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ORIGINAL ARTICLE

Prevalence of Adverse Events Post-COVID-19 Vaccination amongst the Adult Zambian Population

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ABSTRACT

Introduction: COVID-19 continues to be a public health concern despite several practical interventions to curb its spread. Now, widespread vaccination appears to be the most important strategy in winning the fight against this deadly pandemic by promoting herd immunity. However, a lack of independent and local studies on vaccines' safety may adversely impact the vaccine uptake and eventually the overarching goal of reducing disease transmission.

Objective: To determine the prevalence of adverse events post COVID-19 vaccination amongst the adult Zambia population.

Methods: This was a descriptive cross-sectional study conducted among recipients of COVID-19 vaccines in Zambia. The study was conducted between July and August 2021. 584 adult individuals who had access to the questionnaire were enrolled. Relationships between patients' demographics and Adverse Events (AEs) were assessed using the chi-square ($\chi 2$) test given the categorical nature of the data.

Results: Pain at the injection site (79.8%), headache (57.4%), fatigue (55.5%), chills (52.6%), fever (42.3%), and joint pains (37.5%) were the most commonly reported adverse events. When stratified by gender, pain at the injection site ($p = 0.01$), limitation of arm movement ($p < 0.001$), chills ($p = 0.017$), headache ($p = 0.044$), fatigue ($p = 0.004$), nausea or vomiting ($p < 0.001$) were statistically significant, with females mostly affected. There was a statistically significant difference in the case of limitation of arm movement (20.7% *vs.* 9.9%, $p = 0.031$), chills (54.8% *vs.* 36.6%, $p = 0.004$), headache (59.6% *vs.* 40.8%, $p = 0.003$) and fatigue (57.5% *vs.* 40.8%, $p = 0.008$) between those 49 years and below compared to those above 50 years.

Conclusion: Our study provides evidence of adverse events being experienced by the recipient of COVID-19 vaccines and that these have been mainly mild. Healthcare authorities need to educate the public about the possible adverse events associated with COVID-19 vaccines and how to report these events should they experience some. This will improve pharmacovigilance of adverse events associated with COVID-19 vaccines.

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INTRODUCTION

Since the first reported case on 31 December 2019 in Wuhan city, China, the current global pandemic of the novel Coronavirus disease-2019 (COVID-19), caused by severe acute respiratory syndrome coronavirus - 2 (SARS-CoV-2), has continued

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causing global public health crises [1,2]. According to recent reports, SARS-CoV-2 could infect nearly 90% of the world's population and kill approximately 40 million people in the absence of efficient preventative and containment measures [3]. Although several practical interventions such as early and accurate diagnosis, hand hygiene, face masking and maintaining social distancing have been vital in reducing the burden of COVID-19 [4-6], widespread vaccination now appears to be the most important strategy in winning the fight against this deadly pandemic [3,7]. COVID-19 vaccines were introduced to help promote and reach herd immunity against SARS-CoV-2 [8,9].

The emerging focus towards vaccination has motivated development and evaluation of vaccines in extremely short timeframes, with several biotechnology companies completing this vaccine production process in less than one year. Some vaccines have now been authorised by the United States (US) Food and Drug Administration (FDA) for emergency or conditional use in many countries [10]. While unprecedented and based upon a thorough evaluation of high-quality data, this rapid development and authorisation process may imply that vaccines have been introduced for use in the population based on studies with limited population heterogeneity (for example, no children, pregnant women, immunocompromised persons) and limited follow up (~2 months) on recipients in clinical trials [10].

Furthermore, even though large phase III trials were conducted and completed, the extremely high speed at which the vaccine production process proceeded has augmented vaccination hesitancy concerns expressed by many anti-vaccination groups, the general public, and some health care workers who believe that the process was ''rushed" or incomplete [10,11].

Some studies have been conducted to assess the safety and side effects associated with various COVID-19 vaccines in different stages of development. For example, two studies that were done by Logunov, et al. [12] found that the most common systemic and local reactions associated with COVID-19 vaccination were pain at the injection site (58%), hyperthermia (50%), headache (42%), asthenia (28%), muscle and joint pain (24%). Furthermore, most of the reported systemic and local reactions were mild, and changes in laboratory variables were mild and transient.

