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## 6 Dangers of COVID-19 Vaccine Associated Enhanced Disease

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- 8 - COVID-19 vaccines, used in the US and most of EU, provide acceptable immunity against currently  
9 prevalent variants of SARS-COV-2 for up to six months. Evidence suggests that many vaccinated  
10 persons younger than 50 are likely to experience vaccine associated enhanced disease (VAED),  
11 when they encounter SARS-COV-2 later, in the fall or winter this year.
- 12 - The causes are waning antibody immunity and future spread of variants of concern (VoC), resistant  
13 to or even escaping vaccine-induced immunity.
- 14 - These two problems are likely to create a “perfect storm” in the fall of 2020. The time to start  
15 preparing for it is now.
- 16 - Children and adolescents are negatively affected by COVID-19 vaccines more than adults, because  
17 of stronger effect of the COVID-19 vaccines in them, in cross-reaction with the common cold  
18 coronaviruses. Additionally, healthy children and adolescents do not need vaccination against  
19 COVID-19.
- 20 - Mass vaccination of children and adolescents must stop.
- 21 - The fight against COVID-19 should shift from mass vaccination with the current anti-spike vaccines,  
22 which are already obsolete because of the coronavirus evolution, to proven early antiviral  
23 treatments and possibly prophylaxis.

## 24 Abstract

25 Vaccine Associated Enhanced Disease (VAED) is a special case of antibody-dependent enhancement  
26 (ADE) of infectious diseases, caused by vaccination. Disease enhancement is detrimental to the patient.

27 ADE takes place when neutralizing antibodies do not completely neutralize the pathogen. This might  
28 happen when the titer levels are too low or when the antibodies are for another pathogen serotype or  
29 variant. Many (but not all) past attempts to develop vaccines against SARS, MERS, and other  
30 coronaviruses failed because they led to ADE.

31 This problem is even worse in the current COVID-19 vaccines because they only target the spike protein  
32 of SARS-COV-2, which presents unusually few targets for natural antibodies and quickly mutates.  
33 Further, failure to treat infected patients and have created huge amounts of SARS-COV-2 and the ideal

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34 conditions for its evolution. The coronavirus has already used these opportunities to increase its  
35 transmissibility and to avoid some antibodies. It will continue to mutate toward resistance to the  
36 vaccine-induced immunity.

37 ADE was the main concern in the development and emergency authorizations of the COVID-19 vaccines.  
38 The vaccine trials and early administration to adults have not shown immediate ADE. Given the  
39 remarkably high antibody titers elicited by the vaccines, immediate ADE was unlikely. However, this  
40 provides no assurance for the future when the antibodies immunity wanes and distant variants or even  
41 serotypes of SARS-COV-2 appear. Multiple lines of evidence, reviewed below, point to a high likelihood  
42 of future VAED in vaccinated individuals.

## 43 Introduction

### 44 Regulatory Documents

45 FDA, Vaccines to Prevent COVID-19 - Guidance for Industry <sup>(FDA re-Guidance 2020)</sup>

46 FDA, Emergency Use Authorization (EUA) for an Unapproved Product Memo <sup>(FDA re-Pfizer 2020)</sup>

47 FDA, EUA Expansion to the ages 12-15 <sup>(FDA re-Amendment 2021)</sup>

48 FDA, Fact Sheet for Pfizer BNT162b2 <sup>(FDA re Fact Sheet 2021)</sup>

49 EMA, Assessment Report for Comirnaty aka Pfizer-BioNtech BNT162b2 <sup>(EMA re-Pfizer 2021)</sup>

50 EMA, Assessment Report for Moderna <sup>(EMA re-Moderna 2021)</sup>

### 51 Definitions

52 Antibody-dependent enhancement (ADE) is an immune system phenomenon, when neutralizing  
53 antibodies bind to a virus, but instead of or in addition to neutralizing it, help it to enter cells. The term  
54 is also used when these antibodies, not finding targets on the virus, damage the healthy cells <sup>(Hellerstein  
55 2020)</sup>. ADE might happen when the quantity (titer) or quality (matching epitopes presented by the virus) is  
56 low. ADE caused by vaccines is called VAED. In the respiratory diseases, it is sometimes called VAERD  
57 (vaccine associated enhancement of respiratory disease).

58 <sup>(Lee et al. 2020)</sup> reviews ADE as relevant to SARS-COV-2 vaccines and antibody treatments.

