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Short Communication

COVID-19 Vaccination would be more Hazardous than Disease itself in 30 Out of 58 Countries -

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COVID-19 damaged severely worldwide, and many researchers have been searching and developing effective treatments and vaccines to control SARS-CoV-2. Pfizer vaccine and Moderna vaccine are renowned COVID-19 vaccines which use nanoparticle-encapsulated mRNA (BNT162b2 or mRNA-1273, respectably), and vaccines of Johnson & Johnson and AstraZeneca use replication-defective adenovirus vector (human adenovirus or simian adenovirus, respectably) [1]. Effectiveness of protecting COVID-19 infection was known as 95% by Pfizer vaccine [2], 94.1% by Moderna vaccine [3], 90% by the 1st dose and 100% by the 2nd dose of Johnson & Johnson COVID-19 vaccines [4], and 70.4% by AstraZeneca (58.9% against asymptomatic infection) [5]. In the long-run, all of these vaccines introduce S1 subunit of the SARS-CoV-2 spike protein, which contains the Receptor Binding Domain (RBD) that is able to bind ACE2 [6], into the human body whether by nanoparticle-encapsulated mRNA or by adenovirus vector and help to make antibodies to the S1 subunit of the coronavirus. Existing data suggested that COVID-19 vaccines might be instrumental in protecting lives and reducing spread of the disease: it is well suggested that the benefits of vaccines outweigh the risks [7].

Here are caveats. In experimental mice, S1 subunit of the SARS-CoV-2 spike protein easily penetrated BBB (blood-brain barrier) to elicit inflammatory changes and S1 toxicity in the brain [8], which could cause encephalitis, respiratory difficulties, and anosmia in humans [9], and S1 subunit was distributed in the lung of the experimental mice [8], which could be related with a cytokine storm in humans. Circulating S1 subunit of the COVID-19 spike protein, which was found in the brain and heart, might cause multifocal microvascular injury in the brain parenchyma, dysfunctions of Vesicular Monoamine Transporter 2 (VMAT2) [10] and/or of olfactory bulbs, and/or of myocardium to cause myocarditis, myocyte necrosis (11/14, 78.6%), and myocardial infarction (3/14, 21.4%) in experimental mice [11] Above problems, that are related not with intact SARS-CoV-2 but with only S1 subunit of spike protein of SARS-CoV-2, were not evaluated in the safety trials of COVID-19 vaccines. Nor Vaccine-associated Thrombocytopenia, which caused a death of the 56-year-old Florida doctor and several dozen of VAERS (Vaccine Adverse Event Reporting System) reports, were studied or expected in the safety trials. Nor did the safety trials expect those incidental deaths of elderly after COVID-19 vaccinations even they survived and recovered from previous COVID-19 [12]. Nor any vaccine trials expected that coincidental 12,400 cases of positive conversion of COVID-19 after COVID-19 vaccinations [13]. Millions of soldiers received COVID-19 vaccinations because they had an oath to follow orders, and many of them had PTSD (Post-Traumatic Stress Disorders) before vaccinations. Chronic PTSD persons were known to have excessive immune responses after vaccinations and conversely, persons who have high levels of inflammatory cytokines have a tendency to get PTSD after a trauma [14]. This means that PTSD could be occurred after COVID-19 vaccinations, for example a person cried after a COVID-19 vaccination as "They've Killed God; I Can't Feel God; My Soul is dead" [15]. In addition, not all vaccine-related events might be identified by the vaccine safety tests, and VAERS did not enclose more than 1% of the real occurrences of vaccine-associated adverse events [16]. Because there have been contracts that COVID-19 vaccines companies should be immune from any liabilities for any possible injures from the COVID-19 vaccinations, nations are advised to take care of persons with vaccine-associated injuries, disabilities, and PTSD patients.

