peer-reviewed scientific journal "Clinical Infectious Diseases", by R Jafaar et al., in September 2020, [9] when scientists compared the RT-PCR against the gold standard (I.e., viral culture), this is what they found:

Ct = 25, up to 70% of patients have a positive viral culture. (meaning that in 30 percent of samples where RT-PCR was positive, the virus could not be cultured from those people, hence they were not infectious. Thus, at this level the false positive rate of the RT-PCR = 30%) Ct = 30, up to 20% of patients had a positive viral culture Ct = 35, less than 3 percent had a positive viral culture

Hence at 25-30 cycles, false positive rate is 30%-80% (10% increase at every cycle)
30-35 cycles, false positive rate is 80% - 97%

35 cycles & above, false positive rate is 97%-99.9%

In a study titled: "Predicting Infectious Severe Acute Respiratory Syndrome Coronavirus 2 From Diagnostic Samples" published in the journal of Clinical Infectious Diseases in December 2020, [10] the authors took 90 RT-PCR positive Sars-cov-2 samples and performed a viral culture test on them. They found that there was no viral growth in samples where the CT value of the RT-PCR was greater than 24. They also found that there was no viral growth in culture 8 days after symptoms began. Hence they concluded: "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."

According to a **Meta-Analysis of 29 studies**, titled: "Viral cultures for Covid-19 infectivity assessment – a systematic review" published

in "Clinical Infectious Diseases" by T Jefferson et al., in September 2020 in medRxiv [11]: "Twelve studies reported that Ct values were significantly lower & log copies higher in samples producing live virus culture. Five studies reported no growth in samples based on a CT cutoff value, which ranged from CT>24 for no growth to Ct ≥ to 34. Two studies report a strong relationship between Ct value & ability to recover infectious virus & that the odds of live virus culture reduced by 33% for every 1 unit increase in Ct. Cut-off of RT-PCR greater than 30 was associated with non-infectious samples"

Conclusion of this study: "A binary Yes/No approach to the interpretation RT-PCR unvalidated against viral culture will result in false positives with possible segregation of large numbers of people who are no longer infectious & hence not a threat to public health"

Basically, in this paper they are saying that after analysing 29 studies, higher CT values are not associated with active infection of Sars-Cov-2, & that with each cycle increase of the RT-PCR, the chances of someone being infected reduce by 33%. The authors concluded by saying that RT-PCR results should be tested against viral culture, or else a large number of healthy people will be wrongly quarantined & have other restrictions imposed on them.

Even Dr. KK Aggarwal, President of Heart Care Foundation of India, President of Confederation of Medical Association of Asia & Oceania, & past president of the Indian Medical Association, said that if the CT value is above 24, it is likely that the persons viral load is really less & that he won't pass on the infection to anyone else, & if the value is less than 24 then it is highly likely that they are infectious.

## **Practical Issues with the RT-PCR Test**

This is precisely the reason why many people have found that their samples are testing positive in one lab & negative in another. For example, the Honorable Chief Justice of Rajasthan High Court, Indrajeet Mahanty, tested positive on Aug 15 & then tested negative twice later on Aug 16. [13] This has been the experience of thousands of people all across our country.

The above has been seen in the scientific literature as well. A paper from China by Li Y et al. Titled "Stability issues of RT-PCR testing of SARS-CoV-2 for hospitalized patients clinically diagnosed with COVID-19." published in the Journal of Medical Virology on Mar 26 2020. [14] reported on consecutive testing results, defined as either Negative (N), Positive (P) or Dubious (D, presumably intermediate). Results for 29 people with contradictory results out of about 600 patients were: 1 DDPDD 2 NNPN 3 NNNPN 4 DNPN 5 NNDP 6 NDP 7 DNP 8 NDDPN 9 NNNDPN 10 NNPD 11 DNP 12 NNNP 13 PPNDPN 14 PNPPP 15 DPNPNN 16 PNNP 17 NPNPN 18 PNP 19 NPNP 20 PNPN 21 PNP 22 PNP 23 PNP 24 PNDDP 25 PNPNN 26 PNPP 27 PNP 28 PNPN 29 PNP. A study from Singapore did tests almost daily on 18 patients and the majority went from Positive to Negative back to Positive at least once, and up to four times in one patient. [15]

Testing data collected from Massachusetts, New York, Nevada and elsewhere show that upwards of 90 percent of people who test "positive" with a RT-PCR test are perfectly normal and disease-free. [16]

# Why the RT-PCR Can Test Positive Long After Symptom Onset

The RT-PCR is so sensitive that it can pick up non-infectious viral fragments in those who have already dealt with the virus and are not contagious anymore. We have seen the same phenomena in the past, where measles virus cannot be grown in cell culture but is detected as RT-PCR positive 3 months after infection. [17] According to Sergio Santos & Matteo Chiesa, of Department of Physics and Technology, The Artic University of Norway, who wrote an article titled: "RT-PCR positives: What do they mean?" for the Center for Evidence Based Medicine: [18]

"This detection problem is ubiquitous for RNA virus's detection. SARS-CoV, MERS, Influenza Ebola and Zika viral RNA can be detected long after the disappearance of the infectious virus. ... because inactivated RNA degrades slowly over time it may still be detected many weeks after infectiousness has dissipated."

The same thing is taking place with Sars-Cov-2 as well, where people are testing positive weeks & months after the infection. But

instead of questioning the validity & interpretation of the test, most people think that they have got a re-infection.

#### WHO's Position on the RT-PCR Test

In a notice written on January 13, 2021 and published on January 20, 2021, the WHO warned that high cycle thresholds on RT-PCR tests will result in false positives.

To quote their own words: The design principle of RT-PCR means that for patients with high levels of circulating virus (viral load), relatively few cycles will be needed to detect virus and so the CT value will be low. Conversely, when specimens return a high CT value, it means that many cycles were required to detect virus. In some circumstances, the distinction between background noise and actual presence of the target virus is difficult to ascertain.

The WHO confirmed that RT-PCR tests should not be used as the sole method of diagnosing COVID-19; they should only be used where clinical signs and symptoms are present, and they can yield false positive results at high amplification cycles. The package inserts accompanying RT-PCR test kits, state that the test should be administered only to patients with signs and symptoms suggestive of COVID-19. [19]

# Fake Epidemics Created in the Past due to RT-PCR Misuse

We have had many episodes in the past where, based on wrong use of the RT-PCR, false epidemics of diseases have been created. A striking case of this has been highlighted in a New York Times article from 2007, titled "Faith in Quick Test Leads to Epidemic that Wasn't", [20] explaining how a fake whooping cough (also known as pertussis) epidemic was created in 2006. A lady called Dr. Brooke Herndon started coughing nonstop for 2 weeks in Mid-April of 2006. Because of this, an infectious disease expert at the hospital called Dr. Kathryn Kirkland, thought that could be the start of a whooping cough epidemic. By the end of April, few others at the hospital started coughing. Based on this fear that a whooping cough epidemic had started, the hospital tested nearly 1000 healthcare workers with the RT-PCR test, out of that 142 people were told they had the disease. These people were given

antibiotics & vaccines (1445 health care workers took antibiotics & 4524 health care workers took the vaccine). Many beds at the hospital including ICU beds, were reserved solely for whooping cough patients. (Similar to what is happening now)

After 8 months, healthcare workers were shocked to receive an email saying that this whole episode was a false alarm. Epidemiologists at the hospital decided to take extra steps to confirm if what they were seeing really was pertussis. Doctors sent 27 samples from patients they thought had pertussis to the American CDC. There scientists tried to grow the bacteria, & they concluded that there was no pertussis in any of the samples. They also tested 39 samples from patients who had tested positive and had not got themselves vaccinated, but only one of those cases showed an increase in antibody levels indicative of pertussis.

Epidemiologists & infectious disease specialists say the problem here was that they placed too much faith in a quick & highly sensitive molecular test that led them astray.

Dr. Trish M Perl, an epidemiologist at John Hopkins at the time, mentioned that "such pseudo-epidemics happen all the time. This case was one of the largest, but by no means an exception". She also mentioned that "national data on pseudo-epidemics caused by an overreliance on molecular tests like the RT-PCR is not kept."

Dr. Perl also admitted the following: "It's a problem; we know it's a problem. **My guess is that what happened at Dartmouth is going to become more common.**"

And here we are, with the exact same thing having happened with the Covid-19 pandemic! The institution this lady was working for, John Hopkins, is now hosting the official coronavirus cases & deaths data, & their own epidemiologists knew years ago that this very data cannot be relied upon since it is mainly based on RT-PCR tests.

Dr. Mark Perkins, an infectious disease specialist & chief scientific officer at the Foundation for Innovative New Diagnostics, a non-profit supported by the Bill & Melinda Gates foundation, said the following at the time: "You're in a little bit of no man's land with the new molecular tests (RT-PCR). All bets are off on exact

#### performance."

At that time, Dr. Elizabeth Talbot said "Neither coughing long & hard nor even whooping is unique to pertussis infections, and many people with whooping cough have symptoms like those of common cold: a runny nose or an ordinary cough". The exact same problem exists today with Sars-Cov-2 symptoms.

At the end of the whole episode, Dr. Kirkland said: "We were left in a very frustrating situation about what to do when the next outbreak comes". And yet the same quick unreliable tests have been used in the current Covid-19 situation with very little concern for false positives, showing that the medical community has not learnt from their past mistakes!

Dr. Cathy A Petti, an infectious disease specialist at the University of Utah, said the story had one clear lesson: "The big message is that every lab is vulnerable to having false positives. No single test result is absolute and that is even more important with a test result based on the RT-PCR."

At the time of this happening in 2006, the excuse the doctors had used back then is that the RT-PCR is quick & that culturing the bacteria will take two weeks. They do not have this excuse now, for the following reason. According to a study published in "Osong Public Health & Research Perspectives, Korea Centers for Disease Control & Prevention" titled "Traditional and Modern Cell Culture in Virus Diagnosis" published in Jan 2016 by A Hematian et al., [21] they admit the following: "With the recent advances in technology, cell culture is considered a gold standard for virus isolation". This proves our point that virus culture is the gold standard. The paper also admits: "The time required for identification of viruses showed a significant decrease: from 5-10 days (traditional methods) to 24 hours (novel methods)". This means that now no such excuse for time exists and that virus culture can be performed within 24 hours using novel methods.

## **How the Rapid Antigen Test (RAT) works**

Now that we have thoroughly dissected the RT-PCR test & its limitations / incorrect use, let us turn to the Rapid Antigen Test. Instead of detecting

the genetic fragments of the Sars-Cov-2 virus, it detects the proteins on the surface of the virus which are specific to it. Here is how this test works: "A typical antigen test starts with a health-care professional swabbing the back of a person's nose or throat. The sample is then mixed with a solution that breaks the virus open and frees specific viral proteins. The mix is added to a paper strip that contains an antibody tailored to bind to these proteins, if they're present in the solution. A positive test result can be detected either as a fluorescent glow or as a dark band on the paper strip." [22]

This test now makes up 50% of the testing done in Mumbai [23], & according to the ICMR as well as PM Narendra Modi, the RT-PCR test should make up 70% of India's testing, while the remaining 30% can be done via the Rapid Antigen Test. [24] The current mindset among people in our country is fully biased against false negatives, (I.e., if the test tests negative but the person actually has a Sars-Cov-2 infection). Hence the current guidelines in India state that if a person has symptoms & he tests negative on the RAT, then he needs to retest with the RT-PCR. The reasoning according to many is that since for an antigen test to test positive one would need to have many viral particles in their body, the test could miss out on someone who has low levels of viral particles in the body.

But as we have mentioned, viral culture is the gold standard for detecting viral agents, & studies have shown that the RAT correlates much better with virus culture than the RT-PCR does.