59 There are many ADE mechanisms, but they can be classified in two types:

- 60 a) sub- or non-neutralizing antibodies help the virus to enter cells (enhanced infectivity, likely to  
61 increase virulence)
- 62 b) sub- or non-neutralizing antibodies attack healthy cells instead of the virus (enhanced virulence,  
63 might increase infectivity indirectly)

64 Both used to happen in the past attempts to develop vaccines against coronaviruses.

65 AOS (original antigenic sin) is a propensity of the immune system to react to a second pathogen similar  
66 to the one it has already encountered in the same way. Immunization against one strain of a pathogen  
67 might generate ineffective immune response to another, and to trigger ADE <sup>(Vatti et al. 2017), (Fierz and Walz 2020)</sup>.  
68 <sup>(Lyons-Weiler 2020)</sup> describes one virulence enhancement mechanism.

69

## 70 Methods

71 This is a theoretical paper with a short review of the relevant literature.

72

## 73 Discussion

### 74 ADE

75 The current COVID-19 vaccines, used in the US and most Western countries, are mRNA and viral vector  
76 vaccines, targeting only the spike protein of SARS-COV-2. For the purposes of this paper, “COVID-19  
77 vaccines” only refer to these mRNA & viral vector vaccines, unless otherwise specified. Anti-spike  
78 coronavirus vaccines are known to be especially prone to cause ADE. For SARS-COV-2, the selection of  
79 the spike (S-protein) as the only antigen was an especially bad choice <sup>(Hellerstein 2020)</sup>. T-cells, rather than  
80 antibodies, provide long term immunity and do not cause ADE, but only about a quarter of T-cells  
81 associated with SARS-COV-2 target its spike, compared with half to two thirds in previous coronaviruses.

82 Many (although not all) attempts at vaccines against other coronaviruses have failed because they  
83 caused ADE in animal models. This was the case with the experimental vaccines against SARS and MERS.  
84 The same thing happened during the attempt to develop a vaccine against FIPV, a coronavirus disease in  
85 cats <sup>(Agrawal et al. 2016), (Gao et al. 2003), (Dandekar and Perlman 2005)</sup>. On a remarkable side note, Remdesivir was tried  
86 for FIPV in cats and failed. It was then tried on humans for COVID-19 and also failed <sup>(Goldstein 2020)</sup>, but still  
87 received a EUA.

88 The current appearance that the COVID-19 vaccines do not cause ADE is insufficient because of the  
89 short time between vaccination and exposure to SARS-COV-2. Remarkably high antibody titer, elicited  
90 by these vaccines, neutralizes SARS-COV-2. However, vaccine induced antibody titer significantly drops  
91 after 6-9 months following the full vaccination <sup>(Dispinseri et al. 2021)</sup>. This is when the vaccine recipients may  
92 become susceptible to ADE, upon exposure to SARS-COV-2. Another contributing is the coronavirus’  
93 divergence from the original genome, targeted by the existing COVID-19 vaccines. Currently dominant  
94 variants are partially resistant to the natural and vaccine induced immunity. Future variants will be even  
95 more resistant or will completely escape it. These two factors have dangerous synergy.

96 Huge amounts of the coronavirus are in circulation because so many people get infected worldwide.  
97 Lockdowns <sup>(Wittkowski 2021)</sup> and “do not treat” policies have created ideal conditions for the coronavirus’  
98 evolution toward increased infectivity and immunity evasion. The two-shot vaccination protocol also  
99 accelerates the vaccine escape <sup>(Di Caro et al. 2021), (Weisblum et al. 2020), (Wang et al. 2014)</sup>.

100 Accurately predicting ADE is hard, but there are many variants of concern and thousands of subvariants.  
101 They continue to evolve. At least some of them will cause infection enhancement, thus gaining an  
102 evolutionary advantage, and will become prevalent. Thus, the current strategy of excessive vaccination  
103 and lack of early antiviral treatment is all but guaranteed to bring about ADE.

104 The speed of SARS-COV-2's evolution toward immunity evasion was not expected when the vaccines  
105 were developed (Chen et al. 2021), (Wang et al. 2021). Inactivated whole virus vaccines, like the first three vaccines  
106 authorized in China (Baraniuk 2021), also present theoretical danger of ADE, and have less efficacy than mRNA  
107 vaccines.

108 Normally, evolutionary pressure on pathogens is toward lower virulence (milder disease). More virulent  
109 pathogens reveal their presence faster, which leads to treatment and/or isolation of the human hosts.  
110 The public response of isolating healthy people eliminates this pressure. An evolutionary pressure  
111 toward increased virulence of the pathogen always exists – sicker hosts shed more virus. In the midst of  
112 lockdowns, a sicker person is also likely to break the lockdown in order to seek help. Thus, the lockdown  
113 policies contribute to spread of more virulent variants of the coronavirus.

