

Opinion on the response to FOI-1243364

November 8, 2020

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Accept in good faith nothing but that is seen with certainty cannot conceivably be false; where is simply a clear and distinct perception of what is being asserted, and when there is no tiniest reason to challenge it by a hint of doubt.

(Main principle of the Cartesian Method)

The requested information was whether the infectious agent allegedly causing “COVID-19” was properly isolated. The reply was clear “no such information”, with infusion of some seemingly (to someone who composed the reply) relevant excuses why this is actually unnecessary. This statement totally contradicts not only the common sense, but also basic scientific logical principles of reasoning, and is aimed to change the perception of basic definitions in medicine in favor of certain policy decisions.

There is an established set of conditions to be held in order to prove certain biological agent being a primary cause of a disease (medical condition), known as the Koch's triad. In the response, there is a claim that it is not relevant anymore, being overruled by molecular biology methods. I have to be straight, this is a perfect nonsense. For clarity, here are the conditions:

(1) Agent must be found in abundance in diseased organisms, but not in healthy ones

(2) Agent must be purified and maintained in pure culture

(3) Cultured agent from p.2 has to cause disease when introduced into healthy organism

(4) Pp. 1 and 2 have to be satisfied for agent found in infected organism from (3), and the agent must be shown to be identical to one in pp.1,2.

Pt. 4 is, in principle, superfluous, as it is a logical consequence of pp.1-3. These are logical postulates rather than scientific laws. Therefore, one who claims that some "new methodology" overrules them, proves that methodology wrong by *reductio ad absurdum* (i.e. something is true and false at the same time). The point of attack was pt.(2), as there is no such a thing as "pure culture" of a virus, as it's merely the host cell which reproduces it. The point (3) faces ethical issues, although nowadays we are looking at progressing cessation of ethics everywhere. Yet, it is perfectly possible to prove that (a) the virus can be reproducibly isolated and purified from a selection of patients with certain medical condition; (b) higher virus titer in host tissue correlates with more severe symptoms, and titer from tissues of healthy people does not exceed certain "zero" threshold; and (c) the virus to be shown to cause the critical damage to the host cells and tissues. Virus titer values for negative control threshold can be established using selection of

healthy people (i.e., not manifesting any symptoms), and quantitative tests can be calibrated against this value.

Referenced “modern molecular biology methods” are not proper medical diagnostic tools just by themselves. These are indirect methods, and they by no means can prove the source of disease causation, that is, no substitute for Koch’s triad. Additionally, these methods (as implemented) are not quantitative, therefore they give only yes/no type answer to the question whether certain substance, called “the virus”, is present in sample being tested. The cutoff threshold (amount of substance below which the test must give “no” answer) is not well defined. They can be relied upon if and only if the causation is well established by other, direct methods, and an alleged infectious agent (“the virus”) properly characterized and shown to cause the disease it is claimed to cause. For example, development of antibodies for medical and diagnostic use must be carried out using standardized and well-characterized pathogen surface proteins, which require the standardized an well-characterized pathogen itself, to ensure the correctness and reproducibility of the result, including proper negative controls. In the case of widespread coronaviruses the possibility of cross-reaction of antibodies produced by the host towards different strain or (sub)species cannot be dismissed, therefore many possible origins of false positive results when trying to detect a particular strain/ (sub)species must be assessed. Genetic material (RNA) detected by RT-PCR (Reverse Transcriptase Polymerase Chain Reaction, as described in the “CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel” (CDC-006-00019, Revision: 05)) can originate from multiple sources, and by itself does not prove the viral infection, especially if patient does not manifest recognizable symptoms known and proved to be caused by that infection.

Additionally, RT-PCR is highly prone to errors, and they become more prominent (as they are amplified) at high cycle counts (CDC “Diagnostic Panel” sets 40 cycles as a threshold value). That is, the test result is considered positive if the signal barely raises above noise level after 40 cycles. That gives possible amplification factor of 10^{12} , where single molecule can be amplified into something like 4 nM (nanomol per liter), and many fluorimetric instruments have limits of detection well below that value when brightly fluorescent dyes are used as probes (which is the case in real-time PCR kits).

At first, for the “modern molecular biology methods” to be useful for diagnosis, “the virus” that tests are meant to detect, must be a well-characterized biological entity with reproducible characteristics. If there is no solid proof of such entity exists and causes illness, blind “testing” of people, especially these without clear symptoms, for alleged “viral illness” can bear no scientific, nor medical meaning. Large number of “asymptomatic” cases (translation: healthy people showing positive test result) proves that test is not valid, and cannot be used as a diagnostic method. In other words, negative control is being detected as positive by the test (which is a false positive). In its “Limitations” section, CDC document mentioned earlier states, in a somewhat evasive manner, that “Detection of viral RNA may not indicate the presence of infectious virus or that 2019-nCoV is the causative agent for clinical symptoms”.

Scientifically, described above PCR-based “test for the virus” has no sense, because of the way it is implemented. It is quantitative and justified detection threshold value is not established. Given that achievable limit of detection for PCR method can be as low as single molecule per sample, even dismissing other

sources of false positives (and there are many), people with arbitrarily low viral loads will be detected as positive (Koch's postulate 1 is clearly violated).

Interestingly enough, research by not anybody but A. Fauci (doi:10.1086/591708) concluded that the main cause of death during flu epidemics of the past century was the pneumonia caused by bacterial flora inhabiting respiratory tract and skin, rather than the virus infection itself. As the most cases of severe life-threatening pneumonia are known to be of bacterial origin, how can they be diagnosed otherwise than that based solely on test results conducted by research-grade molecular biology methods misused to identify the presence of a pathogen of unknown and uncharacterized origin? CDC "Diagnostic Panel" mentioned above also honestly enlists "This test cannot rule out diseases caused by other bacterial or viral pathogens" as one of the test limitations.

To reconcile all the nonsense, the only possibility remains is to conclude that the process of redefining the very meaning of the word "disease" is underway. It is now meant to serve merely as a label attributed to the people on which some obscure and arbitrary test gives "positive" result. An attempt to overrule Koch's triad is actually nothing less than a pursuit to change the definition of "infectious disease" to something that better serves immediate needs of the pursuer.