CDC (Center for Disease Control and Prevention) said "*Everything is going well*" when Vaccine Adverse Event Reporting System (VAERS) website of the CDC showed that 329 reported deaths worldwide after COVID-19 vaccinations and 9,516 injuries [17]. But probable causal associations between Pfizer/Moderna vaccines and some of the deaths cannot be ruled out based on compatible allergic symptoms and temporal relations. The safety report regarding systemic events by the BNT162b2 mRNA Pfizer vaccine were not shown by numeric letters but shown by bar graphs, but it showed that there were 3.11-fold systemic events in the 2nd dose of Pfizer vaccine than those of the 1st (Fatigue: 36 *vs* 14, Headache: 28 *vs* 8, Chills: 31 *vs* 8, Muscle Pain: 29 *vs* 10, Joint Pain: 17 *vs* 5, Total: 141 *vs* 45 or 311% increase) [2]. The safety report of the mRNA-1273 SARS-CoV-2 Moderna vaccine showed systemic adverse events of 12.7% at the first dose (54.9% in vaccinee - 42.2% in placebo) and of 42.9% at the second dose (79.4% in vaccinee - 36.5% in placebo) [3], which means that the frequency of the sequelae would be increased by 3.38-fold in the second COVID-19 dose compared to that of the first dose. In addition, the efficacy and safety tests enrolled 30,420 volunteers but 1,137 persons of the treatment group (*vs* 1,076 of the control group) did not finish the protocol [3]. Cohort 1a (persons aged between 18 and 30 years) of Johnson & Johnson vaccine (or Ad26.COV2.S Covid-19 Vaccine) trial showed 9% adverse events at 1st and 55% at the 2nd low dose, 20% at 1st and 58% at the 2nd high dose [4]; thus 2nd dose showed 3.89-fold adverse events than that of the 1st dose. Safety data of the AstraZeneca vaccine were vague to understand and were not included in this report. In short, the mean increase of adverse event of the three kinds of vaccines was 3.46-fold (or 4.64 deaths/100,000 vaccinees/6 weeks: 3.11-fold by BNT162b2 Pfizer vaccine, 3.38-fold by mRNA1273 Moderna vaccine, and 3.89-fold by Ad26.COV2.S Johnson & Johnson vaccine) in the 2nd dose than the 1st dose of 1.3 accidental deaths/100,000 vaccinees/6 weeks, but the durations of follow-up and the maximum observation periods of all four kinds of vaccines were less than 4 months, which were too short to observe long-term effects of COVID-19 vaccines such as the impacts of S1 subunit of the SARS-CoV-2 or of microvascular injury/microthrombi on the brain parenchyma, the VMAT2 function, the olfactory bulb, the lung, and the myocardium, or of psychological damages such as vaccine-associated PTSD.

In the United States of America, 285 persons died after COVID-19 vaccinations among 22 million vaccines [17]. This means 1.3 accidental deaths/100,000 COIVD-19 vaccinees (285 deaths/22 million vaccinees in the United States) from December 14, 2020 to January 22, 2021 (for 6 weeks). From this result, we may infer that the coincidental death rates after the second dose of COVID-19 vaccinations could reach to 4.64 (or, 1.3 x 3.46) accidental deaths/100,000 COIVD-19 vaccinees for 6 weeks. In this sense, it would be reasonable to abstain from COVID-19 vaccinations for the people of the low-risk countries whose mean death rate of COVID-19 for 6 weeks is less than 4.64 deaths/100,000 persons (or 0.773 deaths/week/100,000 persons).

COVID-19 associated deaths in the United States as of February 3, 2021 was 15.96 deaths/100,000 population for 6 weeks (457,856 deaths among 331,003,000 U.S. population for 55 weeks); in India 1.29 death/100,000 population for 6 weeks (154,742 deaths among 1,380,004,000 population), in France 13.30 death/100,000 population for 6 weeks (77,238 deaths among population of 67,000,000), in Germany 7.99 deaths/100,000 for 6 weeks (58,059 deaths among the population of 83,800,000), in Italy 16.94 deaths/100,000 population

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for 6 weeks (88,845 deaths among population of 60,500,000), in the Republic of Korea (South Korea) 0.32 death/100,000 population for 6 weeks (1,441 deaths/51,300,000 population), and in England 16.43 deaths/100,000 for 6 weeks (95,172 deaths among the population of 66,830,000) [18,19]. Table 1 shows that peoples of 30 countries, who are in the low-risk of less than 4 deaths/100,000/6 weeks (or 4 mean COVID-19 deaths per 100,000 people for 6 weeks), among 58 countries or 44.8% of 5.8 billion (2,624,768,579 persons of 30 countries among 5,853,187,432 persons of 58 countries) may not need to take COVID-19 vaccines because they have much lower probability of dying of COVID-19 than of dying of COVID-19 vaccinations.