#### 114 **COVID-19 Vaccines Immunity**

115 Unlike narrow immunity from an anti-spike vaccine, an individual who obtained immunity by infection or  
116 exposure, develops a broad and long-term immunity, with T-cells, B-cells, and antibodies against all  
117 antigens presented by the coronavirus in all replication phases. The quick emergence of a variant  
118 evading natural immunity is unlikely. Normal antigenic drift of coronaviruses is slow and allows the  
119 natural immunity to catch up. Some research shows that this happens with the common cold  
120 coronavirus E229 (Eguia et al. 2021).

121 Individuals injected with COVID-19 vaccines might also have difficulty developing normal, broad  
122 immunity, even after multiple encounters with SARS-COV-2. As predicted by the original antigenic sin  
123 effect, their immune reaction to the virus will be directed against its spike. They might remain in  
124 jeopardy even after overcoming moderate COVID-19, and might get it multiple times per season, with or  
125 without ADE.

126 The detrimental vaccine effects described above apply to people naïve to SARS-COV-2. Individuals who  
127 acquired natural immunity by infection or exposure to SARS-COV-2, prior to vaccination, may do better.  
128 Of course, those individuals had already developed broad and robust immunity to SARS-COV-2 and did  
129 not need the vaccination.

130 It is considered impossible to distinguish ADE from ordinary severe COVID-19 (Arvin et al. 2020), especially  
131 because neutralizing and enhancing antibody activities compensate for each other (Wang and et al. 2016).

#### 132 **Expected COVID-19 Wave**

133 A new COVID-19 wave, in the Northern Hemisphere, will likely start in the fall this year. This is when the  
134 antibody immunity of the first vaccinated persons will wane. Additionally, coronavirus season (cold and

135 flu season) kicks in. The emergence of more dangerous SARS-COV-2 variants can bring the new wave  
136 even sooner.

### 137 **Children**

138 Children 12-15 are expected to be impacted especially hard by the COVID-19 vaccines, due to higher  
139 reactivity of their immune systems. A Pfizer study has shown 1.76 higher antibody titers in this age  
140 group compared with 16–25 year-olds <sup>(FDA re-Amendment 2021)</sup> (Table 9). Some research suggests that the  
141 COVID-19 vaccines could possibly interfere with the development of immunity to common cold  
142 coronaviruses. This risk is totally unjustified. Very few persons <18 develop severe COVID-19, and 84% of  
143 them have obesity or other known chronic conditions <sup>(Preston et al. 2021)</sup>.

144 Suspected ADE from COVID-19 vaccines, especially spike protein-based ones, was explicitly linked to the  
145 Multisystem Inflammatory Syndrome in Children (MIS-C) <sup>(Rothan and Byrareddy 2021), (Ricke 2021), (Lawrensia et al.</sup>  
146 <sup>2020)</sup>.

147 A recent study suggests interference of the COVID-19 vaccines with the immune reaction to common  
148 cold coronaviruses <sup>(Amanat et al. 2021)</sup>. Some 12-year-olds, who have not developed natural immunity to all  
149 four common cold coronaviruses, might be unable to develop it because of the original antigenic sin  
150 with the anti-spike vaccine.

### 151 **Regulatory Concerns**

152 Concerns about ADE/VAED potential of COVID-19 vaccines have been expressed by scientists prior to  
153 the emergency use authorization <sup>(Hellerstein 2020), (Garber 2020), (FDA re-Guidance 2020)</sup>, in time of the vaccines review,  
154 and are included in the EUA documents in the US and EU. The EMA (EU counterpart of the FDA) took  
155 note of serious concerns about decreasing neutralization by antibodies, leading to ADE/VAED in both  
156 Pfizer <sup>(EMA re-Pfizer 2021)</sup> and Moderna <sup>(EMA re-Moderna 2021)</sup> vaccines. The regulators acknowledged that they  
157 could not resolve those concerns. This was recognized as the top risk in the FDA's *EUA for an*  
158 *Unapproved Product* <sup>(FDA re-Pfizer 2020)</sup> :

159 *“risk of vaccine-enhanced disease over time, potentially associated with waning immunity,*  
160 *remains unknown and needs to be evaluated further in ongoing clinical trials and in*  
161 *observational studies that could be conducted following authorization and/or licensure”*

162 This language was repeated in the May 10, 2021, in expansion of this *EUA for an Unapproved Product* for  
163 the ages 12-15 <sup>(FDA re-Amendment 2021)</sup>, without referencing any clinical trials or observational studies that  
164 could ameliorate this risk. As of June 4, 2021, no such trials or studies could be found in the literature.