A review that summarised the assessment reports of the European Medicine Agency (EMA) concerning the safety of the three vaccines used in the European Union (EU) (Pfizer, Moderna and Astra-Zeneca) addressed the safety concerns for the vaccines in question. Overall, the most frequent adverse effects reported after the administration of these vaccines consisted of local reactions at the injection site (sore arm and erythema) followed by non-specific systemic effects (myalgia, chills, fatigue, headache, and fever), which occurred soon after vaccination and resolved shortly afterwards [13].

Based on such reported mild side effects, many countries around the globe have since implemented COVID-19 vaccination programmes. Similarly, Zambia joined the rest of the world and officially launched COVID-19 vaccination on 14 April 2021 at the University Teaching Hospital in Lusaka. The vaccine deployment plan prioritised frontline health workers who are essential in sustaining the COVID-19 response, persons most essential in maintaining core societal functions (teachers, immigration, police, religious and traditional leaders), persons at greatest risk of severe COVID-19 disease (those with other underlying diseases and those aged above 65 years) and the population in congregate settings [14]. Since then, the vaccination has now been opened to the general public.

Despite sustainable public awareness campaigns on the importance of vaccination, several factors contribute to limiting the population's adherence to this intervention. Among these factors is the safety of the vaccines. Thus far, all the available data on COVID-19 vaccine side effects have been published by manufacturer-funded studies, which are in compliance with the drug authorities' guidelines and monitored by third parties [11]. However, a lack of independent and local studies on vaccines' safety may adversely impact the vaccine uptake and eventually the overarching goal of reducing disease transmission. Therefore, this study aimed at assessing the prevalence of adverse events experienced among the adult Zambian population who have received the COVID-19 vaccine.

MATERIALS AND METHODS

Study design

We conducted an online descriptive cross-sectional study among recipients of different COVID-19 vaccines in Zambia to investigate the prevalence of adverse events. The study was conducted between July and August 2021 and it captured 584 adult individuals who had received the COVID-19 vaccine and had access to the online questionnaire.

Data were collected via an online semi-structured questionnaire (Alphabet, Inc., Mountain View, California, United States). The questionnaire contained both open and closed-ended questions to allow for unrestricted response. The questionnaire was adopted [11] and modified to align with our study. To ensure face and content validity, the questionnaire was piloted among 20 random respondents. Feedback from the pilot was used to improve the questionnaire and did not form part of the final analysis. To ensure that only vaccinated respondents were included in the study, key demographic variables such as site of vaccination, day and month of vaccination, type of vaccine received, and doses received were included in the questionnaire. The population that was studied was very homogeneous in terms of the vaccines received.

Statistical analysis

All data were entered and analysed using Statistical Package for the Social Sciences (SPSS) version 25 (IBM Corporation, Armonk, New York, USA). The computed descriptive statistics were expressed as frequencies and presented in tables and graphs. Relationships between patients' demographics and Adverse Events (AEs) were assessed using the chi-square ($\chi 2$) test given the categorical nature of the data. P-values of less than 0.05 were considered statistically significant.

Ethics statement

Ethical approval for this study was obtained from the Tropical Diseases Research Centre (TDRC) ethics committee (Institution Review Board registration number: 00002911). The questionnaire contained an information sheet regarding the study and an informed consent statement for participants to agree to participate or not. All participants who declined to participate in the study were immediately withdrawn and did not proceed to respond to the questionnaire. Clearance to conduct this study was obtained from the National Health Research Authority-Zambia (NHRA).