#### **Studies Comparing RAT to the Gold Standard**

The following studies demonstrate that Rapid Antigen Tests correlate better with the Gold Standard (viral culture) than the RT-PCR.

Title: "Antigen-based testing but not real-time RT-PCR correlates with SARS-CoV-2 virus culture" by A Pekosz et al., in 2020.[25] In this study 38 samples with evidence of SARS-CoV-2 by RT-PCR were collected from individuals symptomatic for COVID-19 with onset of symptoms. Samples were tested by rapid antigen test and in laboratory-based cell culture (Gold Standard) to assess infectivity. Of 38 RT-PCR-derived positive samples, 28 were positive, and 10 were negative in virus culture testing. This means that the RT-PCR had 10 false

positive results (rate of 26.3%). By comparing antigen-based test results, the scientists observed that all samples except one that were positive in both the RT-PCR-based and culture-based tests, were also positive in the antigen-based test. (Only one false negative, rate of 3.5%) Of 10 samples that were positive in RT-PCR but negative in viral culture, two were positive in the antigen-based testing. (0 out of 10 RT-PCR tests matched with viral culture here, whereas 8 out of 10 rapid antigen tests matched with viral culture.) These findings indicate the antigen tests perform better in detecting the presence of the infectious virus in patients' samples compared to RT-PCR-based tests.

Another study titled: "Evaluation of Abbott BinaxNOW Rapid Antigen Test for SARS-CoV-2 Infection at Two Community-Based Testing Sites — Pima County, Arizona, November 3–17, 2020" by JL Prince-Guerra et al., in Jan 2021, published in Morbidity & Mortality Weekly Report, [26] BinaxNOW rapid antigen test was used along with real-time reverse transcription-polymerase chain reaction (RT-PCR) testing to analyze 3,419 samples. 274 of these samples that either had a RT-PCR positive or an antigen positive were sent for viral culture. Out of these 124 were RT-PCR positive only, 147 were RT-PCR & antigen positive, & only 3 were antigen positive & RT-PCR negative.

Using viral culture to compare against RT-PCR results, it was found that out of the 124 RT-PCR only positive tests, only 11 could be cultured. This indicates a 91 percent false positive rate for the RT-PCR (with a median CT value of 33.9). Out of the 147 samples that tested positive for both the RT-PCR & RAT, 85 of them could be cultured (giving the RAT a false positive rate of 42%). Using samples which tested positive using the RAT got down the false positive rate to 42%, a marginal improvement over using RT-PCR only positive samples. Further, it was found that the median CT value goes down to 22, indicating higher viral load on samples which test positive on the RAT. No virus could be cultured from the 3 samples that were RAT positive & RT-PCR negative. This study confirms that the RT-PCR has a much higher rate of false positives than the RAT, that lower RT-PCR CT values correlate with higher viral load, & that the RAT correlates better with the gold standard of viral culture than the RT-PCR.

And finally, a study titled: "Evaluation of a SARS-CoV-2 rapid antigen test: Potential to help reduce community spread?" by T Toptan et al., published in December 2020 in the Journal of Clinical Virology [27], out of 32 RT-PCR samples, only 19 could be grown via cell culture, whereas out of those 32 only 27 were Antigen Test Positive.

All of these studies indicate that the RT-PCR test produces way more false positives than the antigen test, & that the antigen tests correlate with the gold standard better than the RT-PCR. Hence the worry about false negatives with the Antigen test is misleading as that is based on treating the RT-PCR as the gold standard, whereas what we have demonstrated here is that the reliability of the RT-PCR test is too low to depend on, & therefore the viral culture must be taken as the true gold standard.

#### **Practical Issues with the RAT**

Just like the RT-PCR, we have seen the same practical results with the antigen test as well, where people are getting different test results from different labs with the same sample.

**Tesla's CEO Elon Musk**, claimed that he was tested positive twice and tested negative twice on the same day:

"Something extremely bogus is going on," Musk tweeted. "Was tested for covid four times today. Two tests came back negative, two came back positive. Same machine, same test, same nurse. Rapid Antigen test from BD." [28]

In the USA, when the health care workers in Nevada and Vermont reported false positives with the RAT, US's HHS (Department of Health & Human Services) defended the Rapid Antigen Tests and threatened Nevada with unspecified sanctions until state officials agreed to continue using them in nursing homes. It took several more weeks for the U.S. Food and Drug Administration to issue an alert on Nov. 3 that confirmed what Nevada had experienced: **Antigen tests were prone to giving false positives, the FDA warned in a report.** 

The FDA laid out various guidelines to reduce the risk of false positives from the Antigen tests, after it was found that this test was producing many false positive in nursing homes. They can be found in an article

titled: "Potential for False Positive Results with Antigen Tests for Rapid Detection of SARS-CoV-2 - Letter to Clinical Laboratory Staff and Health Care Providers".[29] These guidelines must be implemented in India as well.

A paper titled: "Challenges and Controversies to Testing for COVID-19" [30], found that if a quarter of American school kids were tested three times a week with an antigen test that's 98% specific, it would produce 800,000 false positives a week.

#### **Other Tests Used in India**

There are two other tests that are currently used in our country for diagnosis, known as the TrueNAT (True Nucleic Acid Amplification Test) & CBNAAT (Cartridge Based Nucleic Acid Amplification Test). Both of these tests were developed to test for TB. These tests are used at very low levels in our country & hence they're not of much relevance to the discussion. Majority of the testing in the country is done via RT-PCR & the RAT, & only a tiny percentage of them are done via the TrueNAT & CBNAAT. The TrueNAT is based on the same working principle as the RT-PCR but uses a smaller portable kit that gets charged by batteries. The latest versions of the TrueNat machine can detect an enzyme (called RdRp) found in the RNA of the coronavirus SARS-CoV-2. [31]

Since no papers have been published comparing these tests against the gold standard of viral culture, & sensitivity/specificity is only measured in comparison to the RT-PCR, these tests should not be used, until such research is conducted & reliable results are shown.

# **The Myth of Asymptomatic Carriers & Transmitters**

# **Problems with the Case Report Studies**

Panic has been spread among the general population since the beginning of the pandemic, based on the idea of "asymptomatic transmission". This idea was strongly influenced by a case report in Germany, in which an infection was attributed to contact with an asymptomatic person. The report was published in March 2020 in the New England Journal of Medicine, titled "Transmission of 2019-

nCoV Infection from an Asymptomatic Contact in Germany" by Christian Drosten et al. [32] Further investigation revealed that this person had actually been sick and had been suppressing her symptoms with medication. The original misleading paper was never rectified. Also in this paper, the authors admit: "the viability of 2019-nCoV detected on qRT-PCR in this patient remains to be proved by means of viral culture."

A study titled: "Asymptomatic and pre-symptomatic transmission of SARS-CoV-2: A systematic review" published in MedRxiv in June 2020 by Christina Savvides et al [33] highlighted many issues in the case report studies. The authors wrote:

"The early literature of SARS-CoV-2 asymptomatic transmission was dominated by case reports of apparent asymptomatic transmission, and 9 studies that document cases of apparent asymptomatic or presymptomatic transmission were identified in this systematic review. A majority of these cases were individuals exposed during travel to Wuhan or other cities in Hubei Province, who later transmitted the infection to members of their household or other close contacts. Huang and colleagues reported a cluster of asymptomatic transmission among children, who had rapid onset of illness and various nonspecific or atypical manifestations of illness. While many of these case reports took steps to ensure that those infected by asymptomatic or pre-symptomatic individuals did not have other plausible sources of infection, they were unable to definitively rule out other sources or community transmission. Other case reports centre around regions that were believed to not have community transmission, where exposure to other sources of infection is less likely. One example is the case of a Chinese businesswoman who appeared to have asymptomatically infected some of her colleagues during a work trip in Germany. However, after publication, the supplementary material was modified because the original patient recalled that she was experiencing symptoms during her meetings with colleagues. While this paper did not appear in the keyword search, and is not included in this review, it was frequently cited in other papers analysed in this review. **The** subsequent update to the NEJM article is emblematic of the systematic biases in case reports documenting asymptomatic and pre-symptomatic transmission. Patients or practitioners may make errors when recalling or reporting symptom onset date. Another

case report from the keyword search that focuses on areas without broad community transmission reports on seven clusters in Singapore where pre-symptomatic transmission appeared to be the most likely explanation. This study identified 10 cases where pre-symptomatic transmission appeared to occur 1-3 days before symptom onset in the initial patient. The retrospective nature of these studies makes it difficult to rule out mild symptoms being present during transmission, or other sources of infection.

All case reports of asymptomatic and pre-symptomatic transmission are confounded by the highly subjective nature of reporting symptom onset and exposure date. Factors like age, cultural norms, and public communication about the pandemic may influence when people report their symptoms beginning. For example, an older person with chronic illness may attribute muscle and joint pain to age, whereas a younger person may call that a symptom. Additionally, as the pandemic has progressed, our categorization of what is considered a symptom has expanded. In February, the WHO said symptoms of COVID-19 included fever, dry cough, fatigue, sputum production, shortness of breath, sore throat, headache, myalgia or arthralgia, chills, nausea or vomiting, nasal congestion, diarrhoea, haemoptysis, and conjunctival congestion. In late February, Mao and colleagues first reported that anosmia, or loss of sense of smell, were symptoms of COVID-19, and this finding was supported in additional research. On April 17th, the WHO added loss of smell or taste as well as rash and skin discolorations of fingers and toes as additional symptoms of COVID-19. Knowledge of these changing definitions, differing levels of chronic illness, and varying levels of symptom awareness will alter when individuals first report experiencing symptoms.

Two additional reports included in this keyword search inferred the possibility of asymptomatic transmission from positive RT-PCR tests in asymptomatic and pre-symptomatic individuals. Lytras and colleagues noted a high prevalence of SARS-CoV-2 infection in asymptomatic cases in repatriation flights to Greece. While this study supports the well-documented phenomenon of asymptomatic cases, the possibility of asymptomatic transmission is a hypothetical, as a positive RT-PCR test does not confirm that an individual is contagious. This study failed to provide insight into the feasibility of actual transmission during pre-symptomatic or asymptomatic infection because the authors failed to report Ct values of RT-PCR

positive individuals, did not culture virus, and did not identify possible transmission chains. The study by Ochiai and colleagues had similar findings and limitations.

The eight studies reported viral loads were at their highest levels around the time observation began. Therefore, the authors of these studies concluded viral loads peak close to when symptoms emerge. However, this discovery must be prefaced by the limitation that all patients in the studies were enrolled after symptom onset, and therefore presymptomatic viral loads were not measured. This shortcoming is further propagated by the fact that patients often will not see a clinician immediately after symptom onset, in these cases we cannot rule out the possibility that viral load peaks after symptom onset. While studying COVID-19 in China, Zhang and colleagues found that an average of 2.5 days elapsed between symptom onset and first healthcare consultation. Although this decreased from 3.0 to 1.6 days as the pandemic progressed. If individuals are only infectious for 8 days, as Bullard and colleagues report, this delay in seeking care greatly confounds our ability to measure comprehensive viral **dynamics.** Additionally, the studies do not disclose how soon the first swab was taken after symptoms were reported; a margin of error of a day might dramatically change the viral load in patients. While the finding that viral load appears to peak soon after symptoms are detected in patients suggests that pre-symptomatic transmission is plausible, there is not enough information about the distribution of SARS-CoV-2 viral kinetics in pre-symptomatic stage to conclude when infectiousness begins.

The temporal variation in what is classified as a symptom of COVID-19, combined with bias and reporting errors, make anecdotal reports of symptom start date unreliable. These factors confound the case reports that highlight asymptomatic or presymptomatic transmission and make it difficult to draw reliable conclusions."

