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A Critique of the Approach Long Term Care Facilities have Taken to the Prevention of the Transmission of COVID-19

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Preamble

The residents of care homes and long-term care facilities are the most vulnerable members of society regarding the acquisition of COVID-19. Our duty is to "protect the vulnerable" has been the clarion call of managers of such institutions for the past two and a half years. This responsibility resulted in the introduction of draconian testing and isolation policies with little regard to the physical and psychological harms that such measures would cause, not only to the care home residents, but to their families denied visiting rights or allowed access limited by strict physical barriers.

The fact that no risk assessments have been performed on these supposedly curtailment techniques is a sad reflection on the sincerity with which the owners of those facilities view the overall health and wellbeing of those under their care. No effort was made to challenge government guidelines that have the remarkable dual distinction of being devoid of humanity while making a mockery of common sense.

In recent months, Ontario Home Care and Long-Term Care Facilities have adopted a system of "Surveillance Testing" to prevent the transmission of COVID-19 among their residents, staff and visitors. This method relies on the concept of asymptomatic transmission and the efficacy of PCR and rapid antigen tests.

This critique will assess the credibility of asymptomatic transmission, PCR tests and rapid antigen tests. By doing so, it will demonstrate that those institutions have been mistreating residents and their families.

Asymptomatic Transmission

The idea that persons not exhibiting symptoms of COVID-19 could transmit the infection has been a significant driver of many isolation and testing policies. What follows is a repudiation of that concept.

SARS-Cov-2, the cause of COVID-19, is a respiratory virus. As such, it induces infections in the same manner as its endemic coronavirus cousins, which together are responsible for 15-30% of common colds [1]. To initiate an infection, a sufficient dose of the viable (live) virus must leave its host. Respiratory viruses do this by escaping from the respiratory tract via coughs and sneezes, which project potentially infectious amount of the virus [2]. An individual might harbour SARS-CoV-2 and have non-existent to mild non-specific symptoms, but unless the live virus is expelled in sufficient amounts by coughing and sneezing to overcome the natural defences of a secondary host, transmission of the infection **will** not occur. Coughing and sneezing are the significant symptoms associated with COVID-19 transmission [2].

It is accepted medical practice that the diagnosis of an infectious disease depends on two essential coexisting factors, *i.e.*, the presence of its characteristic symptoms and identification of its causative agent. Without the presence of both factors, there can be no confirmed case of COVID-19 [3]. An individual without symptoms is, by definition, well, and a person who is not coughing or sneezing would be expected to be incapable of transmitting COVID-19. These truisms alone should be sufficient reason to doubt the asymptomatic transmission of COVID-19, fortunately there are confirmatory investigations to support this claim.

In a March 2021 article, Craig and Engler stated that, *"Evidence of asymptomatic transmission has been based on only a handful of instances which themselves are questionable"* [4]. Following a thorough analysis of the credibility of these instances they concluded that, *"The evidence that asymptomatic transmission exists at all is tissue thin"* [4]. This opinion has been reinforced by Madewell and colleagues who undertook a meta-analysis of 54 studies from around the world and

found that symptomatic patients passed on the disease to household members in 18% of instances unlike asymptomatic persons who passed on the infection in 0.7% of instances [5]. They concluded that the signs and symptoms of a flu like illness were requisites for the exceedingly rare transmission of COVID-19 within households [5].

If persons, exhibiting no symptoms but living in the close intimate relationships that exist in households, hardly ever spread COVID-19, it is sensible to conclude that the chance of this occurring from an asymptomatic individual visiting a nursing home resident for a couple of hours is so infinitesimally small as to be nonexistent.

The simple reality is that people without symptoms are **not** major drivers of COVID-19. Mandating restrictive practices that fail to appreciate this fact are not respecting the basic needs and rights of vulnerable patients and their loved ones.

PCR Test

It is questionable if prior to March 2020 that many members of the public had heard of a PCR test. However, it quickly became the "go to test" promoted by mainstream media, provincial and federal governments. PCR stands for Polymerase Chain Reaction. It involves a series of sophisticated laboratory procedures by which, "*it is possible to replicate several million times in a test tube, an individual DNA segment of a complicated genetic material"* [6]. The test was invented by Dr. Kary Mullis for which he was awarded a Nobel Prize in 1993.

