Research Article ISSN 2639-9458

Microbiology & Infectious Diseases

Vaccination against COVID-19: Surveillance of Adverse Events in Brazzaville

Yvonne Valerie Yolande Voumbo Matoumona Mavoungou[1], Ange Clauvel Niama[1], Gilbert Ndziessi[1], Ghislain Pandzou[1], Annette Bono[1] and Paul-Macaire Ossou-Nguiet[1]

Faculty of Health Sciences, University Marien Ngouabi, Republic of the Congo.

***Correspondence:**

Yvonne Valerie Yolande VOUMBO MATOUMONA MAVOUNGOU, Faculty of Health Sciences, University Marien Ngouabi, Brazzaville, Republic of the Congo.

Received: 02 Apr 2022; **Accepted:** 25 Apr 2022; **Published:** 30 Apr 2022

Citation: Mavoungou YVYVM, Niama AC, Ndziessi G, et al. Vaccination against COVID-19: Surveillance of Adverse Events in Brazzaville. Microbiol Infect Dis. 2022; 6(2): 1-6.

ABSTRACT

Introduction: *All countries have embarked on vaccinating populations against COVID-19 to reduce the incidence and severe forms of this disease. Several vaccines are used and the risk of occurrence of Adverse Events Following Immunization (AEFI) is not to be neglected. The objective of this study is to describe the AEFI of COVID-19 vaccination in Brazzaville.*

Population and Method: *This was a descriptive cross-sectional study conducted in Brazzaville at all AEFI reporting points of the Expanded Programme on Immunization in the period from March 25th to October 15th 2021. A standardized notification sheet of AEFI cases occurring after vaccination against COVID-19, validated by the WHO, collected the data. These have been analyzed with R Studio software version 4.0.3. Qualitative variables were expressed in numbers and percentages. Quantitative variables were expressed as average, standard deviation, maximum and minimum. Pearson's Chi-2 test and ANOVA's were used to compare variables.*

Results: *The average age of people with AEFI was 46 years ± 12.6 years; men were more affected than women non-significantly (p-value=0.063). AEFI frequencies were 56 per 10,000 people vaccinated. Mild AEFI such as joint and muscle pain (63.07%), headache (59.70%) fever (55.84%) were the most recorded while severe forms were rare. These AEFI appeared most often in the first week of administration of the COVID-19 vaccine and had a favorable evolution in 90.69% of cases.*

Conclusion: *This study revealed that vaccination against COVID-19, can cause AEFI. These are infrequent and in most cases they are mild forms. High vaccination coverage must be a priority objective to better counter the COVID-19 pandemic.*

Keywords

AEFI, Surveillance, COVID-19, Brazzaville.

Introduction

Since its appearance in December 2019 in China, the virus that causes COVID-19 disease, known as SARS-CoV-2, has caused numerous deaths and serious consequences on a global scale [1]. Faced with this global public health challenge, complicated by the appearance of several mutants, the scientific community and global policy makers have mobilised multiple control strategies, including population containment, the closure of land and air borders, and barrier measures, the implementation of which varies [2].

Vaccination against COVID-19 has emerged as the primary response to limit infection, severe disease and mortality from COVID-19. Rapid global deployment of safe and effective

vaccines would contain the pandemic, strengthen health systems, and contribute to the recovery of the world's economies [3,4]. However, efficacy and safety remain the basis for vaccine adoption and widespread use. Thus, in the face of such mass vaccination using a variety of vaccines that have been developed in a very short period of time, it seems essential to address the question of the broad superiority of the expected benefits over the risks incurred by the population by researching post-vaccination effects [5]. In monitoring the safety of the COVID-19 vaccine, WHO and UNICEF report that it is important to record, investigate and report all adverse events following immunization (AEFI) through an administrative surveillance system or household surveys [6].

In Africa and in Congo, very few data are available on post-vaccination manifestations of COVID-19 vaccination. Because of the low literature density on the issue and the need to provide an overview of vaccine vigilance in the context of mass vaccination, the objective of this study is to describe the AEFI related to COVID-19 vaccination in Brazzaville.

Population and methods

Type and period of study

This was a descriptive cross-sectional study conducted from March 25th to October 15th 2021.

Study setting

Our study took place in Brazzaville at the Directorate of the Expanded Programme on Immunisation (EPI) of Congo. The latter has an AEFI surveillance team that records and centralises all data relating to COVID-19 vaccination and notifies all cases of AEFI.