Based on this flawed case report evidence, the "experts" began to promote the idea that this virus behaves differently to other respiratory viruses.

The WHO Controversy over Asymptomatic Transmission

On June 8th, 2020, WHO official Maria Van Kerkhove said that asymptomatic transmission of the coronavirus was "very rare." However, she later clarified this statement saying, "the available evidence from contact tracing reported by Member States [of WHO] suggests that asymptomatically-infected individuals are much less likely to transmit the virus than those who develop symptoms." [34]

What really happened was that Dr. Maria Van Kerkhove answered a reporter's question by explaining that WHO researchers were trying to distinguish between people "reported as not having symptoms" and people who "are in their pre-symptomatic phase, which means it's a few days before they actually develop severe symptoms." When WHO officials had sought to determine whether reported cases "were truly asymptomatic", they discovered that many were not without symptoms but had "really mild disease". (This is distinguished by scientists with the term "paucisymptomatic".)

Detailed contact tracing reports, she explained, were "not finding secondary transmission onward" from cases who tested positive for viral RNA yet remained "truly asymptomatic". "It still appears to be rare that an asymptomatic individual actually transmits onward."

The data, she said, indicated that transmission from truly asymptomatic individuals is "very rare".

This whole controversy with the WHO pushed people to understand the difference between asymptomatic transmission & presymptomatic transmission, which the media has tried to use interchangeably, but they mean different things.

# The Difference Between an Asymptomatic Case & a Presymptomatic Case

A pre-symptomatic case of COVID-19 is an individual infected with SARS-CoV-2, who has not exhibited symptoms at the time of testing, but who later exhibits symptoms during the course of the infection. An asymptomatic case is an individual infected with SARS-CoV-2, who does not exhibit symptoms during the course of infection.

**Studies on Asymptomatic Transmission** 

As far as the scientific literature goes, the evidence is clear: truly asymptomatic transmission (when separated from pre-symptomatic transmission) is very rare.

This position is supported by a large study from the city in China where the SARS-CoV-2 outbreak originated. Published in **Nature**Communications on November 20, the study is titled "Post-lockdown SARS-CoV-2 nucleic acid screening in nearly ten million residents of Wuhan, China".[35]

Researchers in Wuhan did a city-wide screening between May 14 and June 1 using reverse transcription polymerase chain reaction (RT-PCR) assays to detect viral RNA fragments in residents. Among eligible residents, which was those aged six years or older, 92.9 percent participated, which amounted to 9,899,828 people.

With this intensive screening program, there were positive test results for 300 individuals who were asymptomatic. Among these, 63 percent also tested positive for antibodies to SARS-CoV-2, offering additional evidence that they had indeed been infected. Nevertheless, contact tracing of 1,174 close contacts of asymptomatic individuals with evidence of infection revealed none who also tested positive.

The researchers also tried to culture virus from asymptomatic individuals who tested positive, but the results indicated that there was "no 'viable virus' in positive cases detected in this study". Consequently, despite testing positive for viral RNA, none of these individuals appeared capable of transmitting the virus to others. As the authors stated, "there was no evidence of transmission from asymptomatic positive persons to traced close contacts."

Three studies following up on 17,[36] 91,[37] and 455 [38] close contacts of asymptomatic cases, respectively, found no evidence for asymptomatic transmission—an attack rate of "0%".

A fourth study following up on 305 contacts of 8 asymptomatic cases [39] identified one secondary case, for an attack rate of "0.3%".

A fifth study following up on 119 contacts of 12 asymptomatic cases [40] likewise identified one secondary case, for an attack rate of "0.8%".

a sixth and seventh study respectively "indicated an asymptomatic secondary attack rate of 1% and 1.9%". [41,42] An eighth followed up on 106 contacts of 3 asymptomatic cases and found 3 secondary cases, for an attack rate of "2.8%".[43]

The ninth and largest study followed up on 753 contacts of asymptomatic index cases and identified one secondary case, for a secondary attack rate of "0.13%".[44]

Together, the nine studies reported secondary attack rates of "zero to 2.8%", which compared with secondary attack rates for symptomatic cases of "0.7% to 16.2%", which suggests that **people who are infected** with SARS-CoV-2 but never develop COVID-19 "are responsible for fewer secondary infections than symptomatic and pre-symptomatic cases."

In other words, <u>iust because a person receives a positive RT-PCR</u> test does not mean that they should be considered infectious, and <u>pursuing policies based on the opposite assumption—as public health officials in India and other countries have been doing—is a waste of precious resources.</u>

# <u>Problems With the Studies on Pre-symptomatic</u> Transmission

A study titled: "Transmission frequency of covid-19 through presymptomatic and asymptomatic patients in AJK: A report of 201 cases" currently undergoing the process of peer review in Virology Journal, [45] concluded: "The study concludes that the risk of presymptomatic transmission of infection is low (1.12%) and it becomes very rare in contacts made longer than 6 hours before onset of symptoms."

Besides this one study, there are studies that estimate that individuals who are pre-symptomatic, meaning that they do go on to develop disease symptoms, are responsible for a large proportion of community spread. The estimates reported matter-of-factly by the media come from modelling studies that have serious methodological flaws and limitations biasing results artificially toward a higher proportion of pre-symptomatic spread.

**Model outputs are dependent upon the input assumptions.** One key lesson from the pandemic is that findings from models may have little bearing on reality. Estimates from modelling studies do not represent real life pre-symptomatic transmission events.

Take, for instance, the modelling study from the CDC titled: "SARS-CoV-2 Transmission from People Without COVID-19 Symptoms" published in JAMA Network Open in January 2021. [46] This study has been used by the authorities & mainstream media to support the purposefully false claim that "approximately 50% of transmission" is "from asymptomatic persons".

As already noted, that proportion mostly referred to pre-symptomatic transmission. Furthermore, that estimate depended on the assumption that before the person developed symptoms, there was a highly infectious virus incubation period. The incubation period is the time from infection until the development of symptoms.

The reference cited as the basis for that assumption is the **Nature**Medicine modelling study titled "Temporal dynamics in viral shedding and transmissibility of COVID-19" was published in April 2020,[47] but that study has numerous methodological flaws and limitations that give reasonable cause for questioning that assumption.

The first thing to note about it is that the study authors, as they point out, "did not have data on viral shedding before symptom onset". They only had "viral load" data from patients who were already in the hospital and after those patients' symptoms had already developed. This introduced the problem of patient "recall bias" as to when their symptoms actually started. This was an issue with data from other studies estimating the incubation, as well. (In simple terms, instead of the researchers themselves knowing when the patients' symptoms started, they had to rely on the patient's memory for when they started.) The authors acknowledged that recall bias would likely tend toward overestimation of the incubation period, which would in turn bias their findings toward an estimated proportion of presymptomatic transmission that is "artificially inflated."

In addition to an estimated mean incubation period, their calculations also depended on an estimate from another study of the mean serial interval, which is the time from symptom onset in a person who transmits

the virus until symptom onset in the person to whom the virus was transmitted. If the mean serial interval is shorter than the mean incubation period, it "indicates that a significant portion of transmission may have occurred before infected persons have developed symptoms."

Their data on the serial interval was based on "settings with substantial" household clustering" while lockdown measures were in place in China. As the corresponding author, Eric Lau, acknowledged, more frequent and intensive contact within households "results in shorter serial intervals". This in turn results in a greater proportion of estimated presymptomatic transmission and limits the generalizability of their findings to the broader community setting in the absence of "stay-at-home" orders and other lockdown measures. (In simple words, these findings are based on families that have to cluster together in their houses for a long period of time during lockdowns, & hence their results cannot be applied to the general population which is not under movement restrictions. The irony here is that estimates of presymptomatic transmission are used in order to justidy lockdowns & movement restrictions, yet it is the same lockdowns & movement restrictions which make the estimate of pre-symptomatic spread higher in these studies!)

Consequently, as noted in a systematic review of estimates on asymptomatic and pre-symptomatic transmission published on the preprint server medRxiv on June 17, [48] it is "not possible to ascertain if the difference between calculated serial interval and incubation period are true differences, or an artefact of rounding error."

It's also important to note with respect to their data on "viral loads" that when the authors of the modelling study use the term "viral shedding", they don't mean that patients were shown to be expelling infectious virus into the environment around them which was measured via a Gold Standard viral culture test. They mean that RT-PCR tests were used to detect SARS-CoV-2 RNA in patients' nasal cavity or throat. We know through the evidence discussed earlier in the article that at RT-PCR CT>30, the likelihood of being able to culture a virus goes down to 20% (80 percent false positives). Yet in the graphs of the CDC study, patients with mild to moderate symptoms had test results with Ct values greater than 30,

which strongly suggests that most of these patients were not infectious at the time they were tested. It is theoretically possible that most of these patients had been infectious before they went to the hospital and got tested, but the study did not demonstrate this. Instead, they assumed it. This is another flawed assumption that was used in the study.

There are numerous other methodological flaws in the study, which can be found in an article titled: "How the New York Times Lies about SARS-CoV-2 Transmission: Part 4" by Investigative Journalist Jeremy Hammond. [49]

An editorial published in **Dec 2020 in the British Medical Journal titled:** "Asymptomatic transmission of Covid-19" [50] highlighted the shortcomings in our approach to testing, & the futility of trying to find asymptomatic cases. The authors wrote: "Given the variation in prevalence and testing strategies by region, the proportions of people with positive and negative test results should be published alongside the purpose of the testing strategy and the population tested (screening healthy populations in schools, universities, and health and social care, or testing people with symptoms).

Government regulations on recording the age, ethnicity, sex, and place of residence of people with positive results must also be followed.

Searching for people who are asymptomatic yet infectious is like searching for needles that appear and reappear transiently in haystacks, particularly when rates are falling. Mass testing risks the harmful diversion of scarce resources. A further concern is the use of inadequately evaluated tests as screening tools in healthy populations. The absence of strong evidence that asymptomatic people are a driver of transmission is another good reason for pausing the roll out of mass testing in schools, universities, and communities."

## WHO's Statement on Asymptomatic Transmission

The WHO observed in a guidance document about modes of SARS-CoV-2 transmission published on July 9, 2020 titled "Transmission of SARS-CoV-2: implications for infection prevention precautions" [51]: "individuals without symptoms are less likely to transmit the virus than those who develop symptoms." (Note that this statement

includes pre-symptomatic as well as asymptomatic individuals.)

# Other Problems with Studies on Asymptomatic & Presymptomatic Transmission

A study titled: "Asymptomatic and pre-symptomatic transmission of SARS-CoV-2: A systematic review" published in MedRxiv in June 2020 by Christina Savvides et al., [52] highlighted many problems in scientific papers that talk about asymptomatic transmission. Here are the main highlights:

While the existence of asymptomatic cases is well understood, the link between asymptomatic/pre-symptomatic cases and transmissibility is more tenuous. RT-PCR testing does not accurately tell us whether an individual is contagious. Infectivity in cell culture is the standard for determining whether a patient is infectious.

A small number of studies have attempted to look at viral dynamics in asymptomatic and pre-symptomatic individuals. One study, from a skilled nursing facility in Kings County, Washington, found viral culture growth in a patient sample with a cycle threshold (Ct) value of 34, as well as viral culture growth in asymptomatic and pre-symptomatic individuals.

