Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

Therapie 77 (2022) 371—390

Available online at
SciVerse ScienceDirect
www.sciencedirect.com

Elsevier Masson France
EM|consulte
www.em-consulte.com

LETTER TO EDITOR

Balancing the reactogenicity of the ChAdOx1 nCov-19 vaccine against COVID-19 and the urgent need of a large immunization in healthcare workers

KEYWORDS
Vaccine;
COVID-19;
SARS-CoV-2;
Healthcare workers;
Reactogenicity;
Adverse drug reaction

Abbreviations

COVID coronavirus disease
SARS-CoV-2 severe acute respiratory syndrome coronavirus 2

Among the anti COVID-19 vaccine arsenal, ChAdOx1 nCov-19 vaccine relies on a replication-deficient chimpanzee adenovirus vector containing the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) structural surface spike glycoprotein. The vaccine, administered as two intramuscular injections with a 4—12 week interval, has been approved in the UK on 30 December 2020, and across the European union on 29 January 2021 [1,2]. Safety and efficacy have been demonstrated across four clinical trials among adult population [3,4]. In an interim analysis, adverse events and especially serious ones were balanced between groups. Among the vaccinated population, authors report two cases of transverse myelitis, including one possibly related to the vaccine, and one case of high fever (above 40 °C) that recovered spontaneously [3]. However, local and systemic transient reactogenicity was very common, with fatigue reported in more than 50% of participants, and headache and malaise in up to 40% [5]. In the European product information, the most frequently noted symptoms included injection site tenderness or pain (respectively 64 and 54%), headache (53%), fatigue (53%), myalgia (44%), pyrexia [including feverishness (34%) and fever >38 °C (8%)], chills (32%) and arthralgia (26%) [2]. We report here our preliminary experience on the first days of healthcare workers massive immunization in a University hospital with ChAdOx1 nCov-19 vaccine.

We implemented the vaccination of healthcare professionals with ChAdOx1 nCov-19 vaccine in our 903-bed University hospital on 9th February 2021. All vaccinated healthcare professionals have been contacted by phone the third day after receiving the vaccine. Among the 68 persons (median age 34 [IQR 29—42] years) who were first vaccinated (batch number ABV 3025, expiration date May 2021), 54 (79%) reported adverse reactions compatible with systemic reactogenicity (Table 1). Typical presentation consisted in severe flu-like syndrome lasting from 1 to 3 days. Importantly, 32 professionals (47%) reported more than three different marked symptoms, that led to sick leave in 25 (37%). Seven reported fever $\geq$ 39 °C (10%) and two reported hallucinations/delirium. None required in-hospital management. No association with sex, medical history, or previous report of COVID-19 and reactogenicity severity was found. Since the implementation of the ChAdOx1 nCov-19 vaccine in France, similar observations were reported across the country to the French Pharmacovigilance Network [6]. These observations lead the French Medicines Agency to raise a possible safety signal shared with the European Medicine Agency [7]. This possible safety signal does not alter the very substantial benefit-risk balance of the ChAdOx1 nCov-19 vaccine).

While vaccination is central instrumental to control the SARS-CoV-2 pandemic, this report highlights that the reactogenicity profile of the vaccine should be part of the equation when implementing large scale vaccination of healthcare professionals. Unlike mRNA vaccines, local reactions were not very common in our study [8]. Hence, local reactions were reported in up to 75.2% in mRNA vaccinated and in only 15% of our healthcare worker cohort vaccinated with the ChAdOx1 nCov-19 vaccine. On the opposite, systemic reactions were more frequent in our cohort. For instance, fever was reported in 47% of the healthcare workers receiving the vaccine, compared to 8.6% with a first dose of mRNA vaccine, in a population-based study [8]. Foremost, in our cohort, such systemic reactogenicity led to sick leave in more than one third of the vaccinated. This issue should be taken into account to address the paramount needing of rapidly protecting our professionals while maintaining the operation of high-demand services as the pandemic continues to unfold.

Contributors

LC and CC designed the study, performed statistical analysis and drafted the paper. EC and ACo collected the data. RB, ACa and JMT critically reviewed the paper. All the authors approved the final version of the paper. The corresponding author attests that all listed authors meet authorship

Table 1 Cohort presentation.