It is important to appreciate two facts: 1) complete viable viruses are necessary for the transmission of COVID-19; and 2) the PCR test does **not** identify the whole virus, but fragments of genetic material assumed to be representative of SARS-Co-2. If the fragments are identified in the sample, the test is deemed positive. However, it is a leap of faith to suggest that the result is indicative of a live virus present in a sufficient amount to induce infection. Indeed, studies have demonstrated that the fragments might represent **dead or non-infectious** SARS-CoV-2, general cell debris, bits of endemic coronaviruses, other pathogens or contaminants introduced during the collection, transportation and preparation of the sample [7].

For the purposes of this critique, it is not necessary to describe the sophisticated and highly technical laboratory procedures associated with the PCR test. Suffice to say that the fragment is

subjected to processes that cause it to divide into two exact copies of itself. The cycle is repeated producing four copies and so on until after 30-40 cycles there will be billions of copies of the fragment. For example, the approximate number of copies produced by running 24 cycles is 16 million, 33 cycles give 8.5 billion copies, and 40 cycles create about 1 trillion copies.

It is important to appreciate that these amplification cycles do not alter the physical structure of the fragment. All they do is produce more of it for easier identification and subsequent investigation. In his book, *Making PCR,* Paul Rabinow succinctly states of PCR, *"It makes abundant what was once scarce-the genetic material required for experimentation"* [8].

A fluorescent marker is incorporated into the amplification process such that it increases in intensity with each cycle until it can be seen by the naked eye. When this occurs, the sample is considered positive. The Cycle Threshold or Ct is the number of amplification cycles performed until the marker is visible. The assumption is that the more of the fragment there is at the start of the cycling, the fewer cycles it will take to reach a fluorescent intensity or threshold level that has been predetermined to indicate the presumptive presence of SARS-Cov-2.

Recent papers have indicated that a Ct of greater than 24 should not be used to infer the presence of a **live or infectious** virus, since above that level the exquisite sensitivity of the test will amplify fragments of other biological material as noted above [7, 9, 10].

In Canada, there is no uniform testing standard. Laboratories in Ontario use Ct levels between 38-40 [11]. Virologist, Dr. Julie Morrison of the University of California is quoted as saying, *"I am shocked that people would think that a Ct value of 40 could represent a positive"* [12]. Dr. Brenda Stadler, formerly Director of the Institute of Immunology at the University of Bern agrees having stated that, *"even if the infectious viruses are long dead, a corona test can come back positive, because the PCR method multiplies even a tiny fraction of the viral genetic material enough to be detected"* [13].

In July 2020, Dr. Anthony Fauci of the U.S National Institute of Allergies and Infectious Diseases indicated that any COVID-19 testing results using a Ct level above 35 are almost certainly false positives [14]. More significantly, a September 2021 publication demonstrated that 97% of PCR test results were false positives [15]. Other studies have confirmed the 90-97% false positivity rate especially in **asymptomatic** healthy individuals tested at airports and at work [16].

Currently, Ct levels are not recorded on PCR test results, which are given as either positive or negative. The Ct levels used in Ontario (38-40 cycles) are, without doubt, creating the illusion of many more cases than are present. It must be stressed that at these Ct levels it is highly questionable if the sample contained any live potentially infectious SARS-CoV-2. A positive test simply indicates that fragments of genetic material have been identified. It does not indicate that enough life virus is present to cause infection.

Subjecting asymptomatic residents and their loved ones to tests of doubtful accuracy which, if positive, are guaranteed to result in unwarranted quarantines with their myriad of unintended consequences, is an intolerable approach to the care of vulnerable patients.

Rapid Antigen Test

Antigens are molecules and proteins with unique surface characteristics that are recognized by the immune system as foreign. The recognition, in turn, activates the immune system [17]. SARS-CoV-2 has several antigens that will be present in patients **infected** with the virus. The Rapid Antigen Test involves taking a nasal swab, soaking it in a solution to disrupt the virus, and applying the resultant liquid to a test strip. The liquid migrates through the strip and will interact with SARS-CoV-2 antigen specific antibodies embedded in the strip. The antibodies have had luminescent markers added to them so that when an antibody antigen reaction occurs, coloured lines appear on the strip indicating a positive test [17].