However, findings in elder care facility may not reflect the general population. It is difficult to recognize early signs and symptoms of respiratory viral infections in elderly populations due to impaired immune responses associated with aging and the high prevalence of pre-existing and underlying conditions, such as chronic cough and cognitive impairments. Furthermore, elderly and infirm patients have blunted physiological responses that may allow them to remain apparently asymptomatic during infection. Influenza, another respiratory virus, often manifests with few or atypical symptoms in this population, resulting in confounding of when symptoms are first reported and undermining efforts to isolate ill patients. (In this study, the definition of an asymptomatic person was not just a person a person who didn't have symptoms, but also a person who had the same recurring symptoms for a long time prior to the test. Hence, a person who developed symptoms later could also be put in this category and get counted as

#### asymptomatic or pre-symptomatic).

A second report, looking at individuals exposed during a flight from China to Frankfurt, identified one case of asymptomatic infection and one case of pre-symptomatic infection with positive virus culture infectivity. This study does not provide information about the passengers' health or age, and there is likely to be a bias to downplay mild or moderate symptoms in the context of being detained while traveling.

Although these studies have attempted to look at viral dynamics in asymptomatic and pre-symptomatic individuals in specific populations, to date the authors are not aware of any studies that have successfully cultured live virus from asymptomatic or presymptomatic individuals in the general population. Despite the absence of live virus isolation and culturing in the general population, many studies and reports have concluded asymptomatic and pre-symptomatic transmission are prevalent in this pandemic. Modelling studies that are being utilized to predict future case spread and determine the most effective interventions are fundamentally rooted in an understanding of asymptomatic and pre-symptomatic transmission.

Wolfel and colleagues attempted to relate RT-PCR quantification of viral load with infectivity. The authors combined RT-PCR measurement with viral culturing and found that the success of virus isolation in culture was a function of viral load: only samples that contained greater than 106 copies per mL yielded an isolate (although Ct value was not reported in this study, He et al. reports this corresponds to a Ct value of 24). Interestingly no isolates were obtained after day 8, despite continuing high viral loads. This finding suggests persistent RNA detection represents non-viable virus that is not infectious. (In simple words, someone could have a low CT value after their infection & symptoms are over, but they stop being infectious as no virus can be cultured from them). This finding demonstrates that while viral load can be predictive of transmissibility, it is not a perfect correlation. The viral studies of Wolfel et al., Lui et al., To et al., Young et. al. and Yoon et al. were limited by small sample size. However, He et al., Liu et al., and Ding et al. have similar findings with larger sample sizes.

Kim et al. analysed the Ct values of three pre-symptomatic patients and found the highest levels of virus were one to two days before symptom onset. However, this dataset is extremely small (n=3), and one of the patients was on the threshold of detection. It is hard to reliably extract general trends from this limited sample.

#### **Asymptomatic Transmission for Older Viruses**

In a study titled: "Does influenza transmission occur from asymptomatic infection or prior to symptom onset?" by E Patrozou et al., published in April 2009 in the Public Health Report, [53] the authors conclude: "We performed a systematic review of published studies describing the relationship between viral shedding and disease transmission. Based on the available literature, we found that there is scant, if any, evidence that asymptomatic or presymptomatic individuals play an important role in influenza transmission."

However, the decision-makers in this epidemic determined that this does not apply to COVID-19 and every single individual we encounter could be an infectious person capable of killing us. This is contrary to conventional reasoning in medicine and public health. Decisions have always been based on prior knowledge, until there is compelling evidence to disprove what we thought we knew. In clinical medicine, it is known that it is dangerous to place tests & diagnostics above signs and symptoms, due to the risk of false positives & false negatives.

## **Dangerous Viruses Found in Healthy People**

We know from past studies, that many healthy asymptomatic humans harbour multiple viruses associated with diseases in them. For example, in a study titled "Blood DNA virome in 8000 humans" published in Plos Pathogens by A Moustafa et al., March 2017, [54] in 8240 healthy individuals, none of whom were ascertained for any infectious disease, the researchers found that with a lower bound of 2 viral copies per 1,00,00 cells, 42% of healthy individuals had sequences of 94 different viruses, including sequences from 19 human DNA viruses, proviruses and RNA viruses (herpesviruses,

anelloviruses, papillomaviruses, three polyomaviruses, adenovirus, HIV, HTLV, hepatitis B, hepatitis C, parvovirus B19, and influenza virus.) HIV was found to be 5 times more prevalent than Hepatitis C & Influenza in this healthy cohort of 8200 people. If this study group is representative of the human population, there would be around 432 million healthy people with HIV in their bloodstream worldwide.

Another study published in the journal BioMed Central Biology, titled: "Metagenomic analysis of double-stranded DNA viruses in healthy adults" by KM Wylie et al., in September 2014, [55] scientists found that in 102 healthy adults aged 18 to 40, at least one virus was detected in 92 percent of the people sampled, and some individuals harboured 10 to 15 viruses. Herpesvirus 6 or 7 was found in 98 percent of individuals, & certain strains of Papillomavirus were found in about 75 percent of samples. Adenoviruses which are associated with the common cold & pneumonia were also very common. This study was also referenced in an Economic Times article from 2014 titled "Healthy Humans carry viruses too".[56]

Another experiment conducted by researchers at the University of Pennsylvania found that healthy human lungs are a home to a family of 19 newfound viruses – which are present at higher levels in the lungs of critically ill people. This study is titled "Redondoviridae, a Family of Small, Circular DNA Viruses of the Human Oro-Respiratory Tract Associated with Periodontitis & Critical Illness" published in Cell Host & Microbe in May 2019 by AA Abbas et al. [57] These Redondoviruses found are known to be associated with human diseases.

This paper also admits a crucial fact: "Global virome populations, I.e., "the virome" are still mostly uncharacterized", meaning that scientists haven't yet done adequate research on many people to figure out what kinds of viruses are present in healthy people's bodies. Biologists estimate that 380 trillion viruses are living on and inside our bodies right now – 10 times the number of bacteria. [58]

We have been made to fear viruses & bacteria indiscriminately, but the fact is that they have been an integral part of human evolution & have made us who we are today. **More than 50 percent of 20000 human** 

genes we inherited were inserted into our genome by viruses. At least 8 percent of our genes were inserted by RNA retroviruses.

[59] Some mutations that we developed because of viruses have been crucial to our reproduction, memory, stem cell function, etc. Viruses are abundant in the environment, 1 litre of seawater contain as many as 10^10 viruses, 1 gm of soil contains 10^9 viruses, and there are 10^5 viruses in an adult human body. In babies, more than 10^8 viruses per gram of faeces were found by the end of first week. [60]

Associations in the scientific literature have been found between measles & mumps infections lowering cardiovascular mortality. Natural infection with measles during childhood has been associated with a reduced risk of much more serious diseases later in life, including degenerative bone disease, certain tumours, Parkinson's disease, allergic disease, chronic lymphoid leukaemia, both non-Hodgkin lymphoma and Hodgkin lymphoma, and cardiovascular disease. [61]

Given this critical role of viruses in human health & evolution, & the fact that many viruses associated with deadly diseases are present in humans, a RT-PCR positive case is not equal to a patient infected with Sars-Cov-2. RT-PCR positives on asymptomatic people should be treated with care since asymptomatic people are not infectious. This is even when the RT-PCR tests or the antibody tests are positive. This is because viral culture is required to establish if the viral RNA is capable of infecting cells and "reproduce".

Hence if the ICMR is claiming that the RT-PCR is a qualitative test and not a quantitative test [62], they should stop using the RT-PCR to diagnose a case since asymptomatic & presymptomatic transmission aren't proven, as established above. Healthy humans carry many viruses associated with disease in them & hence they should start using the gold standard of virus culture instead to determine infectivity.

However, since we are claiming that the RT-PCR can be used in a quantitative way if a person has symptoms and has a CT value less than 24, then the RT-PCR could be used to get an estimate of viral load. World Experts on the RT-PCR like Stephan Bustin, have formulated the MIQE guidelines since 2009 which can make the RT-PCR's CT value more reliable for viral load. In his 2017 paper, titled "Talking the talk,"

but not walking the walk: RT-qPCR as a paradigm for the lack of reproducibility in molecular research" published in the European Journal of Clinical Investigation, [63] it states: "Despite the impact of the minimum information for the publication of quantitative RT-PCR experiments (MIQE) guidelines, which aim to improve the robustness and the transparency of reporting of RT-qPCR data, we demonstrate that elementary protocol errors, inappropriate data analysis and inadequate reporting continue to be rife and conclude that the majority of published RT-qPCR data are likely to represent technical noise."

This is the reason that the ICMR is saying that CT values aren't reliable [64], but with the studies referenced above we have shown that despite the limitations of the CT value due to the different variables in the RT-PCR influencing it (such as poorly-collected sample, technical competence of the person performing the test, calibration of equipment and pipettes and analytical skills of the interpreters, how well the RNA is extracted, efficiency of the Reverse Transcriptase enzyme, how well the primer binds to RNA secondary structure, how the sample is stored, the RNA integrity number & the efficiency of the RT-PCR doubling cycle) we can still rely on it to a great extent since it correlates well with the gold standard of viral culture in almost 25-30 scientific papers.

The studies we referenced have found strong associations between CT value & viral load without following the MIQE guidelines, hence if these MIQE guidelines are implemented by our Government & ICMR, which can be found in a paper titled: "The MIQE Guidelines: Minimum Information for Publication of Quantitative Real-Time PCR Experiments" [65] then the CT values could be made even more reliable than what they already are. But even without these guidelines we have demonstrated that the CT value of current tests does show a strong association with viral load.

#### <u>Asymptomatic Cases in the First & Second Wave</u>

Now that we have come to see the real meaning of asymptomatic cases & how they don't cause infections in other people, let us take a look at how much of our case burden has come from asymptomatic people. We will first look at last year's data.

In an article by the Print titled: "80% Covid patients in India are asymptomatic, health ministry analysis finds", [66] Analysis of

cases across India until 23 August 2020 shows about 25.93% of the of the symptomatic patients reported with fever and 17.18% with cough. In an article titled "Over 70% children with Covid-19 are asymptomatic: AlIMS data" by the Hindustan Times, [67] as of November 2020, the author wrote: "With 73.5%, the highest proportion of asymptomatic cases was reported among children below the age of 12. The proportion decreased linearly with age, with only 38.4% of the cases among those above the age of 80 being asymptomatic. In an article by Hindustan Times from December 2020, titled: "71 percent active covid cases in Mumbai asymptomatic" [68], the author wrote: "Of the 12,926 active Covid-19 patients in Mumbai, 9,155 (71%) are asymptomatic, displaying no symptoms before undergoing tests for the presence of Sars-CoV-2."

Now let's review the data of the Second Wave (2021). In an article by NDTV from March 30 2021 titled "85,000 Covid Cases In Second Wave, Most Asymptomatic: Mumbai Civic Body" [69], the author wrote: "The second wave of coronavirus in Maharashtra started on February 10 and till March 20, Mumbai logged 85,000 cases, said Iqbal Chahal, the Commissioner of Brihanmumbai corporation, the civic body of Mumbai. Of the total number of cases, 69,500 are asymptomatic, he added. The remaining 8,000 patients reached hospitals with mild symptoms."

In an article from Deccan Herald, titled: "Majority of Bengaluru's Covid-19 patients are asymptomatic" from 19<sup>th</sup> April 2021, [70] the author wrote: "reports show that 95.9 per cent of the state's cases are 'asymptomatic'. The percentage of asymptomatic cases in the state capital of Bengaluru is even higher – 99.4 per cent, according to a report by Bangalore Mirror quoting data from the state's Covid-19 war room.

According to **Dr. Balram Bhargava** himself, **Covid-19 symptoms in** this wave are much less than last year, & that there is no difference in the percent of death between the first wave and second wave. He further said that only a marginally high proportion of COVID-19 patients are of younger age and that the average age of patients in the first wave was 50 years and, in this wave, it is 49 years. A higher number of asymptomatic individuals got admitted this year, than a higher proportion of patients admitted with breathlessness. [71]

Yet, the Indian Medical Research Council (ICMR) warned about asymptomatic patients who can be hidden super-spreaders of the Coronavirus in the country. [72] This is despite all the evidence which shows us that the opposite is true.