Study population

This study focused on the use of the records of all persons vaccinated against COVID-19 who reported one or more cases of AEFI in Brazzaville.

Selection criteria

Inclusion criteria: Our study included people over 18 years of age, vaccinated against COVID-19, who reported one or more AEFI during the study period.

Non-inclusion criteria: Individuals whose symptoms reported as AEFI started before vaccination were not included in the study.

Sampling

This was an exhaustive sampling of all individuals who reported at least one case of AEFI during the study period.

Data collection

The data collection tool was a WHO-validated standardised adverse drug reaction reporting form.

Operational definition

In our study an AEFI is defined as any adverse event occurring after vaccination, which is not necessarily related to the use of the vaccine. It may be a syndrome complained of by the vaccinated person, an abnormal laboratory result, a sign or disease detected by the physician. It is considered serious when it requires hospitalisation or prolongs its duration, is life-threatening, results in death, persistent disability or incapacity, or is a congenital anomaly [7].

Data entry, processing and analysis

Data entry was carried out using ODK software. Data processing and statistical analysis was done using R Studio version 4.0.3. The qualitative variables were expressed in numbers and percentages. Quantitative variables were expressed as mean, standard deviation, maximum and minimum. Chi-2 and ANOVA tests were used to make comparisons, with a significance level of 5%.

The variables considered were: individual characteristics of the respondents (age, sex, medical history, type of vaccinations received, severity of AEFI); type of symptoms reported, evolution of the AEFI (death or remission).

Ethical considerations

We obtained administrative authorisation from the authorities of the Faculty of Health Sciences, the Director of the Expanded Programme on Immunisation (EPI) and the person in charge of coordinating anti-COVID-19 vaccination activities in the Republic of Congo. Confidentiality and anonymity were required throughout this study.

Results

During the study period going from March 25th to October 15th 2021, four types of vaccines were used: Sinopharm and Sputnik V administered in two doses each, and Sputnik light and Janssen administered in one dose each. A total of 178,468 people were vaccinated, of whom 1,010 cases of AEFI, i.e. 56 cases per 10,000 people vaccinated, were reported and included in this study.

Characteristics of the vaccinated persons who reported AEFI

According to the individual variables considered, the distribution of cases of AEFI is as follows (Table 1).

Table 1: Characteristics of vaccinated persons who reported AEFI.

Variables	N=1010	Percentage (%)
Age		
18-45	380	37.6
> 45yrs	630	62.4
Sexe		
Male	773	76.5
Female	237	23.5
Vaccines		
Sputnik light	63	6.2
Sinopharm	601	59.5
Sputnik V	221	21.9
Janssen	125	12.4
Previous Medical History		
Yes	144	14.3
No	866	85.7
Gravity		
Yes	20	2.0
No	990	98.0