RESULTS

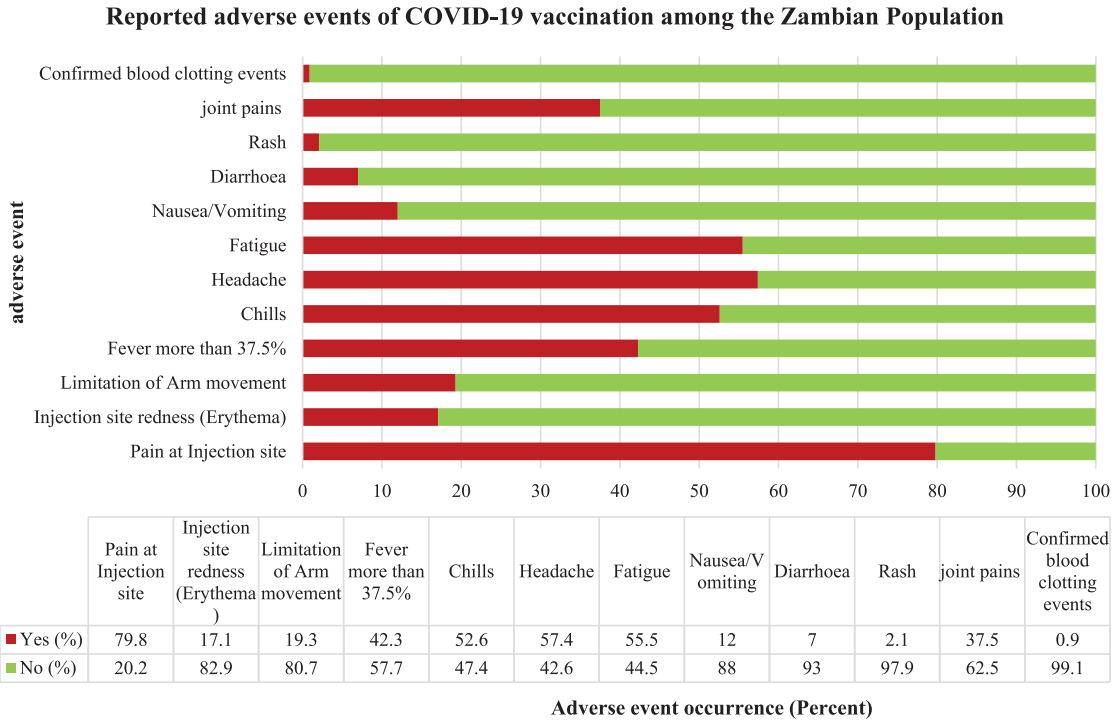
Sociodemographic characteristics of respondents

The study aimed at assessing the side effects of the different COVID-19 vaccines among the adult Zambian population. The majority of the participants were females, [319/584 (54.6%)] most of whom were aged between 18-35 years, [286/584 (49.0%)]. More than 95% of the participants attended tertiary education and were Christians by religion. More than half of the participants were from Lusaka province, [344/584 (58.9%)] and the least from Muchinga province, [6/584 (1.0%)]. Most of the study participants had received the AstraZeneca COVID-19 vaccine, [564/584 (96.5%)] (Table 1).

The most commonly reported adverse events of the COVID-19 vaccines among the Zambian population in descending order were pain at the injection site (79.8%), headache (57.4%), fatigue (55.5%), chills (52.6%), fever (42.3%), joint pains (37.5%) and the least of the reported side effects was confirmed blood clotting events (0.9%) (Figure 1).

Table 1: Demographic characteristics of participants (*n* = 584).

Characteristic		Number (n)	Percentage (%)
Sex	Male	265	45.4
	Female	319	54.6
Age	18-35 years	286	49
	36-49 years	227	38.9
	Above 49 years	71	12.2
Marital Status	Single	216	37
	Married	330	56.5
	Divorced	23	3.9
	Widowed	15	2.6
Highest Level of Education	Secondary School	12	2.1
	Tertiary	572	97.9
Employment Status	Unemployed	35	6
	Employed	454	77.7
	Entrepreneur	51	8.7
	Student	44	7.5
Religion	Christian	566	96.9
	Non-Christian	18	3.1
Province	Central	19	3.3
	Copperbelt	106	18.2
	Eastern	17	2.9
	Luapula	7	1.2
	Lusaka	344	58.9
	Muchinga	6	1
	North Western	30	5.1
	Northern	11	1.9
	Southern	28	4.8
	Western	16	2.7
Vaccine Received	AstraZeneca	564	96.5
	Johnson and Johnson	17	2.9
	Other	3	0.6



	Pain at Injection site	Injection site redness (Erythema)	Limitation of Arm movement	Fever more than 37.5%	Chills	Headache	Fatigue	Nausea/Vomiting	Diarrhoea	Rash	joint pains	Confirmed blood clotting events
Yes (%)	79.8	17.1	19.3	42.3	52.6	57.4	55.5	12	7	2.1	37.5	0.9
No (%)	20.2	82.9	80.7	57.7	47.4	42.6	44.5	88	93	97.9	62.5	99.1

Figure 1 Overall reported side effects of COVID-19 vaccines.