Given all that we have learnt in this document until now, this data should make us pause & think very deeply about all the unnecessary harm to society that has been caused because of our irrational fear of asymptomatic cases.

# **Court Rulings Against the RT-PCR Worldwide**

Multiple courts around the world have given judgements against the RT-PCR test.

A Portuguese court issued the following ruling: "Given how much scientific doubt exists – as voiced by experts, i.e., those who matter – about the reliability of the RT-PCR tests, given the lack of information concerning the tests' analytical parameters, and in the absence of a physician's diagnosis supporting the existence of infection or risk, there is no way this court would ever be able to determine whether C was indeed a carrier of the SARS-CoV-2 virus, or whether A, B and D had been at a high risk of exposure to it,"

"Most importantly, the judges ruled that a single positive RT-PCR test cannot be used as an effective diagnosis of infection."

"In their ruling, judges Margarida Ramos de Almeida and Ana Paramés referred to several scientific studies. **Most notably [a study by Jaafar et al]**, which found that – when running RT-PCR tests with 35 cycles or more – the accuracy dropped to 3%, meaning up to 97% of positive results could be false positives."

"The ruling goes on to conclude that, based on the science they read, any RT-PCR test using over 25 cycles is totally unreliable. The Court was declaring the RT-PCR test alone could not be sufficient for a diagnosis of disease, and it was outrageous to believe it could.

A "case of COVID disease" without a medical assessment of clinical symptoms in the patient is no case at all. It is a misnomer, and, the Court stated, represents a serious breach of the law.

Not surprisingly, this decision received a **total blackout in the mainstream media.** [73]

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On December 31, anti-coronavirus activists won a court case against the Dutch state to ensure a family can return from holiday in Tanzania without having to produce negative coronavirus tests.

The court in The Hague ruled that the family can return from the highrisk country on January 3 without a negative test and ordered the state to pay the legal costs.

The judge said the family have the right to protest about being forced to undergo a RT-PCR test against their will. 'Introducing such a requirement for citizens of the Netherlands who want to return home requires legal grounding, and this is not covered by article 53 or 54 of the public health act,' the judge is quoted as saying.

The fact that further spreading of the virus needs to be tackled urgently is not up for discussion, the judge said. 'But such a far-reaching obligation as this, which concerns physical integrity, requires a concrete legal basis.' [74]

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Following the Portuguese and Dutch rulings, now the Austrian court has ruled that RT-PCR tests are not suitable for COVID-19 diagnosis and that lockdowns have no legal or scientific basis. The Vienna Administrative Court granted a complaint by the FPÖ against the prohibition of its meeting registered for January 31 in Vienna.

"The prohibition was wrong," the court said said in the ruling.

The court stated on the basis of scientific studies that the grounds for the prohibition put forward by the Vienna State Police Department are completely unfounded. It is expressly pointed out that, even according to the World Health Organization, "a RT-PCR test is not suitable for diagnosis and therefore does not in itself say anything about the disease or infection of a person".

A German court in a landmark ruling has declared that COVID-19 lockdowns imposed by the government are unconstitutional. Earlier, an American federal judge ruled coronavirus restrictions in Pennsylvania as unconstitutional. [75]

#### **India's Current Testing Guidelines**

Finally, let us now take a look at what guidelines are being implemented in our country, & what they should be replaced with instead. Currently, a positive case can be listed purely on the basis of a RT-PCR Positive test or a Rapid Antigen Positive Test, without the person having any symptoms.

In Mumbai, a daily target of compulsory 47,800 Rapid Antigen Tests RAT has been set. The BMC is mandatorily conducting random RAT's at crowded places like malls, railway stations (for inbound trains), Maharashtra state road transport corporation bus depots, 'khau gullies', hawkers, market places, tourist places, and various government offices. These tests are happening regardless of the persons having symptoms or not, & if an asymptomatic individual is found to be positive, he will be treated as a case. People who refuse the test would be prosecuted under the British Era Epidemic Diseases Act. [76]

The testing being done in different states in our country is happening at different rates, which is a factor that people should consider when comparing the situation between different places. This got a rare mention in a Business Standard article from 9th April 2021 titled "Election fever? States holding elections slow down Covid-19 testing" [77], which goes into how states which were holding elections kept their testing rates low during those periods. This shows how these tests could be used as a tool to manipulate people as per political agendas.

Across India, the ICMR recommends routine screening of containment zones & screening at entry points. RAT or RT-PCR to be performed on all symptomatic individuals, all asymptomatic high & direct risk contacts of a lab confirmed case & all asymptomatic high-risk individuals. On 9<sup>th</sup> April, Prime Minister Modi asked for 100% testing in containment zones and the tracing of at least 30 contacts within 72 hours. He also said: "If testing leads to more positive numbers, let it be. Our

#### target has to be 70% RT-PCR tests" [78]

ICMR also has guidelines for testing in non-containment zones, where RAT or RT-PCR should be performed on All symptomatic individuals with history of international travel in the last 14 days, all symptomatic contacts of a laboratory confirmed case, all symptomatic (ILI symptoms) health care workers / frontline workers involved in containment and mitigation activities, All symptomatic ILI cases among returnees and migrants within 7 days of illness. All asymptomatic high-risk contacts.

In hospital settings, ICMR has the following recommendations, where RAT or RT-PCR is supposed to be performed on All patients of Severe Acute Respiratory Infection (SARI), All symptomatic patients presenting in a healthcare setting. Asymptomatic high-risk patients who are hospitalized or seeking immediate hospitalization such as immunocompromised individuals, patients diagnosed with malignant disease, transplant patients, patients with chronic co-morbidities, elderly ≥ 65 years, Asymptomatic patients undergoing surgical / non-surgical invasive procedures, All pregnant women in/near Labor who are hospitalized for delivery, All symptomatic neonates presenting with acute respiratory / sepsis like illness, & Patients presenting with atypical manifestations.

Different states in India have different rules for who requires what test. But most states require asymptomatic people to carry negative RT-PCR results with them in order to enter their state. [79]

For all these scenarios, a positive RT-PCR / RAT / CBNAAT / True NAT is counted as a positive case, whereas if a person has symptoms & tests negative on the RAT, then he needs to retest with the RT-PCR. This again shows the inherent bias towards positive cases. If an asymptomatic person gets a negative RAT test, then he is supposed to get retested with the RT-PCR or RAT if symptoms start.

# Why the ICMR needs to change its position on the RT-PCR & RAT

The most important point to note here, is that some days ago, Pradeep Vyas, Health Secretary of Maharashtra, had written to Dr Balram Bhargava, Director General at the ICMR, allegedly seeking to reduce the

CT cut-off for a positive case in the view of rising cases in Maharashtra. He later denied that: ""We never requested GoI to reduce CT value, [we] requested [it] to clarify as it appeared [that] different labs and different states were adopting different practices. The state only wanted to know in view of different standards in different documents of ICMR," [80]

Whatever the real reason was, because of that correspondence we now know that the ICMR recommended Cycle cut-off across India is 35, which according to a major paper referenced in our document here had a 97% false positive rate compared to gold standard viral culture!

The position of the ICMR has always been that the CT value cannot be used as a reliable metric, but we have successfully shown here that despite the limitations of the CT due to different variables, it still correlates strongly with viral culture, & the value of the CT can be made even more robust if ICMR implements the MIQE guidelines. The ICMR has also claimed that the RT-PCR is a qualitative & not a quantitative test. If that is their position despite overwhelming scientific evidence from more than 30 papers to the contrary, then they should discard the RT-PCR & only use the gold standard, I.e., viral culture. As highlighted in our document here, healthy humans carry many viruses that are associated with disease on them, & asymptomatic transmission isn't proven, hence simply finding Sars-Cov-2 in a qualitative & not a quantitative way doesn't tell us anything about the persons infection status.

In the "CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel" from March 30, 2020, [81] it says:

Detection of viral RNA may not indicate the presence of infectious virus or that 2019-nCoV is the causative agent for clinical symptoms. This test cannot rule out diseases caused by other bacterial or viral pathogens.

According to the FDA:

positive results do not rule out co-infection with other viruses. The agent detected may not be the definitive cause of disease.

A very practical way to prove our point would be to test someone

with a RT-PCR for Sars-Cov-2, along with a RT-PCR for Hepatitis, HIV, Adenoviruses, Coronaviruses, HTLVs, Pertussis bacterium, Papillomaviruses, & many other viruses/bacteria that are associated with disease. We can guarantee that whether the person is healthy or sick, they will come back testing positive for multiple agents, as this is exactly what has been seen in the studies we highlighted here on healthy people.

### **Medical Diagnosis of Covid-19 Cases**

The whole concept of asymptomatic transmission is unfounded, and this is the first time in history that we are going & proactively testing most of the human population, including all the healthy asymptomatic people. Tests should never take precedence over signs & symptoms, but that is precisely what has happened since last year.

Diagnosing someone's problem correctly & linking it to one specific infectious agent is a very difficult task as diseases take place due to a multitude of factors, & many diseases have overlapping symptoms along with possibility of multiple infections going on at the same time. Diagnosing someone requires the person doing it to triangulate between symptoms, tests & contact with other confirmed cases. At present, doctors are using CT scans, Ferritin, ESR, Fibrinogen, HS-CRP levels, D-Dimer levels, etc in their diagnostic arsenal at the hospital, but none of these are specific for Covid-19.

According to a study published in RadioGraphics in October of 2020 titled "Chest CT in COVID-19: What the Radiologist Needs to Know" by TC Kwee et al., [82] the authors write: "The interpretation of chest CT examinations may become particularly challenging during influenza season. Some studies suggest that a peripheral distribution of ground-glass opacities is a more typical finding of COVID-19 pneumonia, whereas other studies did not find these features helpful in discriminating COVID-19 pneumonia from influenza pneumonia. At present, there are not much data on other alternative diagnoses (eg, PE, acute interstitial pneumonitis, drug-induced lung disease, alveolar hemorrhage) that may produce false-positive findings and further limit the specificity of chest CT. Lung abnormalities on chest CT images are nonspecific for COVID-19. Owing to these limitations, chest CT should not be used as an independent diagnostic tool to exclude or

### confirm COVID-19.

And yet the Vadodara Municipal Corporation issued orders stating that in cases where RT-PCR is negative but findings in HRCT & lab investigations are suggestive of viral aetiology, the claim should be treated as that of Covid unless proven otherwise". This sentiment is being echoed by many doctors in Gujarat as well, but goes against the peer-reviewed scientific evidence. [83]

A study titled: "Never ignore extremely elevated D-dimer levels: they are specific for serious illness" published by T Schutte et al., in 2016, [84] the authors concluded: "Although D-dimer testing has a reputation for being very non-specific, an extremely elevated D-dimer is uniquely associated with severe disease, mainly including VTE, sepsis and/or cancer."