It is noteworthy that most of the countries in the low-risk group have been using Hydroxychloroquine (HCQ) in the early stage of management of COVID-19 patients, and most of the countries in the high-risk group were adopting "*Fauci-Hahn Strategy*" in the management of COVID-19 patients—leave PCR(Polymerase Chain Reaction)-confirmed cases untreated in strict quarantine until oxygen supplementation is needed and then admit them into the hospital for the late stage of intensive care [20]. Authors of North America reported negatively significantly more than authors from the rest of the world regarding the effects of the HCQ for COVID-19 treatment (p = 0.003): meta-analysis of 121 studies showed 63% reduction of death by early HCQ treatment (RR 0.37, CI: 029-0.48); 34% improvement in pre-exposure prophylaxis with HCQ (RR 0.66, CI: 0.51-0.85, p = 0.0013), and 36% improvement in post-exposure prophylaxis (RR 0.64, CI: 0.47-0.88, p = 0.006) [21]. Singaporeans were reported to have 51.4% of cross-reactive cellular immunity [22], and Germans 81% [23]: the obvious difference of "mean death rate of COVID-19 per 100,000 people for 6 weeks" between two countries (Singapore, 0.057 *vs* Germany, 7.995) may be mainly caused by using or not-using HCQ for the early treatment of COVID-19 patients.

Newly introduced COVID-19 diagnostic criteria of the WHO [24] may help to reduce both the incidence and transmission rates, and help health-care workers to focus on the true COVID-19 cases who need to be treated. The new diagnostic criteria will not only decrease the case mortality rate and victims of COVID-19 but also will decrease unnecessary terror or horror of worldwide people for COVID-19. Before the new COVID-19 Diagnostic Criteria of the WHO, until now, health-care workers could not participate in the COVID-19 diagnosis area because PCR and politicians played all the part of diagnosis; from now on, PCR results should be an aid for health-care workers to diagnose COVID-19. Health-care workers should participate from the beginning stage of COVID-19 diagnosis and from the identification of the COVID-19 cases to active treatment of COVID-19 patients, and to COVID-19 health policies. Table 1 shows that physicians should discard "*Fauci-Hahn Doctrine*" and asks that health-care workers should treat COVID-19 cases from the beginning with the help of *COVID-19 treatment cocktail* (Vit C + Vit D [negative correlation of r = -0.4378 between COVID-19 death and Vit D concentration, p = 0.05] [25] + Zinc [54% additional reduction in mortality than that of HCQ and Azithromycin, p = 0.002][26] + HCQ [63% reduction of COVID-19 death, p < 0.0001][21] + Azithromycin [71% reduction of hazard ratio including mortality when added with HCQ, p < 0.001] [27,28] or/and ivermectin [53% more reduction of mortality in severe COVID-19 cases than that of HCQ and Azithromycin, p = 0.03] [29].

For the people of the low-risk countries and the people who are reluctant to have COVID-19 vaccines in the middle- or high-risk countries, *COVID-19 prevention cocktail* (Vit C + Vit D, [negative correlation of r = -0.4435 between COVID-19 occurrence and Vit D concentration, p = 0.05] [25] + Zinc + HCQ, [36% prevention in post-exposure conditions, p = 0.006]) [21,28] and/or Ivermectin [two-dose of 300 μg/Kg made 73% prevention of COVID-19 infection, p = 0.00] [30] are recommended because prevention cocktails increase innate immunity to eliminate virions as soon as they come into the human body or as they begin to reproduce in the invaded human body, and help human immune reactions to go to TH1 (T Helper 1) pathway to have virus killing effects and to reduce TH2 (T Helper 2) pathway which can incur cytokine storm [28].