Severity of the reported adverse events

Out of all the participants that experienced the side effects, only 46 (7.9%) experienced side effects adverse enough to warrant hospital care (Table 2).

Occurrence of COVID-19 vaccination adverse events by gender

The chi-square test revealed a statistically significant difference in the distribution of some of the commonly reported adverse events following the vaccination between gender. Pain at the injection site (p = 0.01), limitation of arm movement (p < 0.001), chills (p = 0.017), headache (p = 0.044), fatigue (p = 0.004), and nausea or vomiting (p < 0.001) with most of these seen in female gender (Table 3).

Occurrence of COVID-19 vaccination adverse events by age group

All reported side effects were more prevalent in the age group below 49 years than in those 50 years and above. There was a statistically significant difference in the case of limitation of arm movement (20.7% *vs.* 9.9%, p = 0.031), chills (54.8% *vs.* 36.6%, p = 0.004), headache (59.6% *vs.* 40.8%, p = 0.003) and fatigue (57.5% *vs.* 40.8%, p = 0.008) between these two age groups (Table 4).

DISCUSSION

Our study investigated the prevalence of Adverse Events (AEs) experienced by the adult population following vaccination with common COVID-19 vaccines available in the country during the study period using a population based online cross-sectional study.

In our study, the most common reported adverse events were pain at the injection site, headache, fatigue, chills, fever and joint pains. These findings are in agreement with results from clinical trials for different COVID-19 vaccines including AstraZeneca [11,13,15,16]. However, the percentage of individuals that experienced pain at the injection site in our study is slightly higher than those reported in Italy [3] and the United States [17]. This variation in the proportion of individuals that experiences pain at the site of injection may be attributed to several factors including; injection technique, injection velocity and muscle mass. Other factors that may influence the pain experienced by the participants include whether the muscle is relaxed or tense at the time of administering the injection [11]. We, therefore, suggest that healthcare workers involved in COVID-19 vaccination programmes must be given optimal training regarding administering vaccine injections to reduce the pain experienced by patients. In addition, in our study, there were reports of confirmed blood clotting events. While we cannot ascertain that the blood clots were caused by the vaccine, it should be noted that blood clots rarely occur naturally [18].

Most importantly, the reported AEs were mild, with only a few recipients (7.9%) of the vaccines reported to have sought hospital care to manage the adverse events. Our

Table 2: Severity of the reported adverse events.

	Response	Frequency	Percent
If you experienced any of the side effects, were they severe to require hospital care?	Yes	46	7.9
	No	538	92.1
	Total	584	100.0

Table 3: Occurrence of adverse events according to gender.

Adverse event	Males n (%)	Females n (%)	Total n (%)	*p*-value
Pain at Injection Site	196 (74.0)	270 (84.6)	466 (79.8)	0.01
Erythema (redness) at injection site	37 (14.0)	63 (19.7)	100 (17.1)	0.065
Limitation of Arm movement	30 (11.3)	83 (26.0)	113 (19.3)	<0.001
Fever more than 37.5%	109 (41.1)	138 (43.3)	247 (42.3)	0.604
Chills	125 (47.2)	182 (57.1)	307 (52.6)	0.017
Headache	140 (52.8)	195 (61.1)	335 (57.4)	0.044
Fatigue	130 (49.1)	194 (60.8)	324 (55.5)	0.004
Nausea or vomiting	17 (6.4)	53 (16.6)	70 (12.0)	<0.001
Diarrhoea	14 (5.3)	27 (8.5)	41 (7.0)	0.134
Rash	7 (2.6)	5 (1.6)	12 (2.1)	0.362
Joint Pains	88 (33.2)	131 (41.1)	219 (37.5)	0.051
Confirmed blood clotting events	2 (0.8)	3 (0.9)	5 (0.9)	0.808

Table 4: Occurrence of adverse events among respondents 49 years and below compared to 50 years and above.