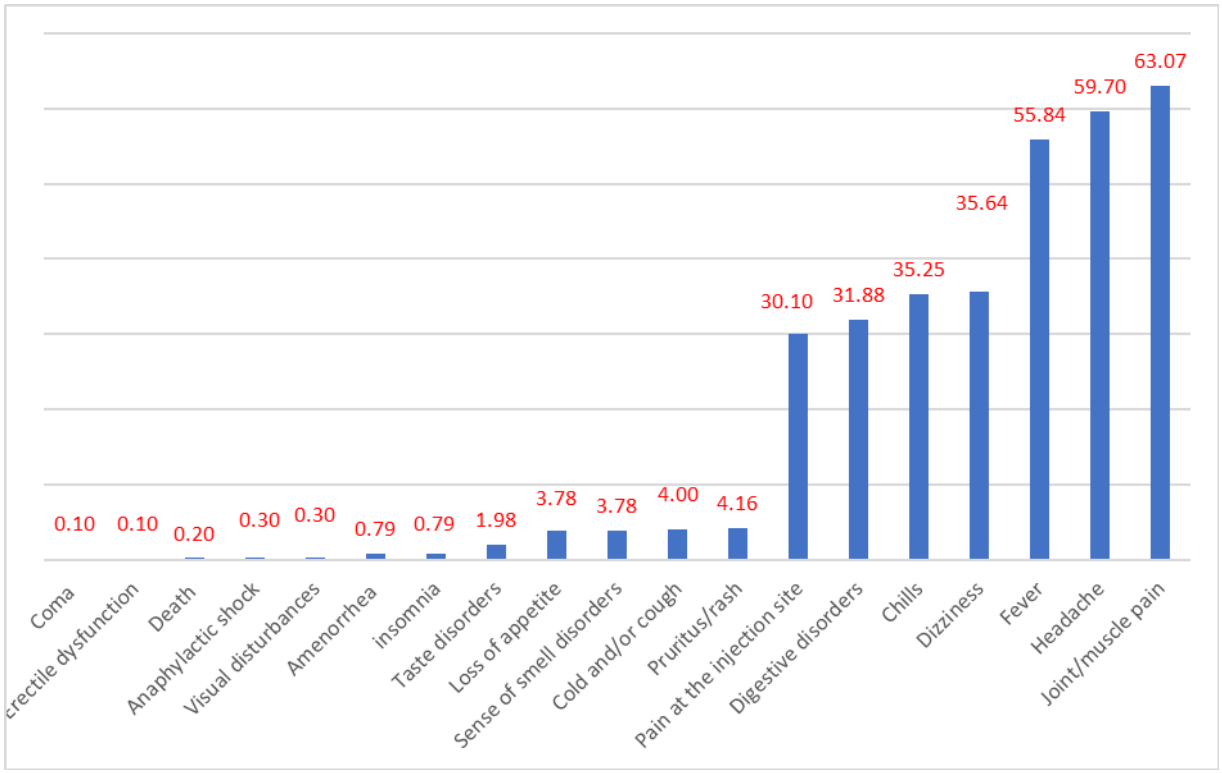

Figure 1: Reported post-immunization adverse events.

