

SARS-Cov-2 Vaccine and Bypassing Animal Trials.

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As various vaccines for Covid-19 (SARS-CoV-2) are being released, biotech companies have skipped animal studies and moved directly to Phase I human clinical trials. Vaccine development typically takes at least 15–20 years and passes through six phases of assessment. (Deb et al 2012). Bypassing animal studies may be good news for entrepreneurs but at what cost to health? In the absence of animal trials with the SARS-CoV-2 vaccine, it is therefore important to examine studies on previous SARS vaccine animal trials. (Deb et al 2012).

Research dates as far back to 2002, when coronavirus outbreaks such as SARS first emerged. Studies showed that sometimes the vaccines actually made the subject worse. “For certain diseases, patients who have been previously infected by one strain of a virus and who are later infected by another strain can suffer outcomes that are worse than those infected only once”. (Eroshenko et al 2020). SARS, aka ‘Severe acute respiratory syndrome’, emerged in China in 2002 and vaccines developed to combat the illness sometimes resulted in a worsening condition of the subject. (Tseng et al 2012). This event is called ‘antibody-dependent enhancement’ or ‘antigen sin’ and can be a common reaction. Whilst these SARS coronavirus vaccines initially helped with the disease and produced antibodies, the animals (ferret and primates) later developed hypersensitivity to the virus causing complications and more damage than the original infection. (Tseng et al 2002).

Thus, instead of protecting the subject, it also sometimes led to higher complications and death of the subject when the subject was reinfected with the original pathogen (Huisman et al. 2009). As a result, severe damage of the liver and the lungs led to death. (Zelleger et al 2020). Lung pathology was often characterized by diffuse alveolar damage caused by inflammation. Liver pathology also included inflammation from infection and includes steatosis, hepatitis and portal inflammation.

Antibody-dependent enhancement (ADE) has also been observed with the human MERS virus and with feline coronavirus (f-Cov). What is of particular concern is that the structure of the SARS-Cov-2 virus is of high risk for antigenic sin because it contains an S protein that exists in other coronaviruses such as SARS and MERS. The spike (S) protein on the surface of SARS-CoV is where the virus attaches to gain entry to the host cells. (Kassmy et al 2020). This is a good reason to compare the animal studies of these other coronaviruses to SARS-Cov-2, because they all contain the (S) spike protein.

Animal trials are very important for vaccine trials as the vaccinated animals can be reinfected with the original pathogen to see if any reaction occurs. At a very minimum, in the absence of testing animals, individuals should satisfy themselves that the vaccine they are being encouraged or mandated to take, has been investigated for antibody-dependent enhancement (ADE) at multiple stages in its development. (Wang et al 2020). However, in terms of safety this does not compete with animal trials or long-term 10+ years clinical trials or indeed with long-term epidemiological studies.

Governments should not recommend the SARS-COV-2 vaccine because the evidence for safety has been for such a short period of observation. More time should be allowed for potential of immunopathological (ADE) reactions occurring among vaccinated individuals on exposure to infectious SARS-CoV-2. Tseng et al (2012) also recommended the same in relation to SARS-CoV. More time for observation is also recommended by other researchers. Eroshenko (et al 2020) reports, “ADE is often observed when antibody concentrations decrease as a result of waning immunity”. Ideally waiting on immunity levels to drop in vaccinated individuals is recommended especially since ADE has already been reported with some SARS-CoV-2 vaccines. (Eroshenko et al 2020).

Vaccine-specific variations in ADE could occur for many reasons, including differences in vaccine adjuvants used and whether prior exposure to other CoV strains has occurred. Wang (et al 2020) therefore recommends further clinical studies to assess this risk in both vaccinated and infected individuals. Individuals and governments should consider this as such data may become even more critical as SARS-CoV-2 virus mutates or becomes seasonal.

The lives of billions of people are dependent upon the safety of SARS-Cov-2 vaccines. Therefore, scientists need more time to develop techniques in immunology to create vaccines that reduce or avoid ADE altogether. (Eroshenko et al 2020). The gold standard of safety for drug companies is double-blind placebo studies to occur over 5-10 years of clinical trials. The same should be mandated for vaccines, especially since they are injected directly into the circulatory system, as opposed to the digestive system as with pharmaceutical drugs. The digestive system provides a natural barrier to toxins and protects the organs. Eroshenko et al (2020) reports that epidemiological studies investigating ADE in individuals with multiple SARS-CoV-2 infections or cross-reactivity to common-cold-causing CoVs will likely take several years.

In summary, in the rush to release a vaccine, animal studies have been skipped so determining what happens when a vaccinated person is reinfected is unknown or compromised. Even if vaccine manufacturers have taken steps along the way to test and mitigate for ADE, more time is still needed to evaluate properly. This is especially true because as Eroshenka et al (2020) reports, it is with the decreasing immunity levels that ADE often occurs. Vaccines have just begun to be released and immunity levels with the vaccinated against SARS-CoV-2 are at their highest. At the very least, governments and individuals should wait at least 3-5 years to determine potential ADE when immunity levels drop and reinfection occurs with new strains. It is therefore premature to recommend the vaccine to anyone on these grounds alone. Further, vulnerable individuals wishing to take the vaccine should be made aware of the potential long-term consequences.

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