In a November 2020 survey, 60% of Americans said YES and 39% said NO to COVID-19 vaccinations, and those who would not get a COIVD-19 vaccine were skeptical to the Warp Speed process of the vaccine development [31]. Other possible reasons that people are skeptical to and reluctant to get COVID-19 vaccines may include: first, in 30 out of 58 countries, which were in the low-risk of less than 4 deaths/100,000/6 weeks, the hazard of COVID-19 vaccinations is higher than the benefit because COVID-19 vaccines will cause more deaths than the COVID-19 disease itself as seen in the table 1; second, real Case Fatality Rate (CFR) of COVID-19 would not be as high as 3~5% but would be "considerably less than 1% … and akin to those of severe seasonal influenza of approximately 0.1%." [32]; third, general population would have considerable immunity already even before COVID-19 vaccinations as seen in Singapore (51.4%) [22], Germany (81%) [23], and Republic of Korea (South Korea, 60%) [33]; fourth, SARS-CoV-2 has been modifying itself very rapidly and COVID-19 vaccine would be useless in the near future—it is human immunity, not COVID-19 vaccines, that can cope with new lineages of SARS-CoV-2 such as P.1 which came from Brazil and B.1.1.7 from UK [34]; fifth, health providers and people learned to control COVID-19 with sufficient measures including non-pharmacological measures focused on the COVID-19 vulnerable and medications such as Corona prevention cocktail, Corona treatment cocktail, Ivermectin, and Exo-CD24 (95%, 29/30 effective to eradicate cytokine storm of severe COVID-19 cases) [35].

Here are some controversies in the interpretation of the Table 1 and about life-threatening events after COVID-19 vaccinations. First, the COVID-19 data adopted in this report may not represent the true reality of COVID-19 disease in each country: some countries like United States could swollen their real COVID-19 death data as CDC admitted [36], or conversely, some countries like China or Cambodia could hid their real death data. If countries in the middle-risk or high-risk have cooked COVID-19 related deaths by 4-fold (in the middle-risk) or 6-fold (in the high-risk), the COVID-19 vaccines would be unnecessary. Second, the data presented here are not fixed or permanent ones. According to the changes of treatments and prevention methods, the death rate will change and then the policy of COVID-19 vaccination should be changed. Even the countries grouped as high-risk can reduce their COVID-19 death rate if they adopt using HCQ and/or ivermectin and/or Exo-CD24 in the prevention and treatment of the COVID-19. Third, the 95% of Pfizer vaccine effectiveness was questioned and the possible vaccine efficacy was suggested as 19% or 29%, which are far below the 50% effectiveness threshold for an emergency use authorization for COVID-19 vaccines [37]. If the benefit of COVID-19 vaccine is negligible, then the hazard of that vaccine would be enormous, and then COVID-19 vaccination would be more hazardous than disease itself in 58 out 58 countries in the Table 1. Fourth, only deaths data of the VAERS were considered here, but there are 3- to 30-fold other

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Table 1: COVID-19 vaccination is more hazardous than disease itself in 30 out of 58 countries. Mean death rate of COVID-19 per 100,000 people for 6 weeks were lower than that of 2nd dose of COVID-19 vaccination in 38 countries out of 58. 1st dose of COVID-19 vaccination in the United States caused 285 lives among 22 million vaccinees (1.3 accidental deaths/100,000 COIVD-19 vaccinees in 6 weeks or 0.2167 incidental deaths/100,000/week as of January 22, 2021. As of Feb 4, 2021, the incidental death became a little elevated than the previous one because the data were collected from people who had received one or both COVID-19 vaccines: 653 deaths among 39.5 million vaccinees was reported, which meant 0.2201 incidental death/100,000/week) [17]. The safety reports of the three kinds of COVID-19 vaccines showed the mean increase of adverse event of 3.46-fold (3.11-fold by BNT162b2 Pfizer vaccine, 3.38-fold by mRNA1273 Moderna vaccine, and 3.89-fold by Ad26.COV2.S Johnson & Johnson vaccine) in the second doses of vaccinations than those of the 1st. This means that the coincidental death rates after the second dose of COVID-19 vaccinations could reach to 4.49 (or 1.3 x 3.46) accidental deaths/100,000 COIVD-19 vaccinees. To have a conservative view, the low-risk group was made less than 4 (instead of 4.49) incidental deaths/100,000/6 weeks, middle-risk as between 4 and 14, and high-risk group as greater than 14. Table 1 shows that 30 countries out of 58 or 44.8% of 5.8 billion people has lower than 4 COVID-19 deaths/100,000 persons in 6 weeks and that the risk of death associated with COVID-19 vaccinations is higher than that of COVID-19 itself in those low-risk countries.