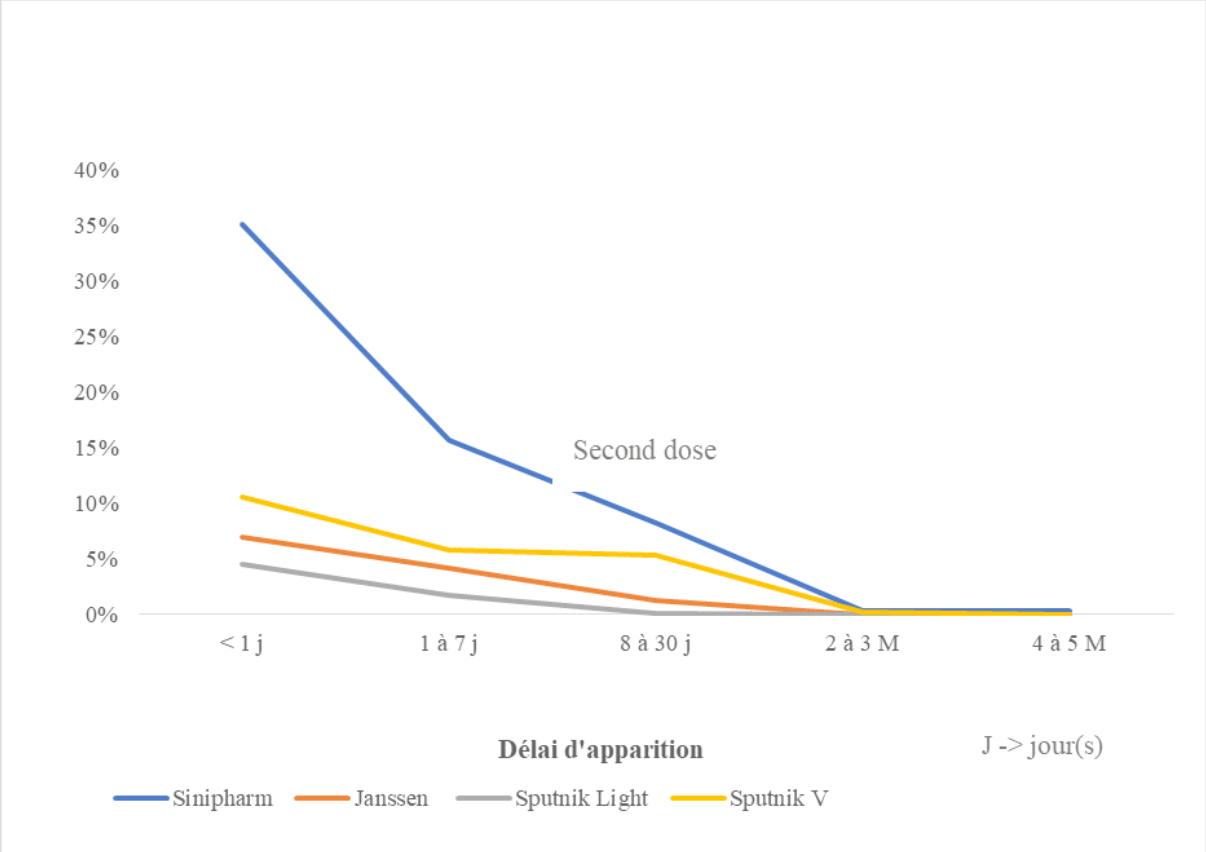

Figure 2: Time to onset of AEFIs by type of vaccine.

The majority of those vaccinated were over 45 years of age (62.4%); the average age of all those vaccinated was 46 ± 12.6 years, ranging from 18 to 96 years. A predominance of males (76.5%). The most commonly used vaccine was Sinopharm (59.5%), followed by Sputnik V (21.9%). Only 14.3% of the cases had medical doctors and in 98% of the cases there was no notion of severity.

The symptoms of recorded AEFI

In our study, the symptoms that were recorded as AEFI reported by the respondents are presented in Figure 1.

Joint or muscle pain (63.07%), headache (59.70%), fever (55.84%), dizziness (35.64%), chills (35.25%), digestive disorders (31.88%), injection site pain (30.10%) and pruritus or rash (4.16%) were the most reported AEFI.

Timing of onset of AEFI according to vaccine type

In general, for all vaccines, AEFI are reported within the first week, from the first day of covid19 vaccination. The MAPI signalling curve decreases over time, with no MAPIs reported after 3 months as shown in Figure 2 below.

Presentation of AEFIs by age and type of vaccines

The average age as well as the extreme ages of people who presented with AEFI varied according to the type of vaccine received as presented in Table 2.

Table 2: Type of vaccines used according to age.

Vaccines	Age (years)			
	Mean	Ecart type	Minimum	Maximum
Sinopharm dose 1 (n=439)	45	12.7	18	96
Sinopharm dose 2 (n=162)	43	12.5	18	79
Sputnik V dose 1 (n=203)	47	12.7	18	82
Sputnik V dose 2 (n=18)	45	13.0	18	76
Sputnik light (n=63)	51	12.7	18	67
Janssen (n=125)	44	11.8	18	72
Global	**46**	**12.6**	**18**	**96**

The ANOVA test shows that there is no significant difference statistically between the different age groups (p-value= 0.6814).

Distribution of registered cases of AEFI by sex and type of vaccine

Table 3 below shows that, overall the proportion of men who suffered from AEFI (63.7%) is higher than that of women (36.73%), and this finding is the same regardless of the type of vaccine received.

Table 3: Type of vaccines used according to gender.

Vaccins	Male		Female		Ratio
	n	%	n	%	H/F
Sinopharm dose 1 (n=439)	269	61.27	170	38.72	1.58
Sinopharm dose 2 (n=162)	101	80.16	61	19.84	1.65
Sputnik V dose 1 (n=203)	146	71.92	57	28.08	2.56
Sputnik V dose 2 (n=18)	12	66.67	6	33.33	2.00
Sputnik light (n=63)	39	62.00	24	38.00	1.62
Janssen (n=125)	72	57.77	53	42.23	1.36
Total	**639**	**63.27**	**371**	**36.73**	**1.72**

The observed difference is not statistically significant (p-value =0.063).

II-3 Evolution of AEFI according to the vaccines used

The reporting of AEFI was done within a maximum of one week after the date of onset, the evolution of AEFI during this period is described in Table 4.

Table 4: Evolution of AEFI according to the type of vaccine.

Vaccines	Remission		Death		Unknown	
	n	(%)	n	(%)	n	(%)
Sinopharm dose 1 (n=439)	412	(93.85)	0	(0,00)	27	(6.15)
Sinopharm dose 2 (n=162)	134	(82.72)	1	(0,62)	27	(16.67)
Sputnik V dose 1 (n=203)	196	(96.55)	0	(0,00)	7	(3.45)
Sputnik V dose 2 (n=18)	15	(83.33)	1	(5,56)	2	(11.11)
Sputnik light (n=63)	58	(92.06)	0	(0,00)	5	(7.94)
Janssen (n=125)	101	(80.80)	0	(0,00)	24	(19.20)
Total	**916**	**(90.69)**	**2**	**(0,20)**	**94**	**(9.31)**

Of the 1010 people who reported AEFI, 90.69% were cured, 0.20% had died, and 9.31% had no follow-up.

