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America's "Testing Mess": The Healthcare System in COVID Testing and Vaccinations.

How Government Is Cutting Out the Middleman

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Let me start by explaining that an antigen test, performed by (minimally trained) personnel in a nursing home, homeless shelter, or other congregate living setting, rather than in a lab, is often the basis for a diagnosis of Covid.

The test does not need to be ordered by a doctor. It is possible that the patient's doctor does not even know their patient was tested, nor will they receive the results. In most cases, there will be no billing of an insurance company. The results are determined within the facility, and the only required reporting is to a local health authority, which forwards results to the CDC.

Like the Covid vaccinations, these Covid tests are being handled completely outside the regular healthcare system. No MD is responsible, nor can anyone be sued if the results are wrong and lead to a bad outcome. Only government employees have access to the results.

States may provide test kits under federal grants to the facilities and require a certain frequency of testing.

In terms of diagnosing cases of Covid, a sole positive antigen test is defined by CDC and the Council of State and Territorial Epidemiologists as a **probable Covid case**, **even without a single symptom**. Some jurisdictions, and the CDC itself, recode probable cases as confirmed cases of Covid.

One positive PCR result is defined as a confirmed case of Covid, even without a single symptom.

Beginning in December, a similar rapid antigen test, called a lateral flow test, was approved for home use. It must be combined with an app, which reports your results to the government.

Both in Europe and the US, these products can be sold solely on the basis of manufacturer data, without independent evaluation by FDA or another regulatory agency. They are authorized under the minimal EUA standard. There are no standard protocols for measuring performance. CDC pretends there are, and suggests that users keep in mind the test

sensitivity when interpreting the results. But you cannot find an accurate measure of sensitivity for Covid tests anywhere. All the numbers available are simply claims made by their manufacturers, when tests were performed under perfect conditions.

Nature magazine noted that Porton Down science park and the University of Oxford had performed some testing of rapid antigen tests; "T*he full results, which have not yet been peer reviewed, were posted online on 15 January. These stated that many fast antigen (or 'lateral flow') tests "do not perform at a level required for mass population deployment..."'*

Nature also pointed out that laboratory scientists achieved nearly 79% sensitivity on all samples (including those with very low viral loads) using the Innova rapid test, but self-trained members of the public got only 58%. (Sensitivity means the chance of getting a positive result when someone has the disease.)

Harvard School of Public Health professor Michael Mina, PhD, perhaps the most vocal proponent of these tests, admitted, "Throwing tools at people who don't know how to use them appropriately is a terrible idea."

Now let's look at CDC's January clarifications regarding these rapid antigen tests.

"As of January 7, 2021

Revised guidance on when to perform confirmatory tests.

- *In general, asymptomatic people who test antigen positive should have a confirmatory test performed. Symptomatic people who test antigen negative should have a confirmatory test performed.*
- *Confirmatory test should be performed with nucleic acid amplifications tests (NAAT) such as reverse transcriptase polymerase chain reaction (RT-PCR).*
- *Expanded the intended audience to include all long-term care facilities, including nursing homes."*

What does this mean? If you think the person is negative and they test negative, stop. Consider them negative. If you think they are negative, but they test positive, get a PCR to supplant the first test, because it is not trustworthy.

If you think they are positive and the test result is positive, stop and treat accordingly. If you think they are positive, but they test negative, get a PCR test to supplant the first result.

Wait, what? Why don't we just get PCR tests on everyone (or else just get them on everyone the doctor or nurse isn't sure about) and forget the antigen tests, which seem to have lots of false positives and negatives? But the US government has spent billions on these rapid tests, so we can't stop using them. They were supposed to save time, but if you really have to do PCR tests whenever the result disagrees with your hunch, they seem to actually waste time.

But how many facilities are actually following up unexpected test results with PCR tests?

In December and January, WHO advised the world to turn down the cycle thresholds on the PCR machines.

WHO issued instructions similar to the CDC instructions above, which said, if you are getting

a result you were not expecting from the PCR test, then do a second PCR test. Hmmm. Are the PCR tests accurate enough to rely on? It does not seem so, but since their performance varies with cycle threshold (CT), if the CT has been adjusted, we need to reevaluate the test sensitivity and specificity.

But, since their cycle thresholds have not been provided, and the actual test performances of the 300 different authorized PCR tests in the US are a secret, we may never learn how accurate these tests really are.

Can I boil this down?

1. With the government approving rapid tests, buying the tests, distributing the tests and collecting all the data from them, the government has a lot of room to influence the reported numbers of probable new Covid cases. [These tests are rolling out very rapidly now.]

2. The government seems to have created a parallel medical system to deal with these Covid tests, and the CDC has issued guidance for how to manage positive cases in long term care facilities. Is part of the goal to cut out the middleman (the doctor) and allow government edicts to make diagnoses and establish the rules for medical care?

3. I found it interesting that vaccinations are not being given in doctors' offices, similarly cutting out the doctor. At first, the reason given was the very low refrigerator temperatures needed for the vaccines. But now those temperatures are allegedly not needed after all.

I suspect that the government does not want people getting the shots in doctors' offices because doctors are a lot more likely to discuss the risks and the unknowns with their own patients than are the unknown paraprofessionals and reserve military servicemembers who are administering many of the shots. They are also more likely to be made aware of side effects and deaths that may occur.

Many Covid vaccine clinics were designed with speed in mind. There is no time for a conversation before the shot. There is also no mechanism nor means for informed consent–there is no doctor on site to explain the risks and benefits of the vaccines, as required by the EUA statute. Instead, recipients are given an information sheet and asked to sign an (uninformed) consent.

4. I think we will need to remain watchful of case and death numbers in our local areas, so we can't be fooled with spurious statistics. While it seems that PCR tests are identifying fewer false positives, it could be that the proliferation of rapid tests will replace the PCR tests with a new method of generating false positives.

With many additional millions of rapid tests to be performed monthly, there might be a huge rise in cases, but no rise in illnesses. Let's remain mindful of the possibilities.

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