165 The showing that ADE does not happen within two months from the vaccination is insufficient.  
166 Remarkably high antibody titer, elicited by the vaccine, neutralizes SARS-COV-2. But even then, reduced  
167 efficacy against new variants was observed. The real question is what happens when antibody immunity  
168 wanes (in 6-9 months) and the individual is exposed to SARS-COV-2.

169

170 It seems such studies were not performed, despite the EUA’s instructions to do so, or yielded results  
171 that the interested parties did not want to make public. There is a considerable political pressure to  
172 vaccinate as many people as possible, which makes it hard to report any adverse results about the  
173 COVID-19 vaccines.

#### 174 **Unresolved Concerns Mean Trouble**

175 On June 4, 2021, PubMed returned 0 results for the search (COVID + VAED) (query  
176 <https://pubmed.ncbi.nlm.nih.gov/?term=COVID+VAED&sort=date>). PubMed returned only five results  
177 for the search (“vaccine enhanced disease” + COVID), only one of which was relevant. It stated that “*no*  
178 *evidence of vaccine-enhanced disease have been reported*” without citing any clinical trials or  
179 observations (Lombardi et al. 2021). It also repeated talking points of the vaccine manufacturers, like efficacy in  
180 the first 100 days after vaccination. Searches for (COVID + vaccine + ADE) and (COVID + vaccine +  
181 “antibody dependent”) yielded many results, none of which were relevant to vaccinated individuals’  
182 chances of developing ADE six months after vaccination.

183 Pfizer and Moderna conducted large scale vaccine trials in the summer 2020. They could or should have  
184 followed up with the vaccinated volunteers to see how they did in the January-February wave of COVID-  
185 19. They have incentives to show the world that their vaccines protect for more than six months and do  
186 not cause ADE. Such papers could not be found. In this case, no good news is bad news.

187 The issue of ADE/VAED was raised in multiple letters from scientists, such as Wodarg – Yeadon Petition  
188 to EMA (Wodarg and Yeadon 2020), without a satisfactory resolution.

189 Pfizer CEO Albert Bourla acknowledged the likely need for a third booster shot within 12 months (CNBC  
190 2021), followed by annual booster shots (NBC News 2021) for the recipients of the Pfizer vaccine. It also sounds  
191 as acknowledgement of ADE/VAED. There is no evidence that such booster shots will work as intended,  
192 and there is not enough time to trial them.

193 Explicit disclosure of the risk of ADE to COVID-19 vaccine recipients before obtaining informed consent  
194 (Cardozo and Veazey 2020) was recommended. Despite this recommendation, ADE risks are not disclosed in the  
195 FDA-approved vaccine Fact Sheets (FDA re Fact Sheet 2021). The absence of benefits for adolescents and the  
196 many existing treatment alternatives are also not disclosed.

197 There are other issues, such as damage with the spike protein, generated by the body in response to  
198 the vaccine (Alexander 2021), which are out of the scope of this paper.

#### 199 **Conclusions**

200 All the above-described risks and potential long-term effects inform the public to stop vaccinating  
201 children and teenagers (<18) and to fully disclose all vaccine risks and existing alternatives to all  
202 recipients. The required disclosures should include the fact that the current COVID-19 vaccines target

203 the original Wuhan coronavirus and that the currently circulating variants are much different and  
204 partially vaccine resistant.

205 Recommended action is to treat symptomatic patients early <sup>(McCullough and et al. 2020)</sup> with antivirals (like  
206 Ivermectin + Hydroxychloroquine + Azithromycin/Doxycycline + Zinc) and treatment adjuvants (vitamin  
207 C, possibly melatonin etc.). Early antiviral treatment <sup>(McCullough 2021)</sup> will also slow down the evolution of  
208 the coronavirus. SARS-COV-2 is unlikely to develop resistance to a triple or quadruple cocktail.

209 Live unattenuated virus vaccine (LUV) may be a better option <sup>(Chen 2021)</sup> against SARS-COV-2. An  
210 individually selected dose of the coronavirus might be administered intranasally, followed by antiviral  
211 treatment against COVID-19. It would contain a single variant, selected to be up to date and to have a  
212 low virulence. Of course, such treatment must be carefully designed and clinically tested.

213

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