Since the antigens are present in infected individuals, it makes sense that the manufacturers of the test kits indicate that the tests should be performed within six days of the **onset** of **symptoms** [18]. In other words, to confirm if an individual who is coughing or sneezing does have COVID-19.

The Cochrane Database of Systemic Reviews is a highly reputable source of evidence-based analysis of clinical investigations. In March 2021, a review was released involving an analysis of 64 studies on the accuracy of rapid antigen tests to detect SARS-CoV-2. [19]

Dr. Jac Dinnes, an author of the report stated that, *"Our review shows that some antigen tests may be useful in healthcare settings where COVID-19 is suspected in people with symptoms. The tests do not appear to perform as well in people who don't have symptoms"* [19].

Another author, Dr. John Deeks concluded that, *"The situation is different for testing people without symptoms, particularly for use of repeated antigen tests to screen for SARS-CoV-2 infection in school pupils and staff, hospital and care home workers. We didn't find any data or studies evaluating the accuracy of these tests when used in repeated screening of people with no known exposure to SARS-CoV-2. These testing polices have been implemented without any supporting real-world evidence"* [19].

The Ontario Covid -19 Science Advisory Table in March 2021 used an earlier Cochrane review of 22 rapid antigen test studies to conclude that, *"a rapid review reveals no real-world evidence to either support or refute the effectiveness of routine asymptomatic screen testing of LTC staff in preventing LTC home COVID-19 outbreaks"* [20]. The prevarication exhibited by the Table might have been less so had it been aware of the results of reviewing 64 investigations into the accuracy of rapid antigen tests.

The Ontario COVID-19 Science Advisory Table in February 2022 noted that:

- Rapid antigen tests are less sensitive for the Omicron variant;
- 2 out of 3 positive rapid antigen tests could be false positives especially in asymptomatic persons;
- The sensitivity of the test varies between manufacturers;
- The sensitivity of the test varies according to collection techniques; and
- Most cases were infectious (*i.e.,* had symptoms) for multiple days before receipt of a positive rapid antigen test result [21].

In addition to these concerns are the very real facts that:

- Repeated rapid antigen tests on asymptomatic persons have induced pain, serious bleeding and infection; and
- Vaccinated asymptomatic persons have little likelihood of receiving a positive rapid antigen test result [20].

A summary of the above would conclude that there is minimal, if any, substantiated clinical evidence to support rapid antigen tests being performed on any individuals who are asymptomatic. Contrary to that opinion, the Ontario Government categorically insists that, *"Antigen screening*

tests ***should only be used on asymptomatic individuals"*** [21]. {Please note the emphasis was applied by the Government.}

This means that repeated tests are being performed:

- Whose efficacy has not been substantiated;
- Which are associated with serious injuries;
- Have a high false positive rate; and
- Which, if positive (falsely), result in personal restrictions.

There is no rational justification for performing Rapid Antigen Tests on persons who are not coughing or sneezing. It is unconscionable that asymptomatic residents, staff and visitors of long-term care facilities should be subjected to such tests when the almost inevitable false positive results will cause the unjustified loss of personal privileges, punitive restrictions on social interactions and the exacerbation of existing medical and psychological conditions.

Conclusions

Surveillance Testing is applicable to long-term care homes that are not experiencing an outbreak of COVID-19. Presumably, the repetitive tests performed on the residents, staff and visitors are intended to identify and isolate cases as early as possible thus preventing, or, at least, controlling spread of an infection.

Such an understanding mandates that the tests can perform such a function. Persons who are not coughing nor sneezing do not spread COVID-19. As noted above, performing PCR and Rapid Antigen Tests on those individuals to identify COVID-19 has no clinical validation. While the tests are to all intents and purposes useless, they are associated with serious unintended consequences which have significant and usually deleterious effects on the test subjects.

The owners of such health care facilities have a duty to prevent this mistreatment. This can be accomplished by them demanding of Public Health Ontario incontrovertible clinical proof that Surveillance Testing is effective. To do otherwise is to deny its residents, staff and visitors the evidence-based procedures that they deserve.

In the meantime, individuals who are not coughing nor sneezing should not be viewed as repositories of SARS-CoV-2, and ought to be treated accordingly.

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