	Low Risk < 4 (n = 30)		4 ≤ Middle Risk ≤14 (n = 19)		14< High Risk (n = 9)	
Mean death rate of COVID-19 per 100,000 people for 6 weeks & country	0	Cambodia	5.604	Lebanon	14.265	Spain
	0.003	Taiwan	5.731	Russia	14.429	Mexico
	0.004	Tanzania	6.285	Greece	15.001	Portugal
	0.037	China	6.391	Canada	15.215	Hungary
	0.057	Singapore	6.595	Israel	15.96	U.S.A.
	0.059	New Zealand	7.993	Iran	16.431	England
	0.07	Cote d'Ivoire	7.995	Germany	16.944	Italy
	0.157	Ghana	9.444	Netherlands	17.661	Czechia
	0.223	Ethiopia	9.754	Ecuador	21.304	Belgium
	0.278	Malaysia	9.965	Austria		
	0.324	Republic of Korea	10.941	Romania		
	0.362	Gabon	11.212	Chile		
	0.379	Kenya	11.256	Poland		
	0.411	Australia	12.237	Argentina		
	0.545	Japan	12.444	Columbia		
	0.556	Bangladesh	12.65	Swiss		
	0.713	Afghanistan	13.293	Sweden		
	0.98	Iceland	13.3	France		
	0.997	Qatar	13.847	Brazil		
	1.032	Arab emirates				
	1.066	Egypt				
	1.108	Moldies				
	1.276	Indonesia				
	1.293	India				
	1.304	Philippines				
	1.426	Finland				
	2.116	Saudi Arabia				
	2.597	Morocco				
	3.642	Turkey				
	3.751	Iraq				

adverse events that could be equivalent sequalae to deaths. Fifth, there is no one who is responsible for the detrimental events after COVID-19 vaccines. Who is going to take care of the COVID-19 vaccine-associated deaths, the PTSD persons, the disabled persons, and the degenerative sequelae such as "Monstrerism", 3 of which occurred in 15,000 vaccinees (0.02%) [38]?

In summary, the COVID-19 vaccine effectiveness was known as 95% by Pfizer [2], 94.1% by Moderna [3], 100% by the 2nd dose of Johnson & Johnson [4], and 70.4% by AstraZeneca [5]. The safety report showed that 3.46-fold accidental deaths (or 4.64 deaths/100,000 vaccinees/6 weeks: 3.11-fold by Pfizer, 3.38-fold by Moderna, and 3.89-fold by Johnson & Johnson vaccine) in the 2nd dose than the 1st dose of 1.3 accidental deaths/100,000 vaccinees/6 weeks, but the duration of observation period was too short to observe long-term effects of COVID-19 vaccines such as the impacts of S1 subunit of the SARS-CoV-2, or of microvascular injury/microthrombi, or of PTSD. Peoples of 30 countries, who were in the low-risk of less than 4 deaths/100,000/6 weeks, among 58 countries or 44.8% of 5.8 billion may not need to take COVID-19 vaccines because they have much lower probability of dying of COVID-19 than of dying of COVID-19 vaccinations. It is noteworthy that most of the countries in the low-risk group have been using HCQ in the early stage of management of COVID-19 patients. Even the countries grouped as high-risk can reduce their COVID-19 death rates if they adopt using HCQ and/or ivermectin and/or Exo-CD24 in the prevention and treatment of the COVID-19, and when the death rate changed, then the policy of COVID-19 vaccination should be changed.

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