The evolution was favourable with spontaneous remission in 622 (67.89%) of the people, 233 (25.44%) had taken an analgesic, 61 (6.67%) had consulted a health professional (doctor or nurse).

Of these, only 47 people had received treatment for malaria after a diagnosis had been made and confirmed by a thick drop.

Discussion

Methodological interest

Our study concerned vaccinated individuals who had experienced post-vaccination effects over a period of six months after vaccination. The methodology adopted in our study enabled us to carry out an exhaustive recruitment in order to better specify the characteristics of the AEFI and to reduce as much as possible the various selection biases.

Sociodemographic characteristics

The average age of the people who presented with AEFIs, all vaccines combined, was 46 ± 12.6 years. This result is higher than that found by Dziedzic et al. in Poland, who reported in their study that cases of AEFI were increased in people under 29 years of age [8].

In terms of gender, the high proportion of males (64%) with AEFI is consistent with trends observed in reports from the national COVID-19 vaccination system. The latter indicates that in Brazzaville, people over 45 years of age and men are more likely to be vaccinated than women; the difference was not statistically

significant [9], which would explain the large number of cases of AEFI in this group of people vaccinated.

This finding is contrary to that made in Poland by Dziedzic et al. who found in their study a predominance of women (79.8%) among the vaccinated subjects [8]. The trend towards feminisation of the medical profession [10], could explain this difference with the Polish data where the study was carried out among health care workers.

Incidence of AEFIs

Our study showed an overall prevalence of 56 mild AEFIs per 10,000 vaccinated persons, of which 1.98% were severe cases. This is in line with the low proportions of AEFI observed worldwide, the frequency of which seems to be homogeneous in all countries. In France, the National Agency for the Safety of Medicines and Health Products recorded 0.11% of post-vaccine events [11]. The difference observed with the data from our study could be explained by the fact that the number of people vaccinated is much greater in France, and the vaccines used are not the same in the two countries.

In the Republic of Congo, AEFIs are more frequent for the Sinopharm and Sputnik V vaccines. These findings could be explained by a large number of vaccinees for Sinopharm. On the other hand, it is possible that the second dose effect induces psychological effects that may be difficult to isolate following the administration of Sputnik V and Sinopharm.

However, both vaccines showed a higher frequency of AEFI with the first dose (9 per 1000 vaccinated persons for Sinopharm and 18 for Sputnik V) than with the second dose (4 per 1000 vaccinated persons for Sinopharm and 2 per 1000 for Sputnik V). Anderson et al. describe the opposite, as their work shows that post-vaccination events are more frequent with the second dose. In addition, the number of severe cases increased with the second dose of the mRNA vaccine [12], which is not used in the Republic of Congo.

Paradoxically, the first dose of Sputnik V, equivalent to Sputnik light, showed more AEFI. This could confirm the hypothesis of the psychological effect of the second dose. The alternative of a single-dose regimen would be more reassuring to the population and would limit stress or anxiety than a two-dose regimen.

Description of the different AEFIs

The most frequently recorded AEFIs were muscle and joint pain (63.07%), headache (59.70%), fever (55.84%), and injection site pain (30.10%). These most frequent results [13] corroborate those of Logunov et al. in Russia [14] and Zhu et al. in China [15] who found similar manifestations, but at higher proportions. These differences are probably explained by non-identical sample sizes and different methodological aspects. For example, the Zhu et al. study was a non-randomised open-label trial in which participants were required to report any post-vaccination effects [15].

Other manifestations found in our study, including pruritus and skin rash (4.16%), colds sometimes accompanied by cough (4.00%), digestive disorders (31.88%), loss of appetite (3.78%), taste disorder (1.98%) and smell disorder (3.78%) are recognised, but described as infrequent in the summary of characteristics of the Janssen vaccine [13].