Similarly, there are a wide variety of reasons for why someone can have elevated HS-CRP levels, ranging from autoimmune conditions, like rheumatoid arthritis (RA), lupus, and certain types of inflammatory bowel disease, such as Crohn's disease and ulcerative colitis, pericarditis, which is inflammation of the lining of the heart, infection, organ and tissue injury, cancer & obesity. [85]

The Cytokine Storm, which is thought to be unique to Covid-19 in today's times, can also occur of a wide variety of causes. In an article from verywellhealth.com titled "What is Cytokine Storm Syndrome", the following are listed as causes of the cytokine storm: genetic syndromes, infections from influenza A virus, Epstein-barr virus, Sars-Cov-2 & cytomegalovirus, autoimmune diseases such as arthritis & lupus, medical treatments like CarT Therapy, organ & stem cell transplant, & immunotherapy, cancer, AIDS and Sepsis. [86]

ARDS (Acute Respiratory Distress Syndrome), also thought to be unique to a Sars-Cov-2 infection, has many causes, such as inhaling toxic substances, sepsis, severe pneumonia, head, chest or major injury, pancreatitis, massive blood transfusions, & burns. [87]

Fibrinogen, that's primarily used to detect the risk of blood clots, also moves because of different reasons. In an article titled: "10

Hidden Causes of High Fibrinogen + Risks & How to Lower It" on selfdecode.com's website, the causes are listed as infection, injury or inflammation, stress, pregnancy, smoking, birth control pills, genetic mutations, age, cold temperature, diet, & obesity. [88]

Ferritin can be elevated due to hemosiderosis, hemochromatosis, inflammatory diseases, liver damage & haemolytic or sideroblastic anaemia. [89]

ESR (Erythrocyte Sedimentation Rate) can be elevated in autoimmune conditions, infections, inflammatory diseases, cell or tissue destruction, & anemia. [90]

Neutrophils are elevated due to bacterial infections or inflammation. Lymphocytes are elevated due to viral infections, crohns disease, other autoimmune diseases, & hypoadrenalism. The neutrophil to lymphocyte ratio could give one an idea about whether one has a bacterial or viral infection, but can't specify which one. [91]

## **Strongly Objectionable**

ICMRs guidelines for diagnosing Covid deaths have mentioned that if the test is +ve & Covid symptoms are not present, then UCOD (Underlying cause of death) must be recorded as Covid & this is what goes in the statistical records. Similarly, if the test is +ve & symptoms are present, & if the test is +ve with symptoms plus underlying comorbidities, then the UCOD is Confirmed Covid. If the test is negative but symptoms are present, UCOD = Clinically -Epidemiologically diagnosed COVID -19, if test is awaited but symptoms are present, then UCOD = Suspected COVID-19, & if Test is inconclusive but symptoms are present, then UCOD = Probable Covid-19. [92] These guidelines make it very easy to label people who have died of other causes with Covid, that too based on unreliable RT-PCR tests. This has given rise to India's death burden as well along with the case burden. Merely basing a case as well as death on a Positive test or symptoms that overlap with numerous other diseases, has led to the creation of a fake pandemic, just like the RT-PCR caused it in 2006 with whooping cough.

### **Awaken India Demands**

Although we would ideally want only the viral culture gold standard of testing to be used for diagnosing a symptomatic case, since a lot of resources have already been spent on ramping up the RT-PCR & RAT, we realise that it might not be feasible for the State to do currently. But thinking about the long run, with scientists talking about new bacteria/viruses having pandemic potential & new variants of Sars-Cov-2, the state should start gradually shifting resources away from the RT-PCR & RAT, & towards Gold Standard of viral culture. Until then, these are our immediate demands:

- There should be no testing of asymptomatic people by the state, to travel, get employment, people in containment zones, or any other way. Testing should purely be voluntary, based on the person's consent for all situations. Asymptomatic people are not a threat to anyone, as we have demonstrated in this document.
- Since the most common symptoms are fever, dry cough & tiredness, a person should have at least two of these to be diagnosed as having covid symptoms, & at least one of the less common symptoms, which include aches & pains, sore throat, diarrhoea, conjunctivitis, headache, loss of taste or smell, a rash on the skin, or discoloration of fingers or toes. If a runny nose/cold is present, then infection from influenza / adenoviruses / other coronaviruses must be considered as well. This is because many of these symptoms overlap with 100s of other diseases, hence this criterion is necessary to not mislabel someone as Covid when he is actually suffering from something else (as had happened in the whooping cough case we highlighted).
- After having these symptoms, this is how the State must proceed. It must give the option to the person to choose between the RT-PCR, the RAT, or virus culture test.
- -If a person chooses virus culture, then a negative is negative & a positive is a positive case.
- -If a person chooses RAT, then a negative test result must be counted as a negative, since we have shown that there is little to no risk of false negatives. If the person comes as positive, then he

needs to go for a retest with the RT-PCR.

- When a person gets his RT-PCR Result after he gets his RAT positive, this is how the results must be interpreted:
- a) If RT-PCR CT comes back positive under 24, then he can be counted as a confirmed case.
- B) If RT-PCR CT comes between 24.1-30, then his sample needs to be sent for the viral culture test. Depending on the result of the virus culture, he would be deemed as a case if positive & not a case if negative.
- C) The RT-PCR cut-off should be at 30 as according to the metanalysis we referenced, CT>30 was associated with non-infectious samples. Hence CT>30 = negative, & then this person is not a case.
- When a person chooses RT-PCR for the first time, this is how the results must be interpreted:
- A) RT-PCR CT<20 = confirmed positive case
- B) RT-PCR CT 20.1-24, send for retest. If retest comes under 24, then confirmed positive case. If retest comes between 24.1-30, send for viral culture, who's results will decide whether the person is a case or not. If retest comes above 30, then the person is confirmed negative.
- C) RT-PCR CT between 24.1-30, send for virus culture, who's results will decide whether case or not.
- D) RT-PCR CT>30, confirmed negative case

Since this is happening for a public health situation, the costs for these tests' musts be subsidized or borne by the state, at least until virus culture labs and facilities are scaled up to meet the necessary demand. We urge the Government & ICMR to conduct their own peer-reviewed study & publish it in a reputed journal, testing & comparing a large number of samples from symptomatic people using viral culture, RT-PCR, RAT, TrueNAT & CBNAAT. Then based on reliable evidence from that study, ICMR can formulate new guidelines for testing.

- The FDA guidelines included above must be implemented so that the risk of false positives with the RAT is minimised.
- The MIQE guidelines mentioned above must be implemented so

### that the CT becomes even more accurate than it already is.

- The absence of the HE gene in both SARS-CoV1 and SARS-CoV-2 makes this gene the ideal negative control to exclude other coronaviruses. The RT-PCR test currently being used may not contain a unique positive control or a negative control to exclude the presence of other coronaviruses. This control should be used if it isn't already, or else there is a possibility of the RT-PCR testing positive with other coronaviruses already present in our bodies since years.
- No asymptomatic contacts of a confirmed case (as defined above) should be tested. Only when a person develops the unique symptoms, then he can be tested by the authorities in the ways mentioned above.

When a Positive Case is determined via these steps, only then can the State place quarantine restrictions on him.

These guidelines might look biased against false negatives, but as we have shown here through multiple studies, there was no risk of false negatives when comparing the RT-PCR or RAT against the gold standard of viral culture, & only a risk of false positives.

## **Harm Caused Due to Unscientific Testing Guidelines**

Because of improper use of the RT-PCR & Antigen Tests, & testing being done on asymptomatic people, we are seeing an explosion of cases as well as deaths, because a case is defined as a positive RT-PCR regardless of symptoms, & death certificates also can list someone as a Covid death just based on a RT-PCR positive and/or broad symptoms. Quick diagnostic tests should never be considered as confirmed markers of evidence, based on which strategic decisions such as isolation, lockdowns & vaccines need to be implemented. They are only temporary tests that need confirmation with the gold standard of viral culture.

Due to this, many healthy people who are not infectious or a threat to anyone have had their fundamental rights taken away from them, have had to pay a lot of money to finance their institutional quarantines, have had to miss out on income because they were wrongly quarantined, have had to be quarantined with people in a

room who are true positives (big risk for the elderly & immune compromised), have had to face societal stigma, & have taken wrong medications because of an incorrect diagnosis, which comes with many side effects. Elderly, Immunocompromised people & those with Co-morbidities, if falsely diagnosed, can die due to medicines given to them like Remdesivir, Favipiravir, etc that have now shown to not be effective & at the same time come with toxic side effects. [92] People who suffer from Covid related symptoms but actually have influenza or the common cold, are put on wrong medications that damage their body unnecessarily. More hospital & ICU beds get occupied as well, as people wrongly think they have Covid.

False positives are not an acceptable price to pay in order to minimise false negatives. Throwing in false positive cases in isolation wards & exposing them to actual infectious disease carriers is no less than throwing innocent people in jail to live among murderers & rapists. Our whole judicial system works on the principle of innocent until proven guilty, hence we must apply the same to healthy asymptomatic people and see them as such, until proven otherwise through the evidence-based methods described above.

A "case" is defined in medicine as an active, symptomatic and diagnosed infection. Not any more: Any "positive" in the faulty RT-PCR "test" or RAT is now counted as a "case". The mass RT-PCR testing & RAT campaign of the general asymptomatic population, which has no clinical or epidemiological utility, thereby feeds media propaganda of fear, and disastrous consequences: RT-PCR/RAT  $\rightarrow$  meaningless-"cases"  $\rightarrow$  propaganda  $\rightarrow$  arbitrary-measures/great-harm.

## Why Lockdowns Are Deadly & Dangerous

Lockdowns & pandemic restrictions have been pushed worldwide, despite there being ample evidence of their ineffectiveness & deadliness. In their 21 July 2020 article "A country level analysis measuring the impact of government actions, country preparedness and socioeconomic factors on COVID-19 mortality and related health outcomes" (50 countries), Chaudhry et al. Found [93]:

Rapid border closures, full lockdowns, and wide-spread testing were not associated with COVID-19 mortality per million people.

In their 19 November 2020 article "COVID-19 Mortality: A Matter of Vulnerability Among Nations Facing Limited Margins of Adaptation" (160 countries), De Larochelambert et al. [94] found:

Results: Stringency of the measures settled to fight the pandemic, including lockdown, did not appear to be linked with death rate.

The American Institute for Economic Research (AIER Staff) reviewed these studies and 22 further studies that make similar conclusions, in their 19 December 2020 report entitled "Lockdowns Do Not Control the Coronavirus: The Evidence" [95]

Therefore, overall, the numbers of total critical cases and total deaths were associated with the pre-existing health and societal status of the population, and this was not ameliorated by the government measures intended to slow transmission.

The lie that lockdowns worked spread as a social contagion, persisting among petrified citizens and ideological opinion-makers who continued to use overblown models as their alternative "what if" scenarios. Many concluded, quite erroneously, that lockdowns had saved millions of lives. Sweden stands as an emphatic refutation of this claim. According to the Imperial College of London model (which has repeatedly been proven to be fantastically incorrect), Sweden would have been looking at a death toll of 80,000 by the end of June 2020 if it didn't lock down. Alas, the true number, by mid-September 2020, after no lockdowns at all, still only stood at 5,880, a vast majority of whom were elderly with comorbidities. In fact, of those, only 872 were a direct result of COVID-19. The rest had one or more conditions that contributed to their death. Covid-19, it turned out, was not only far less deadly than modellers had predicted, but they couldn't credit this to the lockdowns they'd promoted. Sweden clearly showed that failure to lock down did not constitute genocide. [96]

In his op-ed in The Telegraph [97], **Matthew Ridley** points out that viruses will always evolve to be more contagious if they can, but respiratory viruses also often evolve towards being less virulent. Each virus is striving to grab market share for its descendants. The best way of achieving this is to print as many copies of itself as possible while in a

human body, yet not make that person so ill that they meet fewer people. Where the [lockdown] sceptics have a point is that it is a worrying possibility that lockdowns could prevent this natural attenuation of the virus. They keep the virus spreading mainly in hospitals and care homes among the very ill, preventing the eclipse of lethal strains at the hands of milder ones. If so ... then not only do lockdowns fail to wipe out the disease, they may be prolonging our agony."

More Evidence Against the Lockdowns Can be Found Here [98]

### Why Masks Are Ineffective & Harmful

A recent document published by the WHO – in December 2020 – states that there is very inconsistent evidence proving the effectiveness of mask-wearing in the community for the prevention of respiratory virus infections, including COVID-19 [99].

