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Comments on Kämmerer, et al. (2023) regarding RT-PCR Testing

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Abstract

Kämmerer et al., (2023) reviewed the trustworthiness of Reverse Transcription – Polymerase Chain Reaction (RT-PCR) and sought to solve the serious problems that remain challenging its use and the significance of its application for the diagnosis of COVID-19 infections. They proposed certain modifications which they argued will enable more precise and trustworthy diagnostic results. However, this paper has a clear focus on the technical aspect of RT-PCR, which is only one piece of the COVID-19 puzzle, while there are other equally important pieces still missing. In order to establish what could correctly be judged as a true positive diagnosis, one sharply distinct from a false positive diagnosis, it is necessary to consider additional details. We believe their recommendations amount only to a partial solution to the deeper problems their work implicates. We propose to look at the larger perspective: to start from the very beginning, that is the definition of COVID-19 disease.

Keywords: *COVID-19 disease, NAAT, nucleic acid amplification testing, RT-PCR*

Background and Commentary

To define COVID-19 disease, we need: 1) a well identified germ — the presence of which has never been proved by the current RT-PCR testing as Kämmerer et al. abundantly showed — and 2) a well identified disease defined by a distinctive and unique set of clinical symptoms. With regard to the first point, they have written that there is "no diagnostic value of RT-PCR for the proof of an infectious virus" and we agree. As to point 2), the authors suggest that the diagnosis with RT-PCR (a positive result) should be corroborated by clinical symptomatology. But what exactly are the clinical symptoms to be taken into consideration? According to WHO terminology, a *suspect case was defined by*

the presence of at least 3 of 9 signs or symptoms (that ranged from anorexia to headache) OR a clinical picture of severe acute respiratory illness (SARI), for a total of 85 combinations (WHO, 2020).

According to CDC, any suspected case (in the absence of a more likely diagnosis) *needs only 2 of 10 signs/symptoms* similar to those indicated by WHO (2020), OR only 1 of the other 9 (which include coughing, confusion/altered mental status, olfactory disorder, inability to wake up or to stay awake), OR a severe respiratory illness (CDC, 2021). These criteria account for a total of 55 combinations of symptoms that could result in a positive diagnosis.

According to the FDA, *only 1 of 9 signs* would be sufficient for the diagnosis, if associated to a positive result of a Nucleic Acid Amplification Test (NAAT).[1] Among the possible 9 diagnostic symptoms was the vague criterion of "muscle pain" or "chills" (Polack et al., 2020).

Such differences vanish when the main health agencies (WHO, 2022; CDC, 2021; and ECDC, 2020) explain what they mean by "*the confirmed case*" — in other words, a true positive diagnosis of COVID-19 disease. Their only requirement is a positive test result with any form of NAAT without regard for *whatever observable clinical symptoms may or may not be observed*. In other words, not only the expected symptoms of respiratory disorders (deduced by the name assigned to the virus, SARS-CoV-2), but also musculoskeletal, neurologic, and gastrointestinal ones are to be considered. Furthermore, in lieu of a positive NAAT result, any disorder whatsoever can come into play. The latitude introduced allows an infinite spectrum of clinical possibilities for identifying any given case as "confirmed" — but, surprisingly, no clinical criteria whatever are required if the NAAT is judged to be positive. Our objection along this line is supported by Struyf et al. (2020) in the Cochrane review concerning "signs and symptoms" pertaining to "COVID-19 disease". It is a paper which Kämmerer, et al. cite, and in which Struyf's problematic conclusions are the following:

> The individual signs and symptoms included in this review appear to have very poor diagnostic properties, although this should be interpreted in the context of selection bias and heterogeneity between studies. *Based on currently available data, neither absence nor presence of signs or symptoms are accurate enough to rule in or rule out disease* [emphasis added].

The direct consequence is that also a "food craving", for instance, can be diagnosed in the following two ways, according to the international definition of "confirmed case" (example suggested by Killingley et al., 2022):

> Epididymal discomfort + NAAT positive result = COVID-19 disease (potentially fatal)
>
> Epididymal discomfort + NAAT negative result = only "epididymal discomfort"

This leads to the following paradox: even perfect health can be correctly defined as a severe disease (COVID disease) in the presence of a positive test result.

Kämmerer et al. (2023) indicate another unresolved issue: they accept that a causative role between the positive result of the test (falsely equated to the presence of the "new virus") and the severe acute respiratory syndrome (the main clinical expression of COVID-19 disease), has been found in three papers:

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[1] To clarify, this can be any form of PCR applied to any suspected case of COVID-19 disease. A search on June 5, 2023 at this link (a site for "COVID-19 In Vitro Diagnostic Medical Devices") for "RT-PCR" in the "Method" box, returned 645 kits. about 10% of which were discarded, and each kit with somewhat different rules for applying it.

> The local health authorities immediately informed the WHO and *had already identified the causative agent as a coronavirus* [emphasis added] applying whole genome sequencing and RT-PCR (Ren et al., 2020; Zhu et al., 2020; Lu et al., 2020).

Let's see how the cited authors claimed to prove their case.

Causality assessment criteria were taken into account in only one of the cited works (i.e., Zhu et al., 2020), but in that case the authors admit the Koch's postulates were not fulfilled. Other important and well-known criteria for inferring causality — e.g., those of Bradford Hill, Evans, Rivers and Heubner — seem never to have been considered much less tested in all the scientific literature on COVID-19 disease diagnosis. How come? The answer is disarmingly simple: it would be an "impossible mission".

As a matter of fact, in order to test even the first and second of Koch's postulates, we must have a purified germ and a well specified disease. As we have seen, neither of these is available: on the one hand, we have a never validated RT-PCR test (Kammerer et al., 2023) and on the other hand, we are confronted with an infinite spectrum of disorders. Furthermore, it is common knowledge that many persons admitted to hospital with acute respiratory syndrome which were judged to be "probable cases of COVID-19 disease" got a negative NAAT result (e.g., Ai et al., 2020), which means that other causes were necessarily present for the same clinical picture. Given the frequency of cases without any symptoms, albeit with a "high viral load" (Killingley et al., 2022) it follows that a positive NAAT result was neither necessary nor sufficient for a condition of severe acute respiratory disease, even at the space-time epicentre of the epidemic (Ai T et al., 2020).

Conclusions

PCR testing has been erroneously chosen as the gold standard for diagnosing COVID-19 infection and disease, even if it has never been validated, nor standardized. The symptoms of COVID-19 disease cannot be specified, because they can be anything, everything, and nothing at all according to the authorities. They range from clinically observable symptoms likely to lead to death to no symptoms at all — from near death to complete health. All the foregoing shows the entire scope of COVID-19 diagnostic science is flawed. Of this, there should be a deeper and wider, more comprehensive discussion.

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