Adverse event	49 years and below n (%)	50 years and above n (%)	Total (*n* = 584) n (%)	*p*-value
Pain at Injection Site	416 (81.1)	50 (70.4)	466 (79.8)	0.036
Erythema (redness) at injection site	88 (17.2)	12 (16.9)	100 (17.1)	0.958
Limitation of Arm movement	106 (20.7)	7 (9.9)	113 (19.3)	0.031
Fever more than 37.5%	219 (42.7)	28 (39.4)	247 (42.3)	0.603
Chills	281 (54.8)	26 (36.6)	307 (52.6)	0.004
Headache	306 (59.6)	29 (40.8)	335 (57.4)	0.003
Fatigue	295 (57.5)	29 (40.8)	324 (55.5)	0.008
Nausea or vomiting	65 (12.7)	5 (7.0)	70 (12.0)	0.171
Diarrhoea	38 (7.4)	3 (4.2)	s41 (7.0)	0.458
Rash	12 (2.3)	0 (0.00)	12 (2.1)	0.377
Joint Pains	197 (38.4)	22 (31.0)	219 (37.5)	0.226
Confirmed blood clotting events	4 (0.8)	1 (1.4)	5 (0.9)	0.478

findings are similar to those of several other studies which show that most side effects experienced after vaccination are mild and transient [3,11,13,16,17]. The implication from our findings is that these vaccines are trustworthy and safe as the adverse events experienced within the Zambian population are comparable to other countries and are mainly mild.

Similar to other studies we found that AEs were more frequent in female than male participants, and those younger than 50 years [11,17]. We postulate two possible reasons for these observations. Firstly, females exhibit a stronger vaccine-induced immunity due to sex hormones, especially oestrogen, and because of this strong immune response, the side effects experienced also become more frequent [19,20]. However, with age, there is a reduction in the production of some sex hormones (oestrogen and progesterone for females and testosterone for males), and this reduction contributes to declined immune function and, as such less frequency of vaccination adverse events in the older population [19].

The findings from our study are particularly encouraging regarding adverse events from COVID-19 vaccines, majority of which were mild. Therefore, the Zambian population is encouraged to fully participate in the COVID-19 vaccination

programme to curb the pandemic. The older population, a high-risk group, should actively receive the COVID-19 vaccines as studies have demonstrated that they are less likely to experience serious adverse events.

The participants in this study were from all the ten (10) provinces of Zambia; therefore, the findings of this study could be generalised to the Zambian population. However, one of the limitations of our findings is the online survey-based methodology of collecting data which might have resulted in self-selection bias, where only the highly motivated participants with access to the online questionnaire responded to the questionnaire. In addition, the self-reporting nature of the collected data may compromise the objectivity when it comes to clinical evaluation, and participants may have given socially acceptable responses. Further, the study did not categorise the adverse events experienced by vaccine type but only looked at the overall adverse events.

CONCLUSION

Despite having the aforementioned limitations, our study achieved the goal of identifying the prevalence of adverse events post COVID-19 vaccination. The most prevalent adverse events reported in this study were pain at the injection site, headache, fatigue, chills, fever and joint pains. Most of these adverse events were commonly found in those 49 years and below, with females reporting the majority of these. However, more than ninety percent of these reported adverse events were mild. With this knowledge, it is important to strengthen the pharmacovigilance system and making it easier for vaccine recipients to report the experienced adverse events. This would help to reduce vaccine hesitancy among the Zambian population.

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AUTHORS' CONTRIBUTIONS

Conceptualization: MC, GM, VD. Data curation: MC. Formal analysis: MC, VD, MS. Funding acquisition: None. Methodology: MK, SM, VD. Project administration: MC. Writing – original draft: MC, GM, MK, and VD. Writing – review & editing: NMS, MS, MB, SM.

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