When we compare the epidemic curves in places with and without mask mandates, the curves look similar. In fact, we observe a higher number of infections per 100,000 of the population in places with mask mandates. It is very unlikely that an asymptomatic person is infectious. Therefore, it is unjustified to require everyone to wear a mask in the community, even if masks have shown some benefit when worn by individuals with symptoms. This argument becomes even stronger when we take the potential adverse effects of masks into consideration. These include symptoms such as headaches, dizziness, shortness of breath and other problems including psychological impact, acne, respiratory infections and dental problems. [100]

On 18 November 2020, Bundgaard et al. published their large randomized controlled trial (RCT) of participants selected from the general Danish population, titled: "Effectiveness of Adding a Mask Recommendation to Other Public Health Measures to Prevent SARS-CoV-2 Infection in Danish Mask Wearers: A Randomized Controlled Trial" [101]

A total of 3030 participants were randomly assigned to the recommendation to wear masks, and 2994 were assigned to control; 4862 completed the study. **Infection with SARS-CoV-2 occurred in 42** 

participants recommended masks (1.8%) and 53 control participants (2.1%). The between-group difference was −0.3 percentage point. The difference observed was not statistically significant.

On 6 July 2020, for example, Fikenzer et al. published a rigorous study on the physiological effect of masks on 12 healthy males (age 38 ± 6 years), titled "Effects of surgical and FFP2/N95 face masks on cardiopulmonary exercise capacity". [102] They concluded:

Medical face masks have a marked negative impact on cardiopulmonary capacity that significantly impairs strenuous physical and occupational activities. In addition, medical masks significantly impair the quality of life of their wearer.

In November 2020, Borovoy et al. published an extensive review of biological and medical knowledge titled "Masks, false safety and real dangers, Part 2: Microbial challenges from masks" [103] that allows them to infer a large potential for significant harms from masking. They rightly stress the known yet underplayed role of bacteria in viral pandemics, and also review respiratory diseases arising from oral bacteria.

Professor Dennis Rancourt wrote a paper summarising everything we know until now about the dangers & ineffectiveness of masks, which can be found here [104]

## Was Covid-19 Even Deadly & Infectious to begin with?

The latest Infection Fatality Rate (the number of deaths divided by the number of actual infections) was calculated by John loannidis for Covid 19 in his peer-reviewed study titled: "Infection fatality rate of COVID-19 inferred from seroprevalence data" [105]. Here he calculated the IFR for COVID-19 in a review of 61 seroprevalence studies, which was a median of 0.23%, and 0.05% in people younger than 70. There's a 1,000 times difference in mortality among those younger than 19 and those older than 70 — something that should have been taken into account in the pandemic response. The CEBM (Centre for Evidence Based Medicine) at the University of Oxford, currently estimates the CFR (which is the number of deaths divided

by the number of cases which tested positive) globally at 0.51%, and the IFR to be at 0.1%-0.26%. [106] The CFR for Influenza is about 3%, & the IFR for Influenza is 0.1%. [107]

The IFR is always lower than the CFR, since the denominator gets larger. The CFR only looks at those who have been tested via RT-PCR or RAT, whereas the IFR considers all actual infections by the data generated from serosurveys which tell us about how many people have had the infection and developed antibodies.

The Case Fatality Rate in India (which is the number of deaths divided by the number of cases which tested positive) has fallen from over 3% in the beginning of the pandemic to less than 1.5 percent now. India's Infection Fatality Rate is 0.1%. [108]

An analysis of how deadly Sars-Cov-2 is, was penned by Eric Markhoff, an infectious disease epidemiologist. In order to indirectly assess the lethality of SARS-CoV2, he compared the age distribution of deceased individuals who had been tested positive for SARS-CoV2 during the first wave in 2020 with the age distribution of deaths from the death registers of a previous year (2018 or 2019) for Italy, Germany, France, Spain and England separately for men and women. His data comparison for Italy, Germany, France, Spain and England showed that those who died with SARS-Cov-2 tended to be older than all those who died in a reference year (2018 or 2019). In none of these 5 countries does our comparison support the perception of SARS-CoV-2 being a highly lethal "killer virus". [109]

"Experts" made the assumption in the beginning of the pandemic the general population would be immunologically "naive" to this virus and thus 100% susceptible to develop the disease. This was again not consistent with previous knowledge about human immunity to viral agents. Cross-immunity is a well-known fact. One study even found that 81% of people not exposed to SARS-CoV-2, the virus that causes COVID-19, were still able to mount an immune response against it, which "suggests at least some built-in immune protection from SARS-CoV-2. [110]

It is not reasonable to assume that the entire population is immunologically susceptible to SARS-CoV-2, when in fact it is very likely that many individuals have at least partial immunity to the virus due to prior infection with similar viruses or agents with similar antigenic properties. There are several studies showing that individuals have immunity to SARS-CoV-2 by T-Cell mediated mechanisms. [111]

Despite us having Vaccines & Treatments for TB, it still kills way more people than Sars-Cov-2 does, & they both spread in the same way as well.

### **Should We Be Scared of the New Variants?**

It all started a few days before Christmas, when U.K. Prime Minister Boris Johnson announced there's a new, mutated, and far more infectious, strain of SARS-CoV-2 on the loose. The mutated strain, referred to in some places as B1175, reportedly began popping up in patient samples collected in September 2020 across southern England. According to absolutely untrustworthy and disgraced epidemiologist Neil Ferguson (more about his track record below), whose models have been grossly incorrect thus far, B117 could be 50% to 70% more contagious than previous variants circulating in the U.K. A mutated variant of SARS-CoV-2 that has one of the mutations found in B117 was also identified in South Africa. The virus has reportedly picked up one or two mutations per month since the start of the pandemic.

As London and southeast England faced strict, new lockdowns in the days before Christmas, British scientists were demanding to be shown evidence that B117 is in fact 50% to 70% more contagious. Indeed, if the new, wildly different strain was discovered September 20, why all of a sudden was it an emergency a full three months later — especially considering the fact that the research done until then showed us that there was no evidence of the variant being more infectious or deadly?

A paper published in Nature Communications by Lucy et al., titled "No evidence for increased transmissibility from recurrent mutations in SARS-CoV-2" in late November 2020 [112] concluded: "We do not identify a single recurrent mutation in this set convincingly associated with increased viral transmission. Instead, recurrent mutations currently in circulation appear to be evolutionary neutral and primarily induced by the human immune system via RNA editing, rather than being signatures of adaptation. At this stage we

## find no evidence for significantly more transmissible lineages of SARS-CoV-2 due to recurrent mutations."

The authors John Edmunds & Neil Fergusson, who wrote the modelling papers which were used to convince the public of the possibility that VOC (Variant of Concern) B.1.1.7 is associated with an increased risk of death compared to non-VOC viruses, have major conflicts of interest. Edmund's wife Jean Pimenta is, or at least was an employee on GSK. [113] On February 3, GSK announced its collaborating with mRNA-vaccine company CureVac to make vaccines for the new variants. [114] Edmunds is also connected with various groups & organizations that are pushing Covid-19 vaccines, including LSHTM & the UK Vaccine Network. [115] The Author Contributions and Acknowledgements section of the December 23 modelling analysis of B.1.1.7 shows that almost all of the paper's authors and members of the modelling centre's COVID-19 Working Group receive funding from the Bill & Melinda Gates Foundation (BMGF) and/or Wellcome Trust. [116]

Ferguson's modelling has been extremely faulty over the years. This has been thoroughly documented. For example, Ferguson's modelling over-estimated by about 3 million-fold the death toll from the bird flu, also known as H5N1. As a result, a lot of money was made by bird-flu-vaccine manufacturers, ranging from Roche, to Sanofi. Ferguson also grossly overestimated the effects of swine flu, or H1N1. As a result, millions of people were needlessly given GSK's Pandemrix vaccines. This vaccine then went on to cause health issues like Narcolepsy, for which the British Government paid 60million pounds to the victims. [117]

We can clearly see here that <u>the same people that are connected to</u> <u>the vaccine industry & are financially benefitting from it, are also involved in getting the public to fear the new variants.</u>

The fearmongering over this variant has started catching on in other parts of the world in April, like India and the USA. **Dr. Mike Yeadon, ex Vice President at Pfizer**, said the following about the variants [118]: "And they are talking the same sort of future script which is, 'We don't want you to move around because of these pesky 'variants' — (but) 'don't worry, there will be 'top-up' vaccines that will cope with the potential escapees.' They're all saying this when it is obviously

nonsense." There's no denying that the variant is being used to fuel the COVID hysteria and perpetuate the repressive social restrictions.

According to Sunetra Gupta, who is professor of theoretical epidemiology in the Department of Zoology at the University of Oxford, and a Royal Society Wolfson Research Fellow [119]: "... some of these variants could be more transmissible, but the truth is ... even with a marginal increase in transmissibility ... that does not have much of a material effect or difference in how we deal with the virus. In other words, the surge of the virus cannot be ascribed to a new variant. The other question is are these variants more virulent, and the truth is we don't know, but it is unlikely because the data don't seem to say so despite the scary headlines...Pathogens tend to evolve toward lower virulence... because that maximizes their transmissibility ... It is much more probable that these strains will not be materially so different that we would have to alter our policies."

So, according to Gupta, even if the new strains of COVID are more transmissible, it is highly unlikely that they are more lethal. Here's more on the topic from **diagnostic pathologist Dr. Clare Craig**, who provides a more technical explanation [120]:

"SARS-CoV-2 genetic sequence has ~30,000 letters. Alterations in a handful of letters will not change its shape much — if it did it wouldn't function properly anyway. Fear mongering about immune escape is not needed and is irresponsible especially when there is no evidence to support the claims."

In essence, Craig is saying the same thing we said earlier, that the slight mutations to the infection will not impact the immune reaction of people who already had the virus. Thus, the current crop of "variants" should not be a cause for alarm. If you have already had COVID or if you already have prior immunity due to previous exposure to similar infections, (SARS, for example) the new strain should not be a problem. It should also not be a problem if the new vaccines provide the type of broad-based immunity that one should expect of them. Again, the mutations represent only the slightest change in the composition of the pathogen (less than 1%), which means that — if the vaccines don't work — they are, in effect, useless.

For a more detailed medical understanding of why we shouldn't be

afraid of variants, please refer to this article written by Dr. Mike Yeadon [121]

### **Are the Covid-19 Vaccines Safe & Effective?**

Many media outlets, governments & health organizations have repeatedly told us over the last year, that the vaccines are safe & effective. But is this statement fact or fiction? The Indian Government was asked in an RTI as to whether there would be any monetary compensation for those who would take the vaccine & suffer adverse events. They responded, stating that no such compensation would be given, since the vaccines are voluntary. [122] Yet in practice this statement isn't true. In Mumbai, the BMC is asking shop owners & traders to get vaccinated in order to open their stores again. In Gujarat, a university is asking students to get vaccinated in order to appear for their exams. [123] Talk of Vaccine Passports has already started in the Indian Press. [124]

AstraZeneca, the company whose Covid-19 vaccine is being manufactured by Pune-based Serum Institute of India, has lost so many lawsuits, it's hard to count. [125] The company had their covid vaccine suspended in at least 18 countries over concerns of blood clots, and they completely botched their meeting with the US FDA with numbers from their study that didn't match. [126] There are ethical issues surrounding the Astrazeneca (Serum Institute) vaccine, as aborted fetal cell lines have been used in its development. Bharat Biotechs Covaxin threatens the religious beliefs of Hindus, as baby calf blood has been used in its development. [127] Covaxin also contains aluminium, a known neurotoxin which is shown to make people more susceptible to asthma, allergies & autoimmune diseases by skewing their immune response towards Th2.