In our study some manifestations were very infrequent (<1%) such as insomnia, amenorrhea, erectile dysfunction, hypersensitivity reaction, visual disturbances, death, coma, were recorded hence the interest for further investigation. In Senegal, Traoré et al found that the death recorded after anti-COVID-19 vaccination was due to previous cardiac involvement [7]. In France, the National Agency for the Safety of Medicines and Health Products recorded 21% of serious post-vaccination effects, including deaths, although the vaccines in question were not the same [12].

These findings justify the need for specific additional studies to better understand the side effects of the vaccines used. The WHO indicates that for new vaccines, such as those against COVID-19, additional levels of active surveillance and epidemiological studies are necessary to maximize the effectiveness of passive AEFI surveillance [8].

Time of onset and course of AEFI

The onset of AEFI in our study was more frequent in the first month after vaccination and especially in the first week. Our results are similar to those of Zhu, who describes a greater number of reactions at the one-week interval after vaccination [15].

AEFI mostly progressed to remission (90.69% of cases). Two (02) deaths were recorded and about 8% of the people had signs that persisted after more than one week. AEFI had a generally favourable evolution, which would reassure us about the safety of the vaccines.

Conclusion

This study revealed that cases of AEFI related to the Covid-19 vaccine were recorded after the administration of the different vaccines used in Brazzaville. These post-vaccination effects generally occur during the first day after vaccine administration. They are generally infrequent and usually mild with a high remission rate. Severe AEFI are rare and require further investigation to better understand its causes.

The hypothesis of the safety and harmlessness of the vaccine therefore seems credible. Hence the interest in reinforcing public health communications based on scientific evidence, in order to optimise public confidence in vaccination. This is in the interest of maximising vaccination coverage against COVID-19.

References

1. Eric Heyer T, Heyer É, Timbeau X. Évaluation de la pandémie de COVID-19 sur l'économie mondiale. Rev OFCE. 2020; 166: 59-110.

2. Jidar K, Benabdelmoumen G, Lucet C, et al. Impact de la pandémie à COVID-19 sur les voyages internationaux. Infect Dis Now. 2021; 51: S120- S121.
3. Billon Denis E, Tournier JN. COVID-19 et vaccination: une dérégulation globale. médecine/sciences. 2020; 36: 1034-1037.
4. Sarah Schaffer DeRoo, Natalie J Pudalov, Linda Y Fu. Planning for a COVID-19 Vaccination. JAMA. 2020; 323: 2458-2459.
5. Graham BS. Rapid COVID-19 vaccine development. Science. 2020; 368: 945-946.
6. https://apps.who.int/iris/handle/10665/340477
7. http://revues.ml/index.php/msp/article/view/1903
8. https://www.who.int/fr/publications-detail/global-manual-on-surveillance-of-adverse-events-following-immunization
9. Dziedzic A, Riad A, Attia S, et al. Self-Reported Adverse Events of COVID-19 Vaccines in Polish Healthcare Workers and Medical Students. Cross-Sectional Study and Pooled Analysis of CoVaST Project Results in Central Europe. J Clin Med. 2021; 10.
10. https://www.sante.gouv.sn/
11. Bessière S. Sex, gender and health. Rev Francaise Aff Soc. 2005; 17-33.
12. https://ansm.sante.fr/actualites/point-de-situation-sur-la-surveillance-des-vaccins-contre-la-COVID-19-periode-du-14-01-2022-au-27-01-2022
13. Anderson EJ, Rouphael NG, Widge AT, et al. Safety and Immunogenicity of SARS-CoV-2 mRNA-1273 Vaccine in Older Adults. N Engl J Med. 2020; 383: 2427-2438.
14. https://www.msn.com/fr-fr/lifestyle/trucs-et-astuces/vaccins-COVID-19-quels-sont-les-effets-ind%C3%A9sirables-les-plus-fr%C3%A9quents/ar-AAVXhs5
15. Logunov DY, Dolzhikova IV, Zubkova OV, et al. Safety and immunogenicity of an rAd26 and rAd5 vector-based heterologous prime-boost COVID-19 vaccine in two formulations: two open, non-randomised phase 1/2 studies from Russia. The Lancet. 2020; 96: 887-897.
16. Zhu FC, Li YH, Guan XH, et al. Safety, tolerability, and immunogenicity of a recombinant adenovirus type-5 vectored COVID-19 vaccine: a dose-escalation, open-label, non-randomised, first-in-human trial. The Lancet. 2020; 395: 1845-1854.