	Vaccinated professionals (N = 68)	Vaccinated professionals without adverse reactions (N = 14)	Vaccinated professionals with adverse reactions (N = 54)		
			Overall (N = 54)	Adverse reactions leading to sick leave (N = 25)	Adverse reactions without sick leave (N = 29)
Median age—years	34	34	34	34	34
[Interquartile range]	[29—42]	[29—42]	[29—42]	[28—41]	[29—42]
Sex male: female	22:46	4:10	18:36	10:15	8:21
Comorbidities (N =)					
None	59/68 (87%)	10/14 (71%)	49/54 (91%)	22/25 (88%)	27/29 (93%)
1	7/68 (12%)	3/14 (21%)[a]	4/54 (9%)[b]	3/25 (16%)[c]	1/29 (3%)[d]
2+	2/68 (3%)	1/14 (7%)[a]	1/54 (2%)[b]	0[c]	1/29 (3%)[d]
Past history of COVID-19	6/68 (9%)	0	6/54 (11%)	2/25 (8%)	4/29 (14%)
Systemic reactogenicity					
Systemic symptoms—*n*	53/68 (78%)		53/54 (98%)	23/25 (92%)	29/29 (100%)
No symptom	3/68 (4%)		3/54 (6%)[h]	2/25 (8%)[h]	1/29 (3%)[h]
1 symptom	11/68 (16%)		11/54 (20%)	3/25 (12%)	8/29 (28%)
2 symptoms	8/68 (12%)		8/54 (15%)	7/25 (28%)	1/29 (3%)
3+ symptoms	32/68 (47%)		32/54 (59%)	13/25 (52%)	19/29 (66%)
Type of symptoms—*n*[g]					
Fever	32/68 (47%)		32/54 (59%)	18/25 (72%)	14/29 (48%)
Fatigue	27/68 (40%)		27/54 (50%)	11/25 (44%)	16/29 (55%)
Headache	18/68 (26%)		18/54 (33%)	6/25 (24%)	12/29 (41%)
Myalgia/arthralgia	34/68 (50%)		34/54 (63%)	16/25 (64%)	18/29 (62%)
Chills	31/68 (46%)		31/54 (57%)	16/25 (64%)	15/29 (52%)
Other[e]	5/68 (7%)		5/54 (9%)	4/25 (16%)	1/29 (38%)
Duration					
One day	31/68 (46%		31/54 (57%)	12/25 (48%)	19/29 (66%)
Two days	19/68 (28%)		19/54 (35%)	10/25 (40%)	9/29 (31%)
Three days	3/68 (4%)		3/54 (6%)	3/25 (12%)	0
Local reactogenicity[f] (*N* =)	10/68 (15%)		10/54 (19%)	4/25 (16%)	6/29 (21%)

Data are presented as median [interquartile range] or *n* (%). COVID-19: coronavirus disease 2019.
[a] Comorbidities included: type 2 diabetes (N = 2), and hypertension, cardiac disease, and pituitary adenoma (N = 1, each).
[b] Comorbidities included: hypothyroidism (N = 2), including one with obesity, hypertension, past history of preeclampsia, asthma (N = 1, each).
[c] Comorbidities included: hypertension, past history of preeclampsia, and asthma (N = 1, each).
[d] Comorbidities included: hypothyroidism (N = 2), including one with obesity (N = 1, each).
[e] Other symptoms included tachycardia, paresthesia, neck stiffness, hallucinations and dizziness (N = 1, each).
[f] Local reactogenicity consisted in local pain or erythema at injection site.
[g] Total number of symptoms exceeds total number of patients.
[h] These professionals have only local reactogenicity symptoms.

criteria and that no others meeting the criteria have been omitted.

Ethical approval

This research was found to be in conformity with the French regulations by the local Ethical Review Committee and has been approved under the number 2021-08009. In line with the French law, these individual case safety reports have been reported anonymously to the National Pharmacovigilance Database.

Acknowledgments

The authors would like to thanks to all the health-care workers and the French Pharmacovigilance Network involved in large immunization campaign and in its safety monitoring [6].

Disclosure of interests

The authors declare that they have no competing interests.

References

[1] Medicines Healthcare products Regulatory Agency (MHRA). Oxford University/AstraZeneca COVID-19 vaccine approved. GOVUK; 2020, https://www.gov.uk/government/news/oxford-universityastrazeneca-covid-19-vaccine-approved [Accessed 22 July 2021].

[2] Europan Medicines Agency (EMA). EMA recommends COVID-19 Vvaccine AstraZeneca for authorisation in the EU. Eur Med Agency 2021, https://www.ema.europa.eu/en/news/ema-recommends-covid-19-vaccine-astrazeneca-authorisation-eu [Accessed 22 July 2021].

[3] Voysey M, Clemens SAC, Madhi SA, Weckx LY, Folegatti PM, Aley PK, et al. Safety and efficacy of the ChAdOx1 nCoV-19 vaccine (AZD1222) against SARS-CoV-2: an interim analysis of four randomised controlled trials in Brazil, South Africa, and the UK. Lancet 2021;397(10269):99—111.