There have been many attempts to make viral vaccines in the past that ended in utter failure, which is why we did not have a coronavirus vaccine in 2020. In the 1960's, scientists attempted to make an RSV (Respiratory Syncytial Virus) vaccine for infants. In that study, they skipped animal trials because they weren't necessary back then. In the end, the vaccinated infants got much sicker than the unvaccinated infants when exposed to the virus in nature, with 80% of the vaccinated infants requiring hospitalization, and two of them died.

After 2000, scientists made many attempts to create coronavirus vaccines. For the past 20 years, all ended in failure because the animals in the clinical trials got very sick and many died, just like the children in the 1960's. In 2004 attempted vaccine produced hepatitis in ferrets. In 2005 mice and civets became sick and more susceptible to coronaviruses after being vaccinated. In 2012 the ferrets became sick and died. And in one study mice and ferrets developed lung disease. In 2016 a study also showed lung disease in mice after vaccination. [128]

The typical pattern in the studies mentioned above is that the children and the animals produced beautiful antibody responses after being vaccinated. The manufacturers thought they hit the jackpot. The problem came when the children and animals were exposed to the wild version of the virus. When that happened, an unexplained phenomenon called **Antibody Dependent Enhancement (ADE)** also known as Vaccine Enhanced Disease (VED) occurred where the immune system produced a "cytokine storm" (i.e. overwhelmingly attacked the body), and the children/animals died. [129]

Here's the lingering issue. The Covid-19 vaccine makers have no data to suggest their rushed vaccines have overcome that problem. The October 28, 2020, paper, "Informed Consent Disclosure to Vaccine Trial Subjects of Risk of COVID-19 Vaccine Worsening Clinical Disease," [130] stressed that "COVID-19 vaccines designed to elicit neutralizing antibodies may sensitize vaccine recipients to more severe disease than if they were not vaccinated," and criticized vaccine makers for not clearly informing participants in current vaccine trials of this risk.

There is no data to suggest safety or efficacy in the trials conducted regarding:

Anyone younger than age 18 or older than age 55, Pregnant or lactating mothers, Auto-immune conditions, Immunocompromised individuals, No data on transmission of covid, No data on preventing mortality from covid, No data on duration of protection from covid. The Astrazeneca vaccine has used the meningitis vaccine in the control group of its trial instead of a true saline placebo, hence the side effects would get covered up as both groups are getting a vaccine.

The trial data with which Pfizer and Moderna obtained emergency use authorization (not approval), & that of Astrazeneca, does not show that the vaccines are effective for reducing the risk of severe disease, hospitalization, or death from COVID-19; nor does it show that vaccination prevents transmission. In Bhopal, Covaxin trials were conducted in a very unethical way, where participants were told that they were receiving for Covid. After one person died in the trial, no proper follow-up was done by the trial conductors.

A detailed analysis of the trial data can be read here. [131] We have no long-term safety data. In other words, we have no idea what this product will do in the body months or years from now-for ANY population. People are getting Covid despite being fully vaccinated. Equating protection from Sars-Cov-2 with only antibody levels totally ignores the importance & role of cell mediated immunity. [132] Dr Soumya Swaminathan (Ex-ICMR Chief & currently Chief Scientist at the WHO) have admitted that the vaccines haven't been studied to see whether they will stop transmission of the virus or not. [133]

The whole idea of using antibodies as the only metric of evaluating immunity is deeply flawed. As discussed earlier, there are cell mediated immune responses and B cell immunity which is equally important if not more, than antibodies. When exposed to a pathogen naturally, we develop a wide array of immune responses against the pathogen, & the B cells as well as T cells have long term memory, so that when the pathogen reappears next time, the B cells will make antibodies. Antibodies shouldn't be present in healthy people all the time, & in fact higher antibody levels in Sars-Cov-2 are associated with more severe symptoms. Yet all vaccines being developed are only focusing on stimulating antibodies, & the sero-survey data is also based on measuring antibodies in people, which understates how much herd immunity has been developed in the population.

The mRna & DNA vaccines that have been developed by Pfizer, Astrazeneca, Moderna & others, have a real risk of modifying someones DNA. Check this reference to read more about what adverse events the Covid-19 vaccines are causing in India & all over the world, & to learn more about the dangers & ineffectiveness of Covid-19 vaccines [134]

### **Vaccines Impact on the Variants**

According to World-renowned Vaccine Developer Geert Vanden Bossche, the virus is mutating about every 10 hours. How in the world are we going to keep creating vaccines to keep up with that level of mutation? We're not. In an interview he did recently, he explains the following: "Why the covid vaccine may be putting so much pressure on the virus that we are accelerating its ability to mutate and become more deadly, Why the covid vaccines may be creating vaccine-resistant viruses (similar to anti-biotic resistant bacteria), & why because of previous problems with Antibody Dependent Enhancement, we may be looking at a mass casualty event in the next few months/years." [135]

Researchers' serial passaged live SARS-CoV-2 in plasma obtained from a recovered COVID-19 patient that had a high amount of neutralizing antibodies in it. The neutralizing antibodies in the plasma successfully and completely neutralized the virus during the first seven passages, but then, the virus mutated to evade the antibodies. Further down in the paper, they point out that the reason they did this study was to determine "whether the authentic virus, under the selective pressure of the polyclonal immune response in convalescent or vaccinated people, can evolve to escape herd immunity and antibody treatment." [136] Since the virus can mutate to evade neutralizing antibodies, then it could potentially mutate under the "selective pressure" of vaccination as well, which in turn raises the question: If we mass vaccinate, will we end up with a more lethal virus?

A study by researchers at Tel Aviv University and Clalit Health Services in Israel found the South African variant of SARS-CoV-2, dubbed B.1. 351 — which presently accounts for about 1% of COVID-19 cases in Israel — affects people vaccinated with Pfizer's mRNA vaccine to a greater extent than unvaccinated people. [137]

Pfizer's own investigation, published in The New England Journal of Medicine March 8, 2021, found its vaccine was about two-thirds less effective, in terms of neutralizing potency, against the South African variant, B.1.351, compared to other forms of the virus. [138]

### **Conclusion : Solutions to End the Pandemic**

There is no point in being biased to not miss a positive, because finding a positive does not help public health in any way. All lockdowns and social distancing can do (at best) is delay the time it takes for the virus to spread by a little bit, but eventually it is going to infect everyone anyway regardless of lockdowns or social distancing. They cannot prevent any deaths or hospitalizations from happening but only delay them by a little bit.

These measures were theorised to be effective without any evidence, and the potential harms caused by these policies were not calculated or taken into account. This goes against the fundamental principles of public health and medicine, which require the implementation of any intervention to be supported by evidence of its effectiveness. **Never in past epidemics or pandemics have lockdowns been imposed as a mitigation strategy over a large area or for a long period of time.**Studies have shown that lockdowns cause unintended negative consequences to social well-being, mental health, physical health, mobility, employment, education, and the economy at large while undermining fundamental rights. **The comparison of epidemic curves in places with strict lockdowns and those with less stringent measures shows no significant differences in COVID-19 indicators.** The pandemic has also been used to restrict our privacy rights & expand mass surveillance programs via contact tracing. [139]

A jumbo covid facility in Mahalaxmi was shut down last year without seeing a single patient. It has been one year since the situation emerged & in that period our state has had ample time to build capacity, which they did. The current load on hospitals & testing in Maharashtra & Mumbai is taking place due to large scale testing of asymptomatic people as well as false positives terrorising people to get admitted into hospital when they don't need to be there, & would get better treating themselves at home for the common cold. The current vaccination drive is also causing a lot of damage to people's health which is making people get hospitalised (while every vaccine death continues to be dismissed by the Government). Implementing the evidence-based guidelines we have recommended will bring down these loads significantly.

On an individual level, locking us in our home, depriving us of sunlight, fresh air & exercise, is only reducing our odds of successfully beating any viral infection, including Covid-19. There is enough robust scientific evidence now showing that optimising ones Vitamin D levels, being insulin sensitive, not being deficient in important minerals like Magnesium, Selenium & Zinc, are highly effective at cutting one's risk of severe covid outcomes & mild symptoms by many times. Other preventatives like nebulised hydrogen peroxide, fasting mimicking diet (a.k.a 3-step flu diet in India), zinc acetate lozenge consumption & melatonin have been found to be very effective for people with mild to moderate symptoms.

In order to reduce the burden on Oxygen supplies & reduce ventilator mortalities, nebulised hydrogen peroxide, CPAP, BIPAP, high flow nasal cannulas, & hyperbaric oxygen chambers can be used.

For those with severe symptoms, a trial was published by Richard Fleming where 95% effective treatments have been found. He concluded the following in his paper: "The answer to the question is, Yes. The treatment of SARS-CoV-2, like HIV, requires a multi-drug treatment regimen focusing on the immune ITR to SARS-CoV-2. The three successful treatment regimens include (1) Tocilizumab & Interferon alpha-2b, (2) Primaquine, Clindamycin, Tocilizumab & Interferon alpha-2b, and (3) Methylprednisolone. These three regimens were effective 99.83% of the time and shortened hospital stays from 40 ± 3 days to 1–2 weeks.

There is also a treatment regimen called the MATH+ protocol that is being used to treat Covid-19 infections in many countries, which involves using Intravenous Vitamin C, Thiamine, Methylprednisolone & Heparin.

# References to all the articles & studies on Solutions can be found in the description & pinned comment of this video [140]

All of this shows us that the false positive RT-PCR & Antigen tests are being used to create a fake crisis that doesn't really have to exist. There is no need for the population to run & hide from the virus, herd immunity had reached high rates before vaccination even began, & we have highly effective prevention options as well as treatments that already

exist. Hence, we request you to follow the science & implement the guidelines suggested here, so that we can all go live with health, vitality & freedom in the "old normal".

Since ancient times, physicians have been required to take the Hippocratic Oath – first, do no harm. Given the compelling evidence we have presented above, will the ICMR choose to uphold the Hippocratic Oath?


Authors:

**Yohan Tengra**, Functional Medicine Consultant at iThrive Wellness **Ambar Koiri**, MD at Bholanath Precision Engineering Pvt. Ltd.

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CC to:

- 1) President of India, Shri Ram Nath Kovind
- 2) Prime Minister of India, Shri Narendra Modi
- 3) Health Minister of India, **Dr Harsh Vardhan**
- 4) Congress Chief Mrs Sonia Gandhi
- 5) Congress leader Mr. Rahul Gandhi
- 6) All CMs of the States of India
- 7) All Health Ministers of all States of India
- 8) National Institute of Virology, Pune
- 9) Institute of Advanced Virology, Kerala
- 10) Haffkine Institute, Mumbai

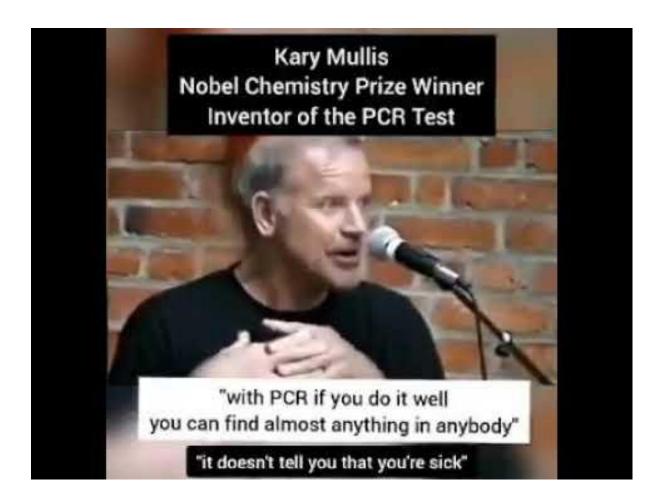
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