[4] Deplanque D, Launay O. Efficacy of COVID-19 vaccines: From clinical trials to real life. Therapies 2021;76(4):227—83, http://dx.doi.org/10.1016/j.therap.2021.05.004.

[5] Folegatti PM, Ewer KJ, Aley PK, Angus B, Becker S, Belij-Rammerstorfer S, et al. Safety and immunogenicity of the ChAdOx1 nCoV-19 vaccine against SARS-CoV-2: a preliminary report of a phase 1/2, single-blind, randomised controlled trial. Lancet Lond Engl 2020;396:467—78.

[6] Lacroix C, Salvo F, Gras-Champel V, Gautier S, Massy N, Valnet-Rabier MB, et al. French organization for the pharmacovigilance of COVID-19 vaccines: a major challenge. Therapies 2021;76(4):297—303, http://dx.doi.org/10.1016/j.therap.2021.05.003.

[7] Agence Nationale de Sécurité des Médicaments (ANSM). Point de situation sur la surveillance des vaccins contre la COVID-19. ANSM: Agence nationale de sécurité du médicament et des produits de santé; 2021, https://www.ansm.sante.fr/S-informer/Points-d-information-Points-d-information/Point-de-situation-sur-la-surveillance-des-vaccins-contre-la-COVID-197 [Accessed 22 July 2021].

[8] Chapin-Bardales J, Gee J, Myers T. Reactogenicity following receipt of mRNA-based COVID-19 vaccines. JAMA 2021;325(21):2201—2.

Laurent Chouchana[a,*], Etienne Canouï[b], Rui Batista[c], Adrien Contejean[b,d], Alain Cariou[d,e], Jean-Marc Treluyer[a,d], Caroline Charlier[b,d,f]

[a] *Regional Center of Pharmacovigilance, Cochin Hospital, AP—HP Centre, Université de Paris, 75014 Paris, France*

[b] *Antimicrobial Stewardship Team, Cochin Hospital, AP—HP Centre, Université de Paris, 75014 Paris, France*

[c] *Pharmacy Department, Cochin Hospital, AP-HP Centre, Université de Paris, 75014 Paris, France*

[d] *Université de Paris, 75006 Paris, France*

[e] *Medical ICU, Cochin Hospital, AP—HP Centre, Université de Paris, 75014 Paris, France*

[f] *Institut Pasteur, Biology of Infection Unit, French National Reference Center and WHO Collaborating Center Listeria, Inserm U1117, 75014 Paris, France*

* Corresponding author. Cochin Hospital, AP—HP Centre, 27, rue du Faubourg Saint-Jacques, 75014 Paris, France.

E-mail address: laurent.chouchana@aphp.fr (L. Chouchana)

Received 23 May 2021;
accepted 20 July 2021
Available online 27 July 2021

https://doi.org/10.1016/j.therap.2021.07.004

Raising public awareness about the misuse of predatory journals: One year after the ''hydroxychloroquine and push-scooters accidents'' hoax

KEYWORDS
COVID-19;
Hydroxychloroquine;
Peer review;
Predatory journals;
Push-scooters

Abbreviations

COVID-19	coronavirus disease 2019
HCQ	hydroxychloroquine
WHO	World Health Organization

Predatory publishers are a threat to the good functioning of scientific research. Leading scholars and several publishers agreed on a standard definition of what are predatory journals and publishers: ''Predatory journals and publishers are entities that prioritize self-interest at the expense of scholarship and are characterized by false or misleading information, deviation from best editorial and publication practices, a lack of transparency, and/or the use of aggressive and indiscriminate solicitation practices'' [1]. The problems raised by predatory journals have been known for a number of years and several people have been working on trying to alert researchers about it or finding ways of addressing it. For example, Jeaffrey Beall published a list in his blog in 2010 with the aim of identifying the different predatory publishers [2]. His work and his list had to be abandoned in 2017 following complaints from various publishers and documentalists. Since then, the work has been taken over by Cabell's International, which offers publishing support services to universities and also a list of potentially predatory publishers based on different criteria [3]. Predatory journals can be considered a part of a bigger problem that also includes the surge of preprints and their misuse, as well as the multiple issues that can plague publication in non-predatory journals, such as expedite reviewing, conflicts of interests, and methodological and statistical issues [4].

In the past, predatory journals have mainly been a problem for researchers and have rarely affected the general public in a direct way. Indeed